40410 Pollution Control Agency Notice of Hearing on PFAS in Products Reporting and Fee Rule

Closed May 21, 2025 · Discussion · 66 Participants · 1 Topics · 66 Answers · 0 Replies · 2 Votes

66	1	66	0	2
PARTICIPANTS	TOPICS	ANSWERS	REPLIES	VOTES

SUMMARY OF TOPICS

SUBMIT A COMMENT

66 Answers · 0 Replies

Important: All comments will be made available to the public. Please only submit information that you wish to make available publicly. The Office of Administrative Hearings does not edit or delete submissions that include personal information. We reserve the right to remove any comments we deem offensive, intimidating, belligerent, harassing, or bullying, or that contain any other inappropriate or aggressive behavior without prior notification.

Brad Bretecher · Citizen · (Postal Code: unknown) · May 06, 2025 10:21 am

1 Votes

Comment attached on behalf of New Flyer / Motor Coach Industries

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Miguel Gascon · Citizen · (Postal Code: unknown) · May 12, 2025 7:48 am

0 Votes

Comment attached on 7026.0100 FEES Subp.2. Initial Report

Mazin Badri · Citizen · (Postal Code: unknown) · May 14, 2025 9:18 am

0 Votes

I’m reaching out for clarification regarding the proposed PFAS reporting rule. Our company distributes hundreds of chemical products in Minnesota, primarily serving the aerospace and defense industries. As such, we understand we may be subject to reporting requirements as we introduce these substances into the state.
We rely on safety data sheets (SDSs) to determine product composition. However, I’m concerned about scenarios where PFAS may not be disclosed on the SDS. Specifically, I would appreciate your guidance on the following:
• Would we be required to obtain declarations from manufacturers for each product we distribute in Minnesota, confirming whether or not the product contains intentionally added PFAS?
o If so, securing these declarations in advance would be a significant challenge. Without confirmation, we may be unable to distribute certain products without conducting our

own testing, which could be prohibitively expensive.
• Alternatively, would reliance on SDSs be considered sufficient, given that PFAS should be disclosed due to their hazardous nature?
Your input on these points would be extremely helpful in planning our compliance efforts.
I look forward to your response.

Thomson Tom · Citizen · (Postal Code: unknown) · May 14, 2025 9:51 am
0 Votes

Comment attached on behalf of Steam Thermal Solutions (Spirax Group)

Steven Kooy · Citizen · (Postal Code: unknown) · May 16, 2025 12:31 pm
0 Votes

Comment attached on behalf of BIFMA members

Amy Neal · Citizen · (Postal Code: unknown) · May 19, 2025 10:15 am
0 Votes

Comments are attached on behalf of Emerson Electric.

Chris Rendall-Jackson · Citizen · (Postal Code: unknown) · May 19, 2025 2:20 pm
0 Votes

Attached are comments on the Minnesota Pollution Control Agency’s proposed PFAS in Products Reporting and Fees Rule. These comments were prepared by, and are being submitted on behalf of, one of Farella Braun + Martel LLP’s clients.

Amanda Duerr · Citizen · (Postal Code: unknown) · May 20, 2025 9:36 am
0 Votes

Attached are comments on behalf of the Minnesota Automobile Dealers Association (MADA).

Jesse McArdell · Citizen · (Postal Code: unknown) · May 20, 2025 1:24 pm
0 Votes

Attached are Comments on behalf of the National Marine Manufacturers Association (NMMA).

Kristin Emery · Citizen · (Postal Code: unknown) · May 20, 2025 1:26 pm
0 Votes

Comment attached on 7026.0100 FEES Subp.3. Annual Update or Recertification.

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Thomas Cortina · Citizen · (Postal Code: unknown) · May 20, 2025 2:26 pm
0 Votes

Attached are comments of the Halon Alternatives Research Corporation (HARC).

Robert Denney · Citizen · (Postal Code: unknown) · May 20, 2025 2:34 pm
0 Votes

Please see attached comments submitted on behalf of the PFAS Pharmaceutical Working Group.

Julia McGowan · Citizen · (Postal Code: unknown) · May 20, 2025 2:34 pm
0 Votes

Attached are comments on behalf of AGC Chemicals Americas, Inc.

Jeffery Sepesi · Citizen · (Postal Code: unknown) · May 20, 2025 6:06 pm
0 Votes

Attached are comments on the Minnesota Pollution Control Agency’s proposed PFAS in Products Reporting and Fees Rule.

Aya Iizuka · Citizen · (Postal Code: unknown) · May 21, 2025 12:57 am
0 Votes

Please find attached comments on behalf of the Japanese four electrical and electronic industrial associations (JP4EE) - JEITA, CIAJ, JBMIA and JEMA.

Judah Prero · Citizen · (Postal Code: unknown) · May 21, 2025 6:42 am
0 Votes

Attached, please find the comments of the Chemical Users Coalition on MPCA's Proposed New Rules Governing the Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing PFAS.

Victoria Mwanza · Citizen · (Postal Code: unknown) · May 21, 2025 6:46 am
0 Votes

Subject: Submission from BioPhorum Regarding 40410 Pollution Control Agency Notice of Hearing on PFAS in Products Reporting and Fee Rule.

Dear Hearing Officer,

On behalf of BioPhorum, we are pleased to submit the following documents in response to the Minnesota Pollution Control Agency’s consultation on the proposed PFAS in Products Reporting and Fee Rule.

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BioPhorum enables the global biopharmaceutical industry to connect, collaborate, and accelerate progress for the benefit of all. Since 2004, BioPhorum has grown into a trusted environment where senior leaders from over 150 member companies—representing more than 98% of global biopharmaceutical manufacturing—work together to address shared challenges and shape the future of the industry.

The documents submitted include:
1.A formal response letter addressing the specific elements of the proposed rule and its potential implications for the biopharmaceutical sector.
2. A background document outlining the broader impact of PFAS restrictions on the BioPharma industry, including insights from global consultations and regulatory developments.

These materials aim to advocate for the recognition of BioPharma as a critical use case in PFAS-related policymaking. They highlight the essential role PFAS play in ensuring the safety, efficacy, and availability of life-saving medicines, while also supporting a collaborative and pragmatic approach to environmental stewardship.

We appreciate the opportunity to contribute to this important dialogue and remain committed to working with regulatory bodies to ensure that public health and environmental goals are met without compromising patient access to essential therapies.

Fredric Andes · Citizen · (Postal Code: unknown) · May 21, 2025 8:04 am
0 Votes

Attached are the comments of the PFAS Regulatory Coalition regarding the MPCA proposed rule on reporting and fees for PFAS in products. If you have any questions, please let us know. Thank you.

Todd Titus · Citizen · (Postal Code: unknown) · May 21, 2025 8:37 am
0 Votes

Hello,

My name is Todd Titus and I am the Director of State and Public Affairs at HARDI. HARDI is a trade association representing HVACR wholesale distributors and is comprised of more than 1,150 member companies, more than 490 of which are U.S.–based. These include 20 wholesaler-distributor members in Minnesota, with 80 locations serving HVACR contractors and technicians in the state.

Attached are HARDI’s comments regarding 40410 Pollution Control Agency Notice of Hearing on PFAS in Products Reporting and Fee Rule. If you have questions or problems viewing our comments attached please let me know.
Thank you.

Craig Tangren · Citizen · (Postal Code: unknown) · May 21, 2025 8:44 am
0 Votes

Please find attached the Leech Lake Band of Ojibwe's comments regarding the proposed

40410 Pollution Control Agency Notice of Hearing on PFAS in Products Reporting and Fee Rule

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PFAS in Products Reporting and Fees rule.

Conor O'Brien · Citizen · (Postal Code: unknown) · May 21, 2025 8:45 am
0 Votes

Comment attached on behalf of the American Apparel & Footwear Association (AAFA).

Bill Erny · Citizen · (Postal Code: unknown) · May 21, 2025 9:30 am
0 Votes

These Comments are submitted on behalf of the RV Industry Association (RVIA).

Dawn Friest · Citizen · (Postal Code: unknown) · May 21, 2025 9:34 am
0 Votes

Please find attached the comments of the Truck and Engine Manufacturers Association (EMA).

Kyla Fisher · Citizen · (Postal Code: unknown) · May 21, 2025 9:41 am
0 Votes

Please find attached some comments from the Flexible Packaging Association (FPA)

Andrew Bemus · Citizen · (Postal Code: unknown) · May 21, 2025 10:13 am
0 Votes

Please see the attached comment letter from the Sustainable PFAS Action Network (SPAN). Please contact SPAN with any comments or questions.

Bruce Nustad · Citizen · (Postal Code: unknown) · May 21, 2025 10:15 am
0 Votes

Please find the attached comments from Minnesota Retailers. Thank you.

Avonna Starck · Citizen · (Postal Code: unknown) · May 21, 2025 10:32 am
0 Votes

Please find the attached from Clean Water Action Minnesota.

Andrew Frisbie · Citizen · (Postal Code: unknown) · May 21, 2025 10:42 am
0 Votes

Wabash National Corporation hereby submits these comments to the Minnesota Pollution

40410 Pollution Control Agency Notice of Hearing on PFAS in Products Reporting and Fee Rule

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Control Agency regarding the Agency's Notice of Intent to Adopt New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per- and polyfluoroalkyl substances (PFAS).

Gary Cross · Citizen · (Postal Code: unknown) · May 21, 2025 10:43 am
1 Votes

Please see the attached comments from the Industrial Truck Association

Latoya Thomas · Citizen · (Postal Code: unknown) · May 21, 2025 11:08 am
0 Votes

Please see attached the thoughtfully prepared comments from Terumo Blood and Cell Technologies.

Edith Nagy · Citizen · (Postal Code: unknown) · May 21, 2025 11:37 am
0 Votes

Attached please find the comments submitted on behalf of the Complex Products Manufacturers Coalition (CPMCoalition) on MPCA's "Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees".

Ian Choiniere · Citizen · (Postal Code: unknown) · May 21, 2025 11:48 am
0 Votes

Please see the attached comments from Syensqo.

Elizabeth Nugent Morrow · Citizen · (Postal Code: unknown) · May 21, 2025 11:57 am

0 Votes

Please see attached comments submitted on behalf of a specialty chemicals company.

Eric Barnes · Citizen · (Postal Code: unknown) · May 21, 2025 12:17 pm
0 Votes

Please see attached comments submitted on behalf of MIC, SVIA, and ROHVA.

Maureen Hardwick · Citizen · (Postal Code: unknown) · May 21, 2025 12:19 pm
0 Votes

Attached please find comments submitted on behalf of the International Pharmaceutical Aerosol Consortium (IPAC). Please let us know if you have any questions. Kind regards, IPAC Secretariat

40410 Pollution Control Agency Notice of Hearing on PFAS in Products Reporting and Fee Rule

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Marcus Branstad · Citizen · (Postal Code: unknown) · May 21, 2025 12:19 pm
0 Votes

Please see attached comments submitted on behalf of the American Chemistry Council's Performance Fluoropolymer Partnership

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Carlos Gutierrez · Citizen · (Postal Code: unknown) · May 21, 2025 12:37 pm
0 Votes

Please see attached comments on behalf of the Consumer Healthcare Products Association.

John Keane · Citizen · (Postal Code: unknown) · May 21, 2025 12:48 pm
0 Votes

Please see attached comments on behalf of the Association of Home Appliance Manufacturers.

Jason Sloan · Citizen · (Postal Code: unknown) · May 21, 2025 1:00 pm
0 Votes

Please see attached comments from the American Chemistry Council's Center for the Polyurethanes Industry.

Tillie Fowler · Citizen · (Postal Code: unknown) · May 21, 2025 1:06 pm
0 Votes

Please see attached comments on behalf of EssilorLuxottica.

Ivan Rydkin · Citizen · (Postal Code: unknown) · May 21, 2025 1:12 pm
0 Votes

Please see attached comments on behalf of Daikin Applied Americas

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Tracy Whitney · Citizen · (Postal Code: unknown) · May 21, 2025 1:12 pm
0 Votes

Please see attached comments on behalf of Conservation Minnesota, our Policy Director Nels Paulsen, and 302 of our members.

Clayton Hall · Citizen · (Postal Code: unknown) · May 21, 2025 1:34 pm
0 Votes

Please see attached comments on behalf of the Medical Device Manufacturers

Association.

Matthew Windrum · Citizen · (Postal Code: unknown) · May 21, 2025 1:41 pm
0 Votes

Please see the attached comments from Plumbing Manufacturers International (PMI).

Erin Herlihy · Citizen · (Postal Code: unknown) · May 21, 2025 1:44 pm
0 Votes

Please see attached comments on behalf of Outdoor Industry Association.

Rob Turner · Citizen · (Postal Code: unknown) · May 21, 2025 2:01 pm
0 Votes

Attached please find comments submitted on behalf of Valmet.

Chris Cleet · Citizen · (Postal Code: unknown) · May 21, 2025 2:35 pm
0 Votes

Please see attached the comments of the Information Technology Industry Council.

Mary Schilling · Citizen · (Postal Code: unknown) · May 21, 2025 2:43 pm
0 Votes

Please find attached the commnts from the Personal Care Products Council.

Riaz Zaman · Citizen · (Postal Code: unknown) · May 21, 2025 2:43 pm
0 Votes

Please see attached comment from the American Coatings Association

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Adrienne Frederick · Citizen · (Postal Code: unknown) · May 21, 2025 2:44 pm
0 Votes

Please see attached for the comments from AdvaMed, the Medtech Association.

Lori Olinger · Citizen · (Postal Code: unknown) · May 21, 2025 2:46 pm
0 Votes

Please see attached comments from Sierra Club North Star Chapter

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Michael Pierce · Citizen · (Postal Code: unknown) · May 21, 2025 3:03 pm
0 Votes

Please see the attached Comments from the Window and Door Manufacturer's Association. If you have any further questions, please do not hesitate to contact me.

Emily Sobel · Citizen · (Postal Code: unknown) · May 21, 2025 3:10 pm
0 Votes

Please see the attached comments from MEMA, The Vehicle Suppliers Association.

Jason Malcore · Citizen · (Postal Code: unknown) · May 21, 2025 3:13 pm
0 Votes

Please see the attached comments from AEM - The Association of Equipment Manufacturers

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Ben Kallen · Citizen · (Postal Code: unknown) · May 21, 2025 3:15 pm
0 Votes

Please see the attached comments submitted on behalf of SEMI and the Semiconductor Industry Association.

Michael Michaud · Citizen · (Postal Code: unknown) · May 21, 2025 3:18 pm
0 Votes

Please find the attached comments on behalf of the Hydraulic Institute.

Diana Rondeau · Citizen · (Postal Code: unknown) · May 21, 2025 3:20 pm
0 Votes

Please see attached comments submitted on behalf of IDEXX Laboratories Inc.

Kiera Callahan · Citizen · (Postal Code: unknown) · May 21, 2025 3:21 pm
0 Votes

Please see the attached PDF for BP Polymers, LLC comments

Javaneh Tarter · Citizen · (Postal Code: unknown) · May 21, 2025 3:37 pm
0 Votes

Please see comments of SOCMA, CPMA and ASC attached.

Heather Rhoderick · Citizen · (Postal Code: unknown) · May 21, 2025 3:41 pm
0 Votes

40410 Pollution Control Agency Notice of Hearing on PFAS in Products Reporting and Fee Rule

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Please see attached comments on behalf of the Valve Manufacturers Association.

Catherine Palin · Citizen · (Postal Code: unknown) · May 21, 2025 3:48 pm
0 Votes

Please find attached comments of the Alliance for Automotive Innovation.

Daniel Moyer · Citizen · (Postal Code: unknown) · May 21, 2025 3:53 pm
0 Votes

Please see attached comments from the Consumer Technology Association

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Ryan Fleming · Citizen · (Postal Code: unknown) · May 21, 2025 3:54 pm
0 Votes

Attached are comments from Freudenberg Sealing Technologies

Hayley Davis · Citizen · (Postal Code: unknown) · May 21, 2025 4:10 pm
0 Votes

Please see the attached comments from the Air-Conditioning, Heating and Refrigeration Institute (AHRI).

Jos Huxley · Citizen · (Postal Code: unknown) · May 21, 2025 4:22 pm
0 Votes

Attached are comments from The Toy Association

Ben Wagner · Citizen · (Postal Code: unknown) · May 21, 2025 4:29 pm
0 Votes

Comments attached from Medical Alley

May 1, 2025

VIA ELECTRONIC SUBMISSION: https://minnesotaoah.granicusideas.com/

Honorable Judge Jim Mortenson
600 North Robert Street
St. Paul, MN 55101

Re: Minnesota Pollution Control Agency's Notice of Intent to Adopt New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per- and polyfluoroalkyl substances (PFAS), Revisor's ID Number R-4828, OAH docket number 5-9003-40410

New Flyer of America Inc. (NFA), a bus manufacturer, appreciates the opportunity to comment on these important proposed rules. Please allow this letter to serve as constructive commentary, as explained in detail in this response.

We ask that MPCA consider providing heavy vehicle OEMs a 2-year extension for complying with the proposed PFAS reporting and fees regulation due to the significant challenges involved in meeting the reporting requirement. Specifically, we request consideration of the difficulty a bus OEM would face in successfully satisfying the reporting requirements within the timeframe between adoption of the regulation and the reporting deadline of January, 2026. The required steps in reporting would include:

1) Determination of which components on a bus contain PFAS: Identifying which components on a bus that contain PFAS will be a significant undertaking. Buses are highly customized vehicles, with thousands of components tailored to meet specific customer requirements (over 15,000 parts that vary based on customer configuration). Determining which components contain intentionally added PFAS will require a thorough analysis. Given that most parts and components are sourced from suppliers rather than manufactured by NFA, this effort will necessitate contacting all suppliers and sub-suppliers.

2) Once a list of components with PFAS is assembled, educate the respective bus component suppliers about the Minnesota reporting requirement, and secure their cooperation in gathering or generating the necessary data. The difficulty of this task will be even greater with sub-suppliers, which have little direct relationship or connection to NFA, and could be located outside of the U.S. There would be little consequence to them if they do not provide the information, or delay in providing it (as this is not an outright prohibition of components with intentionally added PFAS—and so no potential loss of their sales revenue). As such, there is minimal leverage in requesting them to assist.

3) If cooperation is achieved, the suppliers may have to locate and hire external test labs to determine the amounts of PFAS, possibly for various versions of a component. It is anticipated that a large number of companies will be vying for limited testing slots. If suppliers do *not*

provide support, then the vehicle OEM's would have to contract out to do the testing for possibly thousands of parts. With this regulation going into effect, it is anticipated that there will be excessive demand and availability for lab services, presenting challenge to reporting in time.

4) Vehicle OEM's would then have to gather the test data from all the components and assemble into a format for reporting. The significant time required to complete testing, along with added logistics, administrative time, and associated costs, could severely impact business operations.

Each of these steps, on their own, would be challenging. To accomplish all of them in less than a year is not feasible.

NFA further contends that heavy vehicles (mainly operated as commercial vehicles) are unlike consumer products in the potential risks that PFAS-containing components would pose to the general public, based on the following:

a) Reduced exposure to the PFAS containing components relative to consumer products.
The amount of an individual's exposure is limited to passenger trip times, compared to the ever-present consumer product in a home or business.

b) Reduced frequency of disposal of heavy vehicles and their components.
The minimum expected lifespan of a transit bus or motor coach in North America is 12 years and is often much longer. Unlike passenger vehicles, heavy vehicles are often overhauled to extend their lifetime.

Given the challenge associated with reporting, and more importantly, the less urgent risk of PFAS exposure to the general public from heavy vehicles, NFA respectfully requests that heavy vehicle manufacturers be granted a 2-year extension beyond January 1st, 2026, to comply with the reporting requirements.

Regarding reporting fees, NFA feels the amount should not be based on the size of a business, nor on a per-PFAS or PFAS amount basis. In addition, a fee should not have to be paid for updating information, which could be construed as penalization for improving the accuracy of a company's PFAS reporting. It could also potentially de-motivate some from providing timely updates.

In closing, NFA appreciates the opportunity to provide feedback on the proposed regulation. We look forward to further dialogue and are ready to assist in the development of a regulation that is for the betterment of public safety and industry.

Sincerely,

Ian Macpherson

New Flyer of America, Inc. | MCI

Vice President, Engineering Services

ian_macpherson@newflyer.com

RECEIVED
By: OAH on 5/12/2025
Miguel Gascon Attachment

COMMSCOPE®

May 12, 2025

VIA ELECTRONIC SUBMISSION: https://minnesotaoah.granicusideas.com/

Honourable Judge Jim Mortenson
600 North Robert Street
St. Paul, MN 55101

Re: Minnesota Pollution Control Agency's Notice of Intent to Adopt New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per- and polyfluoroalkyl substances (PFAS), Revisor's ID Number R-4828, OAH docket number 5-9003-40410.

As a manufacturer of a wide range of products containing PFAS, many of which do not fit neatly into broader product categories, we find the Agency's description of "initial report" to be open to interpretation. This ambiguity creates uncertainty around how the associated reporting fee should be applied.

Our understanding is that the Agency did not want to impose a per-product fee structure to prevent deterring manufacturers from reporting due to potentially excessive costs. Instead, a flat fee was ultimately considered the most reasonable approach. However, this intent does not appear to be explicitly stated in Section 7026.0100 (Subp. 2).

We respectfully request clarification within the legal text to confirm whether each individual manufacturer is required to pay a **single flat** fee of $1,000 **for the initial report**, **regardless of the number of products or product categories included in the submission**.

Company Name: CommScope, Inc. of North Carolina
3642 E US Highway 70
Claremont, NC 28610 US
Contact: miguel.gascon@commscope.com

Certified by:

Miguel Gascón

Senior Manager Product Sustainability & Compliance

Thomson Tom Attachment

May 14th, 2025
VIA ELECTRONIC SUBMISSION: https://minnesotaoah.granicusideas.com/
Honourable Judge Jim Mortenson
600 North Robert Street
St. Paul, MN 55101

Re: Minnesota Pollution Control Agency's Notice of Intent to Adopt New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per- and Polyfluoroalkyl Substances (PFAS), Revisor's ID Number R-04828, OAH docket number 5-9003-40410

Dear Judge Mortenson,

Steam Thermal Solutions (part of Spirax Group), appreciates the opportunity to submit these comments regarding the Minnesota Pollution Control Agency's (MPCA) proposed rule on PFAS in products: Reporting and Fees.

Executive Summary

As a responsible supplier of steam and thermal control systems, Steam Thermal Solutions supports the overarching objective of environmental protection and transparency. This submission outlines our structured feedback on the Minnesota Pollution Control Agency's (MPCA) proposed PFAS in Products: Reporting and Fees rule. We provide observations and recommendations organised by rule section, with the aim of supporting effective implementation, and aligning reporting requirements with technical realities and supply chain constraints.

1. Company Overview and Context

Steam Thermal Solutions (STS) is a world-leading provider of industrial steam and thermal energy solutions. As a manufacturer of large-scale, fixed industrial installations, STS operates in a fundamentally different space from high-volume commercial markets. Our products are not mass-produced consumer items sold in the millions, but rather specialised components delivered in smaller volumes to support critical infrastructure and industrial processes worldwide. These components serve essential sectors such as:

- Pharmaceutical manufacturing
- Hospitals and healthcare systems
- Oil and gas operations
- Food and beverage production
- General industrial manufacturing

Due to the scale and nature of our installations, along with the strategic importance of the industries we support, our operations are frequently recognised as being outside the scope of certain regulations. For example, within the European Union, our products are currently deemed out of scope for both the RoHS (Restriction of Hazardous Substances) and WEEE (Waste Electrical and Electronic Equipment) directives for these very reasons.

2. Purpose of Submission

Spirax Sarco STS welcomes the opportunity to contribute to the Minnesota Pollution Control Agency's (MPCA) rulemaking process on PFAS in Products: Reporting and Fees. We support

the goal of increasing product transparency and safeguarding public and environmental health. In reviewing the proposed rule, we offer the following consolidated recommendations to support effective implementation and minimise unintended complexity for industrial manufacturers.

3. Summary of Key Observations and Comments on Rule Sections (Parts 7026.0010 to 7026.0100)

Rule parts and subparts are indicated in parentheses for clarity.

We find the definitions section broadly appropriate and aligned with statutory intent. We believe the term "manufacturer" would benefit from additional clarification to explicitly include importers and brand owners who place products on the Minnesota market, particularly in global supply chain scenarios where manufacturing, branding, and sales are distributed across different parties (7026.0010).

In terms of reporting responsibility, we appreciate the clear assignment of obligations for products with intentionally added PFAS (7026.0020, Subp. 1). However, in complex industrial supply chains, formal multi-party reporting agreements may prove administratively burdensome. We therefore suggest that brand owners be permitted to take on reporting responsibility directly, provided they retain documentation demonstrating due diligence (e.g., supplier declarations, MSDS) (7026.0020, Subp. 2).

We strongly support the allowance for grouping similar products and recommend that this approach be extended to product models with the same PFAS content and functional use, such as varying sizes of steam traps or valves (7026.0030, Subp. 1.A). In line with this, we suggest that internal model numbers or manufacturer-assigned codes be accepted in the absence of UPC or global identifiers (7026.0030, Subp. 1.A).

Regarding chemical reporting, we support PFAS disclosure and request further guidance on how to report polymeric PFAS, such as PTFE. These materials are often critical to product performance and safety but may be supplied with limited compositional transparency. We encourage MPCA to permit reporting by base polymer name and CASRN, and to allow manufacturers to invoke a "Not Known or Reasonably Ascertainable" (NKRA) provision such as one that was modelled after TSCA reporting for cases where supplier data is unavailable or protected by trade secrecy (7026.0030, Subp. 1.B/C).

About initial reporting fees, we understand the need for cost recovery but are mindful of the impact on manufacturers with a diverse product portfolio. We suggest allowing manufacturers to submit a bundled report covering multiple product families under a single $1,000 fee, as opposed to fees being levied per product line (7026.0030, Subp. 2).

About due diligence, we support MPCA's requirements and request confirmation that standardised declarations and reasonable supplier engagement are sufficient to meet expectations, especially in cases where suppliers cannot provide detailed chemical data (7026.0080, Subp. 2).

4. Feasibility of Substitution and Long-Term Planning

Experience from other countries shows that regulations covering all PFAS substances under one definition can cause problems. Not all PFAS are the same - some small-molecule types can be harmful, while others, like long-chain fluoropolymers used in STS products (such as PTFE), are stable, non-reactive, and safely contained within industrial equipment. These materials are essential for products that must withstand high temperatures, pressure, and

chemical exposure, such as steam traps and valves. STS uses them only where necessary for performance and safety.

Importantly, STS does not manufacture PFAS substances. Rather, certain components containing PFAS such as seals or seats, that are applied within our products solely to deliver essential performance benefits that our customers rely upon. Identifying and validating viable, drop-in substitutes for these components is not straightforward. We are heavily dependent on the global supply chain to develop and qualify alternatives, and current progress remains uncertain

Feedback gathered in major European consultations has shown that clear distinctions between harmful and essential uses help create more workable rules. We encourage MPCA to consider a similar approach, one that allows the safe and controlled use of PFAS in industrial systems where no alternatives currently exist, while still meeting environmental goals

5. Proactive Measures

STS has begun reviewing thousands of product documents and part numbers across our US Sales and Purchase records. We are also investing in supplier engagement efforts and Material compliance documentation to improve visibility across our global supply chain. These steps are intended to align with the MPCA's reporting objectives.

6. Closing Statement

We respectfully urge MPCA to consider the complexity of B2B product structures, supply chain limitations, and the critical performance roles that PFAS materials play in essential products. We encourage the agency to adopt a risk-based and proportionate approach to rule implementation that protects the environment while remaining achievable for global manufacturers.

We appreciate the opportunity to provide this comment and remain available for further engagement.

Yours sincerely,
Spirax Sarco STS

Contact Details

Name	Email	Department	Address
Thomson Tom	Thomson.tom@uk.spiraxsarco.com	STS Compliance	Spirax Group plc Charlton House, Cirencester Road Cheltenham, GL53 8ER, United Kingdom

BUSINESS + INSTITUTIONAL FURNITURE MANUFACTURERS ASSOCIATION
678 Front Avenue NW | Suite 150 | Grand Rapids, Michigan 49504-5368

BIFMA

Response to Request for Comments

To: Minnesota Pollution Control Agency

From: Steve Kooy

Date: May 16, 2025

Subject: Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees, Revisor's ID Number R-4828, Chapter 7026

The Business Institutional Furniture Manufacturers Association (BIFMA) appreciates the opportunity to comment on PFAS reporting and related fees. BIFMA represents over 150 North American manufacturers and suppliers who provide most of the contract furniture in the United States, Canada, and Mexico. We are proud of our long history of working with government entities to reduce or eliminate harmful chemicals via voluntary actions or in coordination with pragmatic legislation. In the case of PFAS, manufacturers continue to eliminate PFAS and have done so in textiles and other surface treatments.

In response to the request for comments, please consider the following:

Section 7026.0030, Report; Required Information:

> *Subpart 1.* ***Report required****. A manufacturer or group of manufacturers of a product 5.3 that is sold, offered for sale, or distributed in the state and that contains intentionally added 5.4 PFAS must submit a report to the commissioner on or before January 1, 2026. A manufacturer 5.5 or group of manufacturers of a new product with intentionally added PFAS after January 5.6 1, 2026, must submit a report before the product can be sold, offered for sale, or distributed 5.7 in the state. The report must include the following information in a format specified by the 5.8 commissioner:*

BIFMA Comment: Given the extensive investigation required, the complexity of data organization, and the uncertainty surrounding the requested information, manufacturers face significant challenges in meeting the proposed January 1, 2026, deadline. Furthermore, manufacturers are navigating an increasingly complex landscape of state and federal compliance and reporting deadlines related to PFAS and other environmental regulations. To ensure a more practical and coordinated approach, BIFMA recommends that MCPA align its reporting timeline with the EPA's TSCA Section 8(a)(7) deadline of October 13, 2026.

Section 7026.0030, Report; Required Information:

> *A. a product description that includes: (1) a brief description of the product or grouping of similar products. Once established, the identical brief description of the product must be used during any reporting updates on the product.*

BIFMA Comment: BIFMA supports the reporting option of a category or grouping of similar products versus SKU or product-specific identifiers. Due to variations in color, options, dimensions, etc., a furniture product (e.g. task seat) may have millions of variations and SKUs.

Section 7026.0030, Report; Required Information:

> *B. PFAS chemicals used in the product or its components as identified by:*
> *(1) the chemical name; and*
> *(2) the Chemical Abstracts Service Registry number (CASRN) or, if no CASRN exists, another chemical identifying number;*

BIFMA Comment: BIFMA members have repeatedly asked suppliers for specific chemical names with little to no success for several reasons:

1) Suppliers consider this confidential business information. Chemical Abstract Service (CAS) registry numbers are also difficult to obtain without a nondisclosure agreement (NDA) signed by the manufacturer with the supplier. An executed NDA will not allow the information to be disclosed, especially in a publicly accessible database.
2) Specific PFAS and/or other chemistry may change based on cost, changes in suppliers in tier 2, 3, 4, etc. and/or quality issues. Tariffs, lead times, compliance requirements in other countries, provinces or states lead to further variations.
3) Analytical methods are costly, often provide false positives in the form of organic or inorganic fluorine and provide a snapshot in time. If a PFAS compound is intentionally added, it remains difficult and extremely costly to determine the specific chemical and exact concentration.

BIFMA recommends a class-based approach to identify PFAS as intentionally added or not. A class-based approach supports Minnesota's 2032 ban while avoiding the likelihood of bad data and/or legal issues due to confidentiality.

Section 7026.0100 FEES.

> *Subp. 2. Initial report. A manufacturer must pay a $1,000 fee to submit the initial report under part 7026.0030, subpart 1. If a group of manufacturers is reporting or a manufacturer is reporting on behalf of multiple manufacturers as allowed under part 7026.0020, subpart 2, each individual manufacturer must pay a $1,000 fee.*
>
> *Subp. 3. Annual update or recertification. A manufacturer must pay a $500 flat fee for the annual update according to part 7026.0040, subpart 1, or annual certification update according to part 7026.0040, subpart 3. If a group of manufacturers is reporting or a manufacturer is reporting on behalf of multiple manufacturers as allowed under part 7026.0020, subpart 2, each individual manufacturer must pay the $500 fee.*

BIFMA Comment: BIFMA supports a one-time reasonable fee, however the annual fee of 50% the initial fee becomes an annual tax deemed excessive. Reporting fees proposed in many other states should be considered as well given the reporting and the financial burden is growing quickly. BIFMA recommends zero fees for annual updates.

General BIFMA Comment: BIFMA and its members continue to encourage harmonization amongst all states seeking to report and remove PFAS. Businesses have limited resources; therefore more resources are used to support individual state programs reporting requirements and fees which leads to less resources investigating PFAS-free alternatives.

On behalf of the industry members, we welcome the opportunity to work together further on this important issue. Please reach out to Steve Kooy, skooy@bifma.org, with any questions or requests.

Thank you,

Steve Kooy
Director of Health and Sustainability
BIFMA

May 19, 2025

By Electronic Submission

The Honorable Jim Mortenson
Minnesota Office of Administrative Hearings
600 North Robert Street
PO Box 64620
St. Paul, Minnesota 55164-0620

Subject: Minnesota Pollution Control Agency's Notice of Intent to Adopt New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per-and Polyfluoroalkyl Substances (PFAS, Revisor's ID Number R-4828, OAH Docket Number 5-9003-40410

Dear Judge Mortenson:

Emerson Electric Co. (Emerson) appreciates the opportunity to respond to the State of Minnesota's Pollution Control Agency's (MPCAs) request for comments on the PFAS in Products Reporting and Fee Rule. We commend MPCA for giving industry the opportunity to participate in this important process.

In the fiscal year 2024, Emerson reported a global revenue of $17.5 billion, with its subsidiaries in Minnesota contributing more than $4 billion to that total. The company is dedicated to producing products that are safe for both end-users and the environment, aligning with the goals of the MPCA.

Emerson maintains a significant presence in Minnesota, employing over 2,900 people at 4 sites throughout the state. Emerson industrial automation products and solutions proudly invented and still manufactured in Minnesota play a critical role in supporting key industries such as renewable energy, medical technology, and semiconductor manufacturing helping them operate more sustainably while improving productivity, energy security and reliability. Our solutions deliver significant economic, societal, and environmental value to Minnesota and beyond.

Emerson has concerns with the PFAS in Products Reporting and Fee Rule, particularly regarding the implementation timelines, clarity of scope, supplier engagements, due diligence requirements, and the mandate to report PFAS concentration levels. Without modifications, the rule would impose a disproportionate reporting and fee burden on manufacturers of complex products. We offer the following comments as supporting information:

1. *The Enforcement Deadline and Extension Period are Unreasonably Short for Manufacturers of Complex Products.*

The PFAS reporting and fee rule deadline is unreasonable for manufacturers of complex products. As written, the rule will likely necessitate an immediate extension request.

Emerson's large portfolio of complex products, consisting of over 100,000 products and >15,000 suppliers, makes compliance with this reporting rule challenging. Additional time is needed due to:

- **Limited Awareness on PFAS Across the Value Chain.** PFAS knowledge varies significantly across the value chain, requiring fundamental training for some suppliers, which has proven to be time-consuming.

- **Data Collection Complexities.** The process of collecting comprehensive data on PFAS-containing products and components, along with standardizing data collection and reporting processes across Emerson and its suppliers is also very time-consuming.

Our Ask: Is the MPCA able to delay enforcement for six months or grant a longer extension under Rule 7026.0060, Subpart 3B?

Proposed Solutions: Emerson respectfully requests that MPCA Provide a six-month delay in enforcement of the reporting rule or extend the allowable period in Rule 7026.0060, Subpart 3B from 90 days to 180 days.

2. *Applying a Reporting and Fee Scheme to the Entire Supply Chain is Likely Not Possible for Complex Products.*

Imposing disclosure and fee requirements across the entire supply chain for all PFAS-containing products entering Minnesota creates an unmanageable burden for manufacturers of complex products.

While we appreciate MPCA's effort to provide two reporting options: (1) individual manufacturer reporting and (2) one manufacturer reporting on behalf of a group of manufacturers, we find it difficult to envision either approach being feasible for complex products.

Under Option (1), a complex product with a long, global supply chain could involve a dozen or more suppliers. Requiring each of them to submit separate reports is both impractical and overly burdensome.

Under Option (2), companies are unlikely to accept legal responsibility for the actions of other entities within the supply chain or for independent legal entities in general.

A key potential unintended consequence of the PFAS reporting rule and associated fee assessment is the risk of supply chain disruption. Some fluoropolymer components used in our products are sourced from suppliers who may choose to exit the Minnesota market rather than take on the added administrative burden and costs. Emerson often relies on components that, while low in volume and cost, are essential to the function and reliability of critical, high technology and sophisticated instruments. For instance, a fluoropolymer o-ring used to protect sensitive electronics from harsh environments may be inexpensive, yet it plays a vital role in ensuring product performance, reliability, and safety. In this scenario, Emerson would need to explore alternative manufacturing options or locations for its products.

Supplier confidentiality is another general key concern. Complex manufacturers often rely on multiple sources and strategically manage their supply chains to maintain a competitive edge. Compliance with Minnesota's reporting rule conflicts with this approach and could compromise proprietary sourcing strategies.

Our ask: Can Section 7026.0020, Subparts 1 (Scope) and 2 (Reporting on Behalf of Other Manufacturers), be revised to eliminate the requirement for suppliers to report on individual components and pay associated fees?

Our proposal: Modify Section 7026.0020, Subparts 1 (Scope) and 2 (Reporting on Behalf of Other Manufacturers) to permit the manufacturer of the final product to submit a single, consolidated report at the **parent company level,** covering all subsidiaries, product groups, and components containing PFAS. This report would apply to products sold into or manufactured within Minnesota, thereby eliminating the need for component suppliers, global or domestic, to report separately and pay fees. Under this approach, only one fee would be payable for the entire group of covered subsidiaries.

3. Reporting Requirements Lack Clarity and are Potentially Overly Burdensome.

Rule 7026.0030, Subpart 1 defines the scope of reporting and sets out two distinct scenarios: one for products to be sold after January 1, 2026, and another for new products, which mandates reporting prior to any sale occurring after January 1, 2026.

The challenge with the first scenario is that the rule does not clearly define how such products should be identified. Is the intent to base reporting on a company's entire product catalog, encompassing everything that could potentially be 'offered for sale' in Minnesota? Of the 100,000 products in Emerson's catalog only a fraction will be sold or distributed for sale in the State of Minnesota. Requiring disclosure of an entire product catalog would be excessively burdensome and unlikely to provide meaningful value to either the MPCA or the reporting entity.

The second scenario involving new products sold after January 1, 2026 is clear.

Our Ask: Can MPCA clarify the scope of PFAS-containing products to include in the report that is due by January 1, 2026?

Proposed Solution: Clarify that only projected sales be included in the report due on January 1, 2026 and not the entire product catalog. This change allows manufacturers to set a basis for the products to be included in the report.

4. *Due Diligence Expectations are Unrealistic and are not Likely to be Met by January 1, 2026.*

Meeting the mandatory supplier disclosure standard under the PFAS Reporting Rule by January 1, 2026, poses a significant burden for companies operating within complex, global supply chains. In our experience, the probability of achieving a high rate of success is very low.

Our peers in the industrial automation industry have invested heavily in efforts to obtain full material disclosures from suppliers and other sources with limited success. This is primarily due to supplier reluctance to share sensitive information and limited resources on their part.

We recommend modifying the reporting standard, at least for the first two to three years, from mandatory supplier disclosure to a standard based on known or reasonably ascertainable information. This approach is more aligned with regulatory precedent and operational realities. Further justification includes:

- **Due Diligence Approach is Mis-Aligned with Precedent**: Mandatory supplier disclosure deviates from established PFAS reporting due diligence standards. Agencies such as the U.S. EPA under TSCA, Environment and Climate Change Canada (ECCC), and several state-level programs recognize reasonably ascertainable information as a valid and sufficient due diligence standard.
- **Disproportionate Administrative & Cost Burden**: Imposing a uniform, mandatory disclosure requirement across all products and suppliers creates a disproportionate administrative & cost burden on companies with complex supply chains and multi-tiered sourcing structures.
- **Compliance Flexibility is Needed**: The reasonably ascertainable standard is not a shortcut. It allows companies the flexibility to collect relevant information through a combination of supplier outreach, document review, and internal processes, while still demonstrating a robust and defensible compliance effort.

Our Ask: Can MPCA change the due diligence reporting standard from ‘Mandatory Reporting Disclosure’ to ‘Reasonably Ascertainable’.

Proposed Solution: Consider adopting the due diligence standard of "reasonably ascertainable," consistent with the precedent set by EPA TSCA, Canada’s ECCC, and the State of Maine.

5. *The PFAS Concentration Requirement Lacks Clarity and is Likely to Cause Confusion Among Companies that are Solely Downstream Users of Fluoropolymers, a Group that Represents the Majority of Reporting Entities.*

Emerson recognizes the difficulty MPCA faces in distinguishing between fluoropolymers, the non-polymeric PFAS processing aids used within fluoropolymers, and other PFAS compounds present in companies' supply chains.

This complexity often results in overly broad regulatory decisions that unintentionally penalize the majority of companies using fluoropolymers responsibly, in an attempt to regulate a small subset who are not. The issue of concentration is a good example. The largest users of PFAS are typically downstream manufacturers who incorporate fluoropolymer components into their products. However, these users generally do not have access to the sophisticated laboratory capabilities required to detect trace amounts of PFAS processing aids in fluoropolymers.

Further complicating the matter is the fact that fluoropolymers are themselves classified as a PFAS. This makes it arguable that their PFAS concentration is always close to 100%, even though the actual concern lies with trace residuals. Additionally, performing Total Organic Fluorine (TOF) testing across the wide variety of parts potentially containing PFAS is both impractical and cost-prohibitive.

As a result, reported concentration data from downstream users is likely to be of low quality. Many may unintentionally confuse concentration with total mass, rely on estimates due to time constraints, or provide inaccurate information, creating frustration for both submitters and the MPCA.

Our Ask: Can MPCA assign a checkbox and a corresponding designated concentration for fluoropolymers in section 7026.0030, Subpart 1, Section C?

Proposed Solution: In section 7026.0030, Subpart 1, Section C, we respectfully recommend that the MPCA assign a designated concentration for fluoropolymers and an accompanying checkbox to simplify reporting of fluoropolymers. Concentration data can still be required for other, more relevant PFAS substances.

Contact Details: Amy Neal | **Amy.Neal@emerson.com**

Comments on the Reporting and Fees
for the Proposed Permanent Rules Relating to PFAS in Products

May 2025

We would like to express our gratitude for the opportunity to provide comments during the public consultation on the proposed permanent rules relating to PFAS in products. After reviewing the proposed rules, we would like to submit the following comments:

1. Proposal to Exempt Fluoropolymer-Containing Products

Fluoropolymers such as PVDF and PTFE exhibit long-term stability against air, water, sunlight, chemicals, and microbial activity, extending product lifespan and reducing maintenance frequency and waste generation. They can be safely incinerated under proper conditions, minimizing environmental impact. In society, fluoropolymers play crucial roles in various industries such as healthcare, renewable energy, transportation, and advanced electronics. Their chemical inertness and performance in extreme conditions enhance safety and efficiency. Additionally, their production methods are designed to be sustainable, minimizing environmental impact. Thus, fluoropolymers provide stability and durability to the environment while serving essential roles across multiple industries.

Looking at the legislative landscape in the United States, New Mexico's state law HB212 has already excluded fluoropolymer-containing products from the regulation, and California is also advancing discussions on SB730, a bill that similarly excludes fluoropolymer-containing products from regulation. Differences in regulatory approaches among states could lead to confusion in the U.S. industrial sector and negatively impact the development of related industries. Considering these developments in other states, Minnesota should also exclude fluoropolymer-containing products from the scope of regulation.

2. Proposal to Exempt Certain Critical Applications

Maine's PFAS regulations (38 MRS § 1614) include provisions in Section 4 that exempt certain applications from the scope of regulation, such as automobiles, semiconductors, and semiconductor manufacturing equipment and materials. These applications are essential and rely heavily on the use of fluoropolymers. Differences in regulatory approaches among states could lead to confusion in the U.S. industrial sector and negatively impact the development of related industries. Considering these developments in other states, Minnesota should also establish exemptions for certain critical applications, such as automobiles and semiconductor-related uses, separate from the CUU (currently unavoidable use) provisions,

and exclude them from the scope of regulation.

3. Proposal to Extend the Reporting Deadline by More Than One Year

The proposed rule sets the reporting deadline as January 1, 2026. However, as of now, with only about six months remaining until this deadline, the rule has not yet been finalized and is still in the public consultation phase. Considering the time required for the rulemaking process, there will be less than six months between the finalization of the rule and the reporting deadline. Imposing such a tight schedule on manufacturers would place a significant burden on them and could lead to incomplete or inaccurate submissions due to insufficient preparation time. Therefore, we propose extending the reporting deadline by at least one year to allow manufacturers sufficient time to gather the necessary information.

4. Proposal to Eliminate the Annual Update and Recertification Requirements

The proposed rule requires annual updates to the reported information in cases of significant changes and mandates annual recertification even when no updates are necessary.

Considering the role of the proposed rule in collecting information on PFAS-containing products and balancing the burden on both manufacturers and state authorities, it would be more appropriate to adopt a principle of one-time reporting. Annual updates should not be required, and updates should only be mandated in cases where there are significant changes to the previously submitted information.

Furthermore, the requirement for annual recertification even when there are no changes to the reported information is clearly an excessive obligation. This imposes a significant burden on manufacturers and should therefore be eliminated.

Lastly, we recognize that Minnesota is one of the states in the U.S. that is about to adopt the most stringent regulations regarding PFAS. Regulations that are significantly stricter than those of other states could result in the loss of essential PFAS applications (especially those related to fluoropolymers) and lead to an exodus of industries to other states. For the further development of your state, we believe it is necessary to align with the efforts of other states and the U.S. federal government and introduce an appropriate form of regulation that is not excessive.

Amanda Duerr Attachment

May 20, 2025

The Honorable Jim Mortenson
Minnesota Office of Administrative Hearings
600 North Robert Street
PO Box 64620
St. Paul, Minnesota 55164-0620

Your Honor:

On behalf of the Minnesota Automobile Dealers Association (MADA), the trade association representing the state's franchised new motor vehicle dealerships, we appreciate the opportunity to provide feedback on the Minnesota Pollution Control Agency's (MPCA) Proposed Permanent Rules relating to PFAS in Products: Reporting and Fees Rule, Revisor's ID Number R-4828, OAH docket 5-9003-40410.

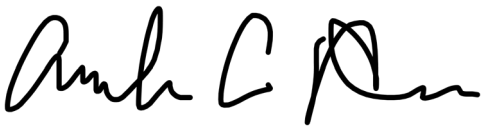
While MADA recognizes that the scope of these proposed rules is directed at manufacturers, we are concerned with their effect on the retail sector. By imposing complicated reporting measures, Minnesota becomes a national outlier and a more difficult place to do business.

The lack of clarity surrounding the reporting of individual products or components and group submissions will no doubt lead to significant administrative expense on the part of manufacturers. On top of that, the initial reporting fees and subsequent annual updates will add real costs to products sold in Minnesota. We are keenly aware that these costs will be passed along to retailers, and ultimately our customers.

We are further concerned that some manufacturers may opt out of Minnesota entirely, given our relatively small market, due to the costs and regulatory complexities. This further hurts the Minnesota consumer.

MADA urges the MPCA to listen to the feedback being provided by manufacturers and take action to reduce this Proposed Rule's cost and administrative burdens.

Sincerely,



Amanda Duerr
Director of Government Affairs
Minnesota Automobile Dealers Association

Jesse McArdell Attachment

National Marine Manufacturers Association

May 20, 2025

The Honorable Jim Mortenson
Minnesota Office of Administrative Hearings
600 North Robert Street
PO Box 64620
St. Paul, Minnesota 55164-0620

Re: Comments of the National Marine Manufacturers Association on the Minnesota Pollution Control Agency's PFAS in Products Proposed Rule (Revisor's ID Number R-4828; OAH Docket No. 5-9003-40410)

Your Honor,

The National Marine Manufacturers Association (NMMA) appreciates the opportunity to comment on the Minnesota Pollution Control Agency's (MPCA) Proposed Permanent Rules Relating to Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) in Products. NMMA is the leading trade association representing North American recreational boat, engine, and accessory manufacturers. Our members produce over 80% of marine products sold in the United States, contributing significantly to Minnesota's outdoor recreation economy.

We are committed to sustainability and support sound science-based policies that protect human health and the environment. However, we are concerned that the current draft rule presents significant and disproportionate compliance challenges for the recreational marine industry, especially given the complexity of modern boat manufacturing, the structure of supply chains, and the limited availability of PFAS use information.

I. Definitions: Complex Products and Product Component

We support the inclusion of the term "complex product" in the rule. Marine products—such as boats—are comprised of thousands of components sourced from global supply chains. These include electronics, fuel systems, seats, coatings, and adhesives, each of which may contain PFAS compounds for specific and often essential performance reasons (e.g., water and oil repellency, chemical resistance).

We urge MPCA to ensure that definitions for "product component" and "complex product" are aligned with terminology used in other jurisdictions (such as the U.S. EPA's TSCA reporting

guidance and the European Chemicals Agency's SCIP database), to promote consistency and reduce unnecessary regulatory burden.

II. Product Reporting Scope and Timelines

The current deadline for initial reporting, January 1, 2026, is not feasible for manufacturers of complex products like boats. NMMA urges the agency to extend the implementation timeline and consider a phased or tiered reporting approach, like frameworks adopted in other states. For example, Maine recognized the unique challenges posed by watercraft and fully exempted them from reporting requirements in 2024.

Marine manufacturers often do not have direct knowledge of all the materials or substances used in each component of their products, especially when those components are proprietary or imported. Requiring full disclosure of intentionally added PFAS by this deadline would place an unreasonable burden on manufacturers and their suppliers.

III. Due Diligence Requirements

NMMA supports a due diligence standard for PFAS reporting that is reasonable and attainable. Given the global and multi-tiered nature of the marine industry's supply chain, manufacturers must rely on upstream suppliers for accurate material content information.

To this end, the rule should explicitly recognize that due diligence includes the following activities:

- Conducting supplier surveys using standardized industry tools such as the IPC-1752A or IMDS systems.
- Reviewing safety data sheets (SDS), technical data sheets, and other supplier-provided documentation.
- Requesting declarations or certifications of compliance from suppliers.
- Using risk-based approaches to prioritize inquiry based on product type, use, or historical presence of PFAS.
- Engaging third-party compliance service providers or consultants to conduct assessments.

If, after making good-faith efforts through these means, a manufacturer is unable to obtain complete information, this should be considered compliant under the due diligence standard. The rule should clarify that self-reporting based on available information, accompanied by a clear statement of data limitations, fulfills the requirement.

Recognizing the limitations of information gathering is particularly important when PFAS are used in trace amounts or as impurities, or when suppliers invoke trade secret protections (see below).

IV. Trade Secret Protections

The recreational marine industry frequently sources components that are proprietary, including electronics, coatings, sealants, and specialized composites. Suppliers may justifiably refuse to disclose full chemical formulations due to intellectual property concerns. Without robust trade secret protections, these suppliers may choose to exit the Minnesota market entirely, which would harm both consumers and manufacturers.

We urge MPCA to ensure the final rule:

- Provides clear, accessible mechanisms for asserting trade secret protections in compliance with the Minnesota Government Data Practices Act.
- Allows submitters to withhold or mask specific chemical identities where disclosure would cause competitive harm, provided that sufficient justification is submitted.
- Enables upstream suppliers to submit secret trade information confidentially and directly to the agency, without routing through downstream manufacturers.
- Protects both chemical identities and concentration data when appropriate.

Additionally, MPCA should clarify how it will secure and manage confidential business information (CBI) to prevent unintended disclosures, particularly for manufacturers relying on supplier declarations.

V. Fees and Cost Considerations

We recommend that MPCA establish a fee structure that reflects the scale of reporting and the capacity of businesses. NMMA supports:

- A tiered fee structure based on company size and number of product lines reported.
- Fee waivers or reductions for small businesses and manufacturers with limited market presence in Minnesota.

Overly burdensome fees will discourage compliance and may reduce product availability for Minnesota consumers.

VI. Coordination with Other Jurisdictions

Manufacturers selling into multiple states already face a patchwork of differing PFAS disclosure requirements. To the extent possible, MPCA should:

- Align reporting categories and data elements with the Maine PFAS in Products program and the Washington State Safer Products initiative.
- Accept equivalent reports submitted to other states or federal agencies, including the EPA's TSCA PFAS reporting rule, where appropriate.

This harmonization will promote compliance, reduce duplicative work, and ensure consistent data quality.

Conclusion

NMMA supports efforts to improve transparency and reduce unnecessary use of PFAS in consumer products. However, the proposed rule must account for the realities of complex product manufacturing and the current limitations of global supply chains. We urge MPCA to extend the compliance timeline, clarify the due diligence and trade secret provisions, and align its framework with other state and federal programs.

We appreciate your consideration of these comments and welcome further engagement to develop a workable and effective PFAS reporting program.

Sincerely,

Jesse McArdell

Senior Manager of
Midwest Government
Relations
National Marine
Manufacturers Association

RECEIVED
By: OAH on 5/20/2025

Kristin Emery Attachment

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May 21st, 2025

Via Electronic Submission: https://minnesotaoah.granicusideas.com/

The Honorable Jim Mortenson
Minnesota Office of Administrative Hearings
600 North Robert Street
PO Box 64620
St. Paul, Minnesota 55164-0620

Subject: Minnesota Pollution Control Agency's Notice of Intent to Adopt New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per-and Polyfluoroalkyl Substances (PFAS, Revisor's ID Number R4828, OAH Docket Number 5-9003-40410

Dear Judge Mortenson,

Yukon Medical is grateful for the opportunity to provide feedback on the proposed PFAS reporting and fees rule.

Yukon Medical appreciates the importance of PFAS reporting and the need to provide ongoing confirmation in the form of recertification to confirm that the reported information is still accurate, However, the $500 per report annual recertification fee (7026.0100 Fees, Subp. 3) will be especially prohibitive to small businesses such as ours that operate with tight margins. We recommend lowering the annual recertification fee amount to $100 or less so that small businesses can continue to sell into Minnesota instead of foregoing the market or having to pass the costs on to customers.

We appreciate the opportunity to provide this comment.

Yukon Medical
4021 Stirrup Creek Dr.
Stuie 200
Durham, NC 27705

Contact Details: Kristin Emery kemery@yukonmedical.com

Thomas Cortina Attachment

May 20, 2025

Minnesota Pollution Control Agency
520 Lafayette Road North
St. Paul, Minnesota 55155-4194

Submitted online via OAH Rulemaking eComments Website

Re: Proposed Rule for Reporting and Fees for Products Containing Per-and polyfluoroalkyl Substances (PFAS), Revisor's ID Number R-4828

The Halon Alternatives Research Corporation, Inc. (HARC) appreciates the opportunity to provide comments to the Minnesota Pollution Control Agency (MPCA) on the proposed rule for reporting and fees for products containing PFAS. HARC is a non-profit trade association formed to promote the development and approval of halon alternatives that serves as an information clearinghouse and focal point for cooperation between government and industry on issues of importance to special hazard fire protection. HARC members encompass all levels of the fire protection industry including agent manufacturers, equipment manufacturers, distributors/installers, recyclers, and end-users.

Need for a Currently Unavoidable Use determination for HCAs used in fire protection

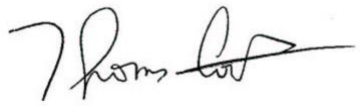
The halogenated clean agents (HCAs) used for fire protection that meet the definition of PFAS in the Minnesota law are FK-5-1-12, HFC-227ea, HFC-125, HFC-236fa, 2-BTP and HCFC Blend B. On March 1, 2024, HARC submitted comments to MPCA on the need for a currently unavoidable use determination for HCAs used in fire protection. HARC's comments noted that there are important uses of HCAs in facility, aviation and military applications for which non-PFAS alternatives do not exist and are not currently in development. As such we expect there to be continuing uses of HCAs for fire protection well beyond January 1, 2032.

Request to delay the deadline for PFAS reporting to January 1, 2027

HARC would respectfully request that the deadline for PFAS reporting be pushed back to January 1, 2027. There are only six months until the reporting is due, and the rules have not been finalized and the reporting system has not been developed. There are questions about who along the supply chain must report and how the required information would be shared among different parties in the supply chain. HARC believes it would be onerous to finalize the reporting system in October or November and expect manufacturers to report by the end of the year. Rather than have numerous manufacturers requesting an extension, MPCA should push back the deadline.

Please let us know if you have any questions or would like to discuss these issues in further detail.

Respectfully submitted,



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May 20, 2025

Submitted via the Minnesota Office of Administrative Hearings eComments Website

Katrina Kessler
Commissioner, Minnesota Pollution Control Agency
520 Lafayette Road N
St. Paul, MN 55155-4194

Re: Comments on Proposed Reporting Rule Regarding Products Containing Per- and Polyfluoroalkyl Substances (PFAS)

Dear Commissioner Kessler:

The PFAS Pharmaceutical Working Group[1] is a group of manufacturers and distributors of drugs, biologics, animal drugs, and medical devices. PPWG appreciates the opportunity to provide comments on the Minnesota Pollution Control Agency (MPCA) proposed rule concerning submission of information on products containing PFAS (the Reporting Rule), implementing Minn. St. § 116.943 (Section 116.943), subdivision 2.

PPWG submitted comments in November 2023 and in December 2024 in response to the MPCA's first and second request for comments, respectively, to inform initial drafting of the Reporting Rule.[2] PPWG incorporates those earlier comments by reference and reiterates two threshold recommendations in these comments. First, as discussed in PPWG's 2023 comments, the MPCA should state expressly as part of this rulemaking, and in line with the principles of federal preemption, that U.S. Food and Drug Administration (FDA)-regulated products and their packaging are out of scope of the Reporting Rule.

Secondly, as explained in PPWG's 2024 comments, in the event that the MPCA does not make a statement that FDA-regulated products are out of scope, the MPCA should specify that the material restriction in Section 116.943, subdivision 2(d) does not apply to FDA-regulated products. The law states that a person must receive notification under subdivision 4 for this restriction to take effect, and subdivision 8 makes clear that subdivisions 4 and 5 of the statute do not apply to FDA-regulated products. The MPCA must therefore follow the Minnesota Legislature's direction and find that FDA-regulated products cannot be restricted under subdivision 2(d). This finding is crucial

[1] PPWG's member companies, which include their subsidiaries and affiliates, are Amgen Inc.; Bristol Myers Squibb Company; GSK; Merck & Co., Inc.; Pfizer Inc.; and Roche.
[2] PPWG's November 2023 and December 2024 comments on the MPCA's planned Reporting Rule can be viewed in the Minnesota Office of Administrative Hearings' public commenting portal at https://tinyurl.com/bdefn5h9 and https://tinyurl.com/2nz75c8h, respectively. The Group also submitted comments on the MPCA's planned PFAS Currently Unavoidable Use Rule, which can be viewed at https://tinyurl.com/97vxk9u9.

to provide certainty to patients, medical professionals, and others that life-enhancing and life-saving FDA-regulated products will remain on the market in Minnesota in the event that such products are in scope of the Reporting Rule.

PPWG also has recommendations that will make the Reporting Rule more workable for the MPCA to administer and for industry to comply with. Namely, the MPCA should:

- Extend the January 1, 2026 reporting deadline by at least one year, given that the Reporting Rule is expected to be finalized (and the reporting portal is expected to be made available) just shortly before this current deadline. The Reporting Rule must be finalized and the reporting portal must be operational well in advance of the reporting deadline in order for companies to structure due diligence in a manner that will generate PFAS data that is of practical use to the agency. This extension should be granted now as part of this rulemaking, rather than waiting for potentially thousands of individual extension requests to be received by the agency once the Reporting Rule is finalized.

- Incorporate the federal "known to or reasonably ascertainable by" (KRA) reporting standard. The due diligence section in the proposed Reporting Rule states that manufacturers must request detailed disclosure of reportable information from their supply chain "until all required information is known." This requirement is overly burdensome, unrealistic, and at odds with PFAS reporting requirements in other jurisdictions. Instead, the MPCA should employ the KRA standard as developed by the U.S. Environmental Protection Agency (EPA) under the Toxic Substances Control Act (TSCA).

- Confirm that manufacturers are not required to conduct PFAS testing in preparation for reporting. PPWG reads the proposed Reporting Rule as not requiring companies to conduct PFAS testing. PPWG asks the MPCA to confirm this interpretation, because any broadly applicable testing requirement would be overly burdensome, unrealistic, and contrary to the statute. Instead, and consistent with the KRA standard PPWG is requesting that the MPCA adopt, companies should only need to report information they already have (or can reasonably determine) on PFAS in their products. Testing products for PFAS is often cost prohibitive and inaccurate, particularly given the lack of available test methods.

- Allow companies to report at the product level, rather than requiring reporting at the product component level. The proposed Reporting Rule would require companies to report at the product component level; this requirement fosters ambiguity and would be overly burdensome for companies reporting complex products that contain hundreds or thousands of components. Allowing reporting at the product level will help ensure manufacturers can provide accurate data in the compressed timeline provided for reporting.

- Allow reporting through product groups by using appropriate assumptions when there are PFAS variations in product versions. Products should still be able to be reported in a group even if some of those products contain a smaller number of specific PFAS and/or if the PFAS concentrations vary among product versions. Manufacturers should therefore be allowed to organize product groups using appropriate assumptions about PFAS content –

i.e., the group should be able to be based on the specific products in the group with the highest number and concentration of PFAS.

- Remove language suggesting that, for new products introduced after January 1, 2026, reports must be submitted before these new products are placed on the market. The proposed rule contains contradictory statements about when reports will be required for products newly placed on the market after January 1, 2026. MPCA should retain language stating that reports will be due for those products on February 1 in the calendar year following the first sale in Minnesota. MPCA should delete language stating that reports must be submitted prior to the first sale in Minnesota. Requiring the latter would be overly burdensome and inconsistent with the statute.

- Clarify that manufacturers may request that any reported information be considered trade secret. The proposed Reporting Rule specifies that chemical name, chemical identifying number, and certain supply chain information can be claimed as trade secret. There may be scenarios where other reporting elements warrant protection as trade secret data under existing Minnesota law, and the MPCA must account for this possibility in the Reporting Rule.

The recommendations listed above and discussed in detail below are focused on areas specific to the language in the proposed Reporting Rule and corresponding topics described in PPWG's previous comments. In addition to the topics discussed in this document, certain requests from PPWG's 2024 comments remain unchanged and are hereby incorporated into these current comments by reference, including that (1) reporting should be limited to a specified list of PFAS with CAS Numbers; (2) the Reporting Rule should incorporate a de minimis threshold to not require reporting on PFAS below 0.1% by weight in the product; and (3) a packaging exclusion should be incorporated into the Reporting Rule.

I. Extend the Reporting Deadline To Help Ensure There is Sufficient Time to Prepare Reports After Rule Finalization.

Subdivision 3(d) of Section 116.943 grants the MPCA the authority to extend the reporting deadline if the agency determines that "more time is needed" for manufacturers to comply. PPWG believes that to be the case for all manufacturers in the current situation. The original January 1, 2026 reporting deadline is less than 8 months away, and the rulemaking schedule posted by the MPCA states that the Reporting Rule will be finalized "by Jan. 1, 2026."[3] The MPCA also noted on slide 48 of a webinar presentation that the reporting system will not go live until "Late 2025,"[4] which is alarming given the large volume of data the reporting system will need to support almost immediately after the system becomes operational in anticipation of the January 1, 2026 reporting deadline.

As explained in PPWG's 2024 comments, companies cannot finalize and implement effective due diligence programs in preparation for reporting until the information to be submitted is specified in

[3] MPCA, PFAS in products: Reporting and fees, https://www.pca.state.mn.us/get-engaged/pfas-in-products-reporting-and-fees.
[4] MPCA, Progress on PFAS Rule Development (July 18, 2024), https://www.pca.state.mn.us/sites/default/files/20240718-presentation-pfas-in-products-rulemaking.pdf.

a finalized Reporting Rule and in an operational reporting program. Regulatory agencies have acknowledged these sorts of logistical considerations, including most recently by EPA under the TSCA PFAS reporting rule. Earlier this month, EPA delayed the reporting window under this rule by an additional 8 months in part because "the current reporting timeline is no longer tenable, and maintaining that timeline would require entities to submit data before EPA has sufficiently verified that the technological capacity is in place to accept that data."[5] The MPCA should employ a similar reasoning to extend the reporting deadline for the Reporting Rule.

While PPWG appreciates the process provided in the proposed Reporting Rule for manufacturers to request extensions to the reporting deadline, the current situation warrants a blanket extension of at least one year in addition to the process provided for manufacturers to request additional extensions. Before Maine's PFAS in products law was amended to in part delay that law's reporting deadline, the Maine Department of Environmental Protection granted reporting deadline extensions to thousands of manufacturers.[6] The MPCA should expect a similar number of requests, and it would be inefficient and costly for the MPCA to evaluate this large number of individualized requests when the Reporting Rule is finalized – particularly given that rule finalization is expected to occur right around when reports are due. The MPCA should avoid a bottleneck scenario and grant a blanket extension as part of this rulemaking.

At the very least, the MPCA should grant a reporting deadline extension of at least one year for manufacturers of certain categories of products, including FDA-regulated products. The materials for these products are sourced globally with numerous tiers of suppliers, manufacturing facilities, and distribution channels. Adding to this complexity, supply chains in this industry involve not just manufacturing and distribution, but also oversight by regulatory bodies that control these activities and ensure products can be brought to market around the globe. Accordingly, it is simply not practicable to develop a full understanding of the chemical composition of all FDA-regulated products in a manner sufficient to report intentionally added PFAS by the January 1, 2026 deadline. This reality is emphasized by the fact that the Reporting Rule requires reporting on intentionally added PFAS, where "PFAS" is defined using a broad structural definition encompassing tens of thousands of substances. In contrast, and for example, Environment and Climate Change Canada's (ECCC's) PFAS reporting notice only requires reporting on 312 specific PFAS all of which are listed in the notice.[7] A reporting requirement, such as that in the Reporting Rule, applying to the entire universe of PFAS in all products is unprecedented, meaning that manufacturers need a significant amount of time to comply.

Reporting preparation involves performing internal due diligence for each product sold into Minnesota to assess whether these products may contain intentionally added PFAS. Moreover, this preparation may involve external outreach with suppliers, which takes a considerable amount of effort and time given that products in this industry are produced through a global web of many suppliers. Then, all acquired information will need to be analyzed against the information responsive to the Reporting Rule and uploaded in the reporting portal, neither of which have been

[5] 90 Fed. Reg. 20236 (May 13, 2025).
[6] Maine Department of Environmental Protection, List of manufacturers with an approved extension of the January 1, 2023 PFAS in products reporting deadline, https://www.maine.gov/dep/spills/topics/pfas/PFAS-products/Approved-manufacturers.pdf.
[7] Canada Gazette, Part I, Volume 158, Number 30: Supplement, Notice with respect to certain per- and polyfluoroalkyl substances (July 27, 2024).

finalized as of yet and are not expected to be finalized until late 2025 at the earliest. A reporting deadline extension of at least one year for FDA-regulated products will help address these concerns.

II. Incorporate the KRA Standard into the Reporting Rule to Harmonize with Other PFAS Reporting Requirements.

PPWG's 2024 comments recommended that the Reporting Rule incorporate the KRA standard for several reasons. For one, as the MPCA noted in a Q&A last year,[8] a reporting standard "acknowledges the challenges posed by unknowns in best testing practices, the unavailability of data from all supplier levels, and the varying costs of information gathering across organizations with different resources." The MPCA also stated in the Q&A that a due diligence standard will "ensure that due diligence efforts are reasonable and feasible for manufacturers."

Second, use of the KRA standard specifically would harmonize the Reporting Rule with PFAS reporting obligations in other jurisdictions. For instance, EPA has applied the KRA standard in its TSCA chemical data reporting rule for many years and recently extended its application to the TSCA PFAS reporting rule.[9] Maine also incorporated the KRA standard into its PFAS in products law through the amendment passed last year.[10] Similarly, ECCC's PFAS reporting requirements limit reporting to information that a company "possesses or . . . may reasonable be expected to have access to."[11]

The proposed Reporting Rule states in the due diligence section that "manufacturers must request detailed disclosure of [reportable information] from their supply chain until all required information is known." This requirement is not a due diligence standard that is "reasonable and feasible for manufacturers" as the MPCA indicated in its Q&A from last year; instead, this requirement is more akin to a strict liability obligation where manufacturers will be expected to exhaust all internal and external resources in preparation for reporting. Furthermore, MPCA's Statement of Need and Reasonableness (SONR) for the proposed Reporting Rule includes no discussion of why the KRA standard was not used, despite several clear requests from stakeholders – including from PPWG – that this standard be incorporated into the rule. Instead, the due diligence section in the SONR states that "The MPCA recognizes that manufacturers rely on complex global supply chains, making it difficult to identify PFAS at various stages of production." The MPCA then contradicts this statement by requiring manufacturers "to continue to request information from their supply chain until the reporting requirements can be fulfilled."

PPWG therefore reiterates its previous recommendation that the KRA standard be used in the Reporting Rule by incorporating the following provision and definition:

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[8] MPCA, Progress on PFAS Rule Development Webinar: Questions and Answers (September 2024), https://www.pca.state.mn.us/sites/default/files/c-pfas-rule1-00.pdf.

[9] *See*, e.g., 40 C.F.R. § 711.15; 88 Fed. Reg. 70516 (Oct. 11, 2023).

[10] 38 M.R.S. § 1614(2)(A) ("The manufacturer shall submit to the department a written notification that includes, to the extent known to or reasonably ascertainable by the manufacturer…").

[11] Canada Gazette, *supra* note 6.

A manufacturer or group of manufacturers is only required to report information under this part to the extent such information is known to or reasonably ascertainable by the manufacturer or group of manufacturers.

"Known to or reasonably ascertainable by" means all information in the manufacturer's possession or control as well as all information that a similarly situated company might be expected to possess, control, or know.

III. Confirm That Manufacturers Do Not Need to Conduct PFAS Testing in Preparation for Reporting.

The MPCA noted several times in the SONR that testing products for PFAS is difficult, costly, and often inaccurate given the lack of available PFAS testing methods. For instance, the MPCA states on page 45 of the SONR:

> Testing products is a much more intrusive and costly endeavor to obtain knowledge on where and how PFAS is being used in products. The high cost of staff time and expenses to run lab analysis on such tests made this alternative infeasible. In addition, without knowing exactly what chemicals to test for, it would be nearly impossible to get an accurate picture of what PFAS are used in which products. There is no realistic means to comprehensively test all relevant products to cover the scope of the reporting requirements in the proposed rule.

This statement was made in the context of an option considered, as an alternative to the proposed Reporting Rule, where the MPCA would test products in Minnesota commerce for PFAS. The same concerns would exist if manufacturers were required to test their products for PFAS in preparation for reporting.

PPWG reads the proposed Reporting Rule as not imposing a testing requirement and PPWG asks MPCA to confirm this interpretation. For example, if manufacturers are unable to determine the PFAS concentration in a product, lines 7.15 – 7.18 would give the manufacturers the option to either report the concentration as "unknown" or to test for total organic fluorine. For these reasons, in conjunction with incorporating the KRA standard into the Reporting Rule as discussed above, the MPCA should add the following statement to the rule or at least in a guidance document:

> *This part does not impose a requirement to conduct PFAS testing of products. Instead, manufacturers must report information they already have, or can reasonably ascertain, on PFAS in their products.*

This statement is similar to a statement EPA made in the preamble for the TSCA PFAS reporting rule.[12]

Relatedly, PPWG appreciates the inclusion of PFAS concentration ranges in the proposed Reporting Rule, though a de minimis level of 0.1% by weight of PFAS should be added to the rule as

[12] 88 Fed. Reg. 70535 (October 11, 2023) ("[The KRA standard] is not a testing requirement; rather it asks reporters to share with EPA the information they already have (or can reasonably determine) on their manufactured and imported PFAS").

discussed in PPWG's 2024 comments. Predefined concentration ranges known well in advance of the reporting deadline are critical for manufacturers to structure their due diligence around.

IV. Allow Companies to Report at the Product Level, Rather Than Requiring Reporting at the Product Component Level.

If a product has multiple PFAS-containing components, lines 5.23 – 6.10 of the proposed Reporting Rule would require manufactures to report each component. Reporting at the component level is not required or envisioned by the statute. Reporting at the component level would be overly burdensome for manufactures of medical, pharmaceutical, and animal health products, since many of these products have hundreds or thousands of components.

In addition, determining what qualifies as a "component" – particularly under the MPCA's proposed definition for this term – is a subjective inquiry and there is likely to be significant variation between manufacturers on how this determination is made. Similar concerns exist if a PFAS-containing component is a sub-component to a larger component of a product – if reporting is required at the component level, there could be double counting, or at the very least the reporting system may not be able to handle nuanced, nested component structures that often exist in this industry's products. Likewise, variation in how manufacturers distinguish components would result in reported data that lacks uniformity, thereby limiting accurate comparisons by the MPCA. The development of uniform standards for breaking down complex products into their components is a challenging, technical endeavor that is the main focus of a 100+ page EU guidance document.[13] Adopting such standards here may eclipse the time and effort the MPCA puts into developing the Reporting Rule itself, and the MPCA should avoid this scenario.

PPWG therefore recommends that lines 5.23 – 6.10 in the proposed Reporting Rule be replaced with the following provision:

> *If the product consists of multiple PFAS-containing components, the manufacturer must indicate whether the PFAS is present in an internal component, external component, or both.*

An obligation to note whether the PFAS is present in an internal or external component is reasonable as a means to track potential PFAS exposure risks to consumers, as opposed to more detailed component-level data that is unlikely to be relevant to this risk.

Manufacturers should also be allowed to report PFAS concentration at the homogenous material level, component level, or product level depending on whether PFAS concentration at the more granular level is KRA to the manufacturer, consistent with the KRA standard as discussed above. Other regulators have permitted PFAS concentrations to be calculated this way, including under ECCC's PFAS reporting notice.[14] To that end, the following provision should be added to the Reporting Rule:

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[13] European Chemicals Agency, Guidance on requirements for substances in articles (June 2017), https://echa.europa.eu/documents/10162/2324906/articles_en.pdf.

[14] ECCC, Guidance manual for responding to the: Notice with respect to certain PFAS, page 8 (July 27, 2024), https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/pfas-s71-

To report the concentration of PFAS chemicals in a product containing multiple components, the manufacturer must calculate the concentration using the following hierarchy of the most preferred to least preferred option. The most preferred option that is known to or reasonably ascertainable by the manufacturer must be used, and the option selected must be indicated in the report:

(a) Calculate the concentration at the homogenous material level in the component that contains the PFAS;
(b) Calculate the concentration at the component level; or
(c) Calculate the concentration at the product level.

V. Allow Use of Appropriate Assumptions When Organizing Product Groups.

PPWG generally supports the options in the proposed Reporting Rule for manufacturers in the same supply chain to report on behalf of others and for manufacturers to report product groups. This flexibility in reporting is necessary given the complex webs of supply chains and different versions of products that exist in this and other industries. However, PPWG believes some adjustments are appropriate. Lines 5.13 – 5.22 in the proposed Reporting Rule would allow manufacturers to report by product group if the PFAS composition in the products is the same, the PFAS fall into the same reporting concentration ranges, the PFAS provide the same function in each product, and the products have the same basic form and function with only minimal differences that do not impact PFAS composition. This product grouping requirement is too limited to be of practical use where there may be some PFAS variations in different product versions.

As discussed in PPWG's 2024 comments, medical, pharmaceutical, and animal health products are often designed, formulated, and dosed for the specific setting these products will be used in, with each variation in presentation being a separate product. Further, presentations may change over time as the FDA approves alterations to a product, and some presentations may be discontinued. To account for these variations, PPWG recommend the following provision be added as romanette (v) after line 5.22 in the proposed Reporting Rule:

> *Notwithstanding the foregoing, manufacturers may group different versions of the same product that have variations in the number and concentration of PFAS, provided that (i) all specific PFAS present across the grouped product versions are identified, and (ii) the highest concentration of each identified PFAS within the grouped product versions is reported.*

Allowing this type of grouping reflects the practical realities of how companies formulate different versions of their products, and this grouping will also permit the MPCA to focus its assessment of reported data on significant trends and avoid being skewed by minute PFAS variations across product versions. Moreover, use of PPWG's recommended appropriate assumptions on reporting all specific PFAS present and the highest concentration of each of these PFAS will help ensure PFAS data is not underestimated.

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guidance-manual.html (explaining that "For imported manufactured items, you should calculate the concentration on the component that contains the substance . . . If information is not reasonably accessible for components, calculate the concentration for the entire manufactured item").

VI. Correct The Unnecessary and Contradictory Requirement That New Products Be Reported Before Introduction into the Minnesota Market.

Lines 5.4 – 5.7 of the proposed Reporting Rule could be read to require new products that will be introduced to the Minnesota market after the January 1, 2026 reporting deadline to be reported "before the product can be sold, offered for sale or distributed in the state." The statute does not require such new products to be reported before they are introduced to the Minnesota market. Instead, the legislature specified that a report must be submitted "whenever a new product that contains intentionally added PFAS is sold, offered for sale, or distributed in the state." Requiring submission of a report before a product is introduced to the Minnesota market is inconsistent with how the statute uses the past tense to refer to sale, offer for sale, and distribution for this scenario.

Furthermore, imposing a requirement to report before a product launch would present serious confidentiality and practical challenges. For instance, regulatory bodies such as the FDA and U.S. Department of Agriculture, along with numerous other regulatory bodies around the world, control the approval processes for medical, pharmaceutical, and animal health products. The exact date of this approval is not something manufacturers in this industry necessarily know, meaning that at the very least a requirement to report these products before product launch could result in an unwarranted delay in the availability of this industry's lifesaving and life-enhancing products.

Lines 5.4 – 5.7 are also in tension with line 9.8 which would require manufacturers to report new products as part of the annual update by February 1 of the calendar year after the new product is put on the market. Requiring new products rolled out in the previous year to be reported as part of this annual update is much more reasonable, and more consistent with the statute, than requiring new products to be reported before product launch. PPWG therefore requests that the requirement to report new products in lines 5.4 – 5.7 be deleted so that the requirement in line 9.8 governs this scenario.

VII. Allow Manufacturers to Request That Any Reported Information Be Considered Trade Secret, Consistent with Minnesota Law.

PPWG appreciates that the MPCA included procedures for protecting trade secret information in the proposed Reporting Rule. As explained in PPWG's 2024 comments, there is a significant need to protect this sort of information in the medical, pharmaceutical, and animal health product industry. The industry depends on innovation to enable breakthroughs that save lives and improve health outcomes, and this innovation in turn requires protections for trade secret information.

Nonetheless, a clarification is needed in the trade secret data section of the proposed Reporting Rule. Lines 12.17 – 12.23 list chemical name, chemical identifying number, and certain supply chain information as data elements that can be claimed as trade secret. However, there will likely be situations where reported information outside of these three categories is trade secret under existing Minnesota law. For example, the fact that PFAS is present in the product (as would be indicated through the reported "brief description of the product") may be trade secret if this fact is confidential and divulging this information to the public would cause competitive harm.

"Trade secret information" is defined in Minn. St. § 13.37 as "government data, including a formula, pattern, compilation, program, device, method, technique or process" that was supplied by a private party, is maintained as confidential by that private party, and which has economic value

derived from that confidentiality. The MPCA acknowledged on page 36 of the SONR that this definition demonstrates the "broader intent of Minn. St. § 13.37 to safeguard proprietary business interests." Limiting trade secret data protection to the three reporting elements mentioned above would not align with this broad legislative intent.

The MPCA should therefore confirm that manufacturers may request that any reported information be treated as trade secret, as long as this information falls under the applicable definition of "trade secret information." To this end, PPWG suggests that the MPCA add the phrase "but is not limited to" at the end of line 12.20 to indicate that the three reporting elements that can be trade secret comprise a non-exhaustive, representative list.

VIII. **Conclusion.**

PPWG thanks the MPCA for considering its comments on the proposed Reporting Rule. If you have any questions, please feel free to contact me.

Sincerely,

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May 21, 2025

Honorable Judge Jim Mortenson
Office of Administrative Hearings
600 North Robert Street,
PO Box 64620 St. Paul,
Minnesota 55164-0620

Re: Proposed Rules Relating to PFAS in Products Reporting and Fees

Dear Judge Mortenson:

AGC Chemicals Americas ("AGCCA") and its parent company, AGC America, Inc., appreciate this opportunity to provide comments on the Minnesota Pollution Control Agency's (MPCA's) Proposed Permanent Rules Relating to PFAS in Products for Reporting and Fees ("Proposed Rules") Revisor's ID Number R-4828, OAH docket number 5-9003-40410, pursuant to Minnesota Statutes § 116.943 (the "Law"). AGCCA manufactures and supplies a range of specialized industrial chemicals and materials, including resins, coatings, films and membranes, that are incorporated into a wide range of products essential to the daily lives of Minnesota residents and businesses. We offer the following comments on some of the most problematic provisions in the Proposed Rule.

MPCA Should Extend the Reporting Deadline

We urge MPCA to exercise its authority under the Law (Minnesota Statutes §116.943, subdivision 3) to grant a blanket extension of the reporting deadline for all manufacturers, since it is unreasonable to expect that manufacturers will be able to provide compliant notifications by the current deadline of January 1, 2026. Until the final rule is issued, and the concerns and uncertainties are resolved, manufacturers will not understand precisely what information needs to be obtained, including from whom and by what mechanism, to comply with the reporting requirement. Similarly, without access to the reporting tool, manufacturers will be unable to assess whether the specific features and limitations of the tool will impose unforeseen barriers to submitting fully compliant reports.

Without a full understanding of the reporting requirements, and the limitations and requirements of the reporting tool, manufacturers cannot fully prepare for reporting. Under these circumstances, it would be unreasonable to require manufacturers to comply with currently unknown and undefined reporting requirements by January 1, 2026. This is especially

evident when one considers the unprecedented scope and scale of the reporting requirement, which covers roughly 15,000 different chemicals incorporated into hundreds of thousands of different product and product components that move through supply chains consisting of hundreds of thousands of manufacturers spread across the globe. For these reasons, we strongly urge MPCA to extend the reporting deadline to at least 6 months after MPCA has finalized these regulations and the reporting tool itself (with an opportunity to beta test the reporting tool before rollout of the tool).

Unclear and Unworkable Definitions

We appreciate MPCA's attempt to define various terms, but offer the following suggestions to three definitions: Chemical Identifying Number, Chemical Name and Manufacturer.

- **Chemical Identifying Number**. Submitters should be permitted to use any acceptable chemical identifying number in their reports, regardless of whether a CAS number exists for a substance.

- **Chemical Name**. Manufacturers should be allowed to provide MPCA with chemical names other than specific IUPAC names. Since, for proprietary chemicals, specific IUPAC names are often trade secret and confidential information, it is reasonable to expect that manufacturers of proprietary PFAS chemicals will in many cases be unwilling to share specific IUPAC chemical names with other manufacturers further down the supply chain (or across multiple supply chains). For this reason, submitters should be permitted to provide commercial or trade names as an alternative to specific IUPAC names. Specifically, we urge MPCA to modify the definition of "chemical name" to include the IUPAC name for the substance, the trade name for the substance, or the name associated with the substance's chemical identifying number.

- **Manufacturer**. The proposed definition of "manufacturer" creates substantial uncertainty regarding the entity or entities that bear primary responsibility for reporting on a product—which can be expected to result in widespread overreporting and/or non-compliance.

  We urge MPCA to specify in the regulations that primary responsibility for reporting a product containing intentionally added PFAS falls on the entity that first sells the product or offers the product for sale in the State of Minnesota. Only these entities will know with certainty which products are sold in the State, and placing responsibility squarely on these entities will help ensure that there will be no double counting of products sold or offered for sale. Accordingly, to provide added clarity, we urge MPCA to modify the proposed definition as follows:

  "Manufacturer" means the person that creates or produces a product, that has a product created or produced, or whose brand name is legally affixed to the product,

whichever is first to sell, offer for sale, or distribute for sale the product in the state. In the case of a product that is imported into the United States when the person that created or produced the product or whose brand name is affixed to the product does not have a presence in the United States, manufacturer means either the importer or domestic distributor of the product, whichever is first to sell, offer for sale, or distribute for sale the product in the state.

Unrealistic, Unworkable and Unclear requirements on Parties Responsible for Reporting

The Proposed Rule, specifically Subparts 1 and 2 of Section 7026.0020, is inconsistent with other sections in the Proposed Rule and is based on unrealistic assumptions that manufacturers will be able to identify and reach agreements with all other manufacturers in their supply chains and gather, share and report all relevant information required for group reporting within the unreasonably short window remaining before January 1, 2026.

- Subpart 1 of this section appears to require a report for "each" product or component that contains intentionally added PFAS. This is inconsistent with 7026.0030, which allows for product and component grouping within the same report. This language should be changed to "each product or component or group of products or components."

- Subpart 2 contemplates that multiple manufacturers in the same supply chain will agree to share reportable information and select an authorized representative to report on behalf of the group. The late issuance of MPCA's proposed rules makes the formation of supply chain agreements contemplated in the section highly unlikely, if not impossible, within the few months remaining before the current deadline for product reporting, since there is insufficient time to identify all relevant manufacturers in the supply chain, negotiate responsibilities, put legal agreements in place and collect and aggregate data for reporting. For this reason, we reiterate our request that MPCA extend the reporting deadline to at least 6 months after MPCA has finalized these regulations and the reporting tool.

Reporting Requirements are Burdensome, Unworkable and Fail to Recognize Complex Multi-Layered Supply Chains

The Proposed Rules fail to adequately take into account the realities of information flow through complex, multi-layered, global supply chains. As MPCA acknowledges, for complex products in particular, PFAS-containing components, such as gaskets, coated wires, valves, circuit boards, etc., can enter a supply chain at multiple points in time (and on multiple continents), as base materials are processed to create individual components that are then combined to create parts and sub-assemblies that are further combined to produce the product that is ultimately introduced into commerce in Minnesota. Tracing those supply chains, and extracting detailed information about the basic chemicals used throughout such a supply chain, can be nearly

impossible. Similarly, organizing the various manufacturers in a supply chain to support "group" reporting can also be impossible, especially within the Proposed Rule's reporting deadline. Thus, the reality is that many manufacturers will be unable to provide all of the information elements that they "must include" in the report detailed in this section. It is unreasonable for MPCA to expect otherwise.

The Proposed Rules also fail to address what will happen when a manufacturer, despite best efforts, is unable to provide all of the information elements that they "must include" in their report—creating unreasonable uncertainty about when a manufacturer will be in or out of compliance. We strongly urge MPCA to reconsider this section—and section 7026.0080 (Due Diligence)—such that a manufacturer's inability to provide some of the required information because, as an example, entities in its supply chain are unresponsive or affirmatively refuse to provide requested information, is not considered out of compliance if the manufacturer can provide documentation of its good faith information collection efforts.

Similarly, requiring manufacturers to provide annual recertification whether or not there is any updated product information is unnecessarily burdensome and in direct contrast with the Law, which requires only updates and revisions "whenever there is significant change in the information." AGCCA suggests these updates be limited accordingly to be consistent with the Law.

Requiring Manufacturers to Request Information from Their Supply Chain "Until All Information is Known" is Unreasonable

Section 7026.0080 of the Proposed Rule requires a manufacturer or group of manufacturers to request detailed disclosure information from their supply chain "until all required information is known." The requirement to investigate "until all required information is known" is unreasonable and ignores the realities of supply chains, as described earlier. Suppliers will not provide their trade secret information in response to a customer inquiry unless they have confidence that the customer will continue to protect it as carefully as the supplier, which cannot be guaranteed, even with the use of instruments such as non-disclosure agreements—especially if that information is destined to be shared across multiple levels of a supply chain or multiple supply chains. We offer the following language to make the expectation here more reasonable:

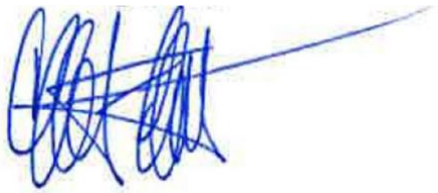
- A manufacturer or group of manufacturers must request detailed disclosure of information required in part 7026.0030 from their supply chain and take reasonable steps to obtain responses.

MPCA must clarify that a manufacturer will not be deemed non-compliant if the manufacturer can document diligence in its requests for information from supply chain vendors and good faith reliance on the information received (or not received) from those vendors. Alternatively, MPCA should adopt the due diligence standard used by EPA for the TSCA 8(a)(7) PFAS reporting rule: requiring information to be reported to the extent it is "known to or reasonably ascertainable by" the manufacturer.

***

Please let us know if you have any questions regarding the information presented in these comments. We would welcome the opportunity to discuss this with you, and we would be happy to provide you with additional relevant information.

Sincerely,



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May 21, 2025

VIA ELECTRONIC SUBMISSION: https://minnesotaoah.granicusideas.com

Honorable Judge Jim Mortenson
600 North Robert Street
St. Paul, MN 55101

Re: Minnesota Pollution Control Agency's Notice of Intent to Adopt New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per- and Polyfluoroalkyl Substances (PFAS), Revisor's ID Number R-04828, OAH docket number 5-9003-40410

Dear Judge Mortenson

Environmental Law and Science PLLC appreciates the opportunity to respond to the Minnesota Pollution Control Agency's (MPCAs) request for comments on the proposed PFAS in Products Reporting and Fee Rule. These rules implement subdivision 2 of Minn. Stat. 116.943, also as known as Amara's Law (referred herein as the statute). The following comments are being submitted on behalf of one of our clients, who is both a major employer in Minnesota and a supplier of advanced products for individuals, business and industry.

1. **MPCA Needs to Extend the Reporting Start Period**

The PFAS reporting and fee rule deadline is unrealistic and unreasonable, especially for manufacturers of complex products and those with complicated supply chains. By the time the rules and reporting system are finalized, companies will have insufficient time to prepare information to submit PFAS product reports. The reporting deadline should be extended well beyond the current deadline of January 1, 2026.

Among many reasons, more time is needed because of the time and the effort needed: (1) for suppliers and customers to determine their respective reporting responsibilities and develop legally binding reporting agreements between them, if group reporting is elected; (2) to obtain complete and accurate PFAS information from component suppliers; (3) to collect and standardize data collection and reporting processes across supply chains to report information consistent with new rule requirements and definitions; and (4) to achieve alignment of suppliers where PFAS knowledge varies across the value chain.

MPCA needs to learn from Maine's experience when it tried to implement the product reporting provisions of its 2021 PFAS law (PL 2021, Chapter 477). The Minnesota legislature essentially copied and pasted the product notification requirements of the Maine law into Amara's law. Maine DEP initially received over 2800 reporting extension requests from

manufactures. This led to the Maine legislature first extending the reporting period in 2023, and in 2024, functionally eliminating the PFAS product reporting requirement, except for very narrow future situations where PFAS use in a product was deemed unavoidable.

It is requested that the reporting deadline be delayed to at least 12 months after the final rules and reporting system are approved and released. To the extent MPCA believes that the January 1, 2026 deadline cannot be changed without legislative action, MPCA should announce that it will exercise enforcement discretion and not enforce the reporting requirement for 12 months following promulgation of the final rule. MPCA should also amend the Chapter 7026.0060 rules to automatically provide a six month extension to any manufacturer as a matter of right without having to comply with the more extensive proposed requirements for extension contained therein.

2. Pre-Sale New Product Reporting - Proposed Chapter 7026.0030

The second sentence of proposed Chapter 7026.0030 states, "A manufacturer or group of manufacturers of **a new product** with intentionally added PFAS after January 1, 2026, must submit a report **before the product** can be sold, offered for sale, or distributed in the state." This presale reporting requirement for new products exceeds the reach of the statute and conflicts with proposed Minn. R. 7026.0040, Subpart 1, which requires reporting by February 1"if during the previous 12 months … a new product was sold, offered for sale, or distributed in or into the state."

The statute mandates that, "A manufacturer must submit the information required under this subdivision whenever a new product that contains intentionally added PFAS is **sold, offered** for sale, or **distributed** in the state." By using the past tense, the statute is clearly only authorizing post-sale reporting of new products, and not pre-sale reporting. MPCA's pre-sale notification requirement in Chapter 7026.0030 is in conflict with the plain intent of the statute. It is also burdensome, unreasonable and not necessary.

The proposed Minn. R. 7026.0040, Subpart 1 will provide MPCA with timely information regarding the sale of new products with intentionally added PFAS in the state. The proposed rolling reporting requirement for new products provides no benefit, requires duplicative reporting of new products, both before and after introduction and increases the already substantial burden on manufacturers. Moreover, the SONAR is completely silent regarding why this pre-sale reporting is reasonable or necessary.

Comment Summary: MPCA should strike pre-sale reporting from the proposed rule.

3. **Product and Component Group - Chapter 7026.0030, Subpart 1.A(1)(a) and (b)**

The proposed reporting rule explicitly allows "grouping of similar products comprised of homogenous materials." Grouping is allowed where, for a given group of products, the PFAS chemicals, their concentration range and function are the same and the products have the same basic form and function. Minn. R. 7026.0030, Subpart 1.A(1)(a).

The proposed rule also makes product components a distinct reporting element requiring that the manufacturer "must report each component under the product name provided in the brief description of the product." Where a product consists of multiple PFAS-

containing components, the manufacturer is required to report each component under the product name, but the proposed rule allows grouping of similar components if they meet the same criteria used for grouping products. Minn. R. 7026.0030, Subpart 1.A(1)(b). The statute defines product component" to mean "an identifiable component of a product, regardless of whether the manufacturer of the product is the manufacturer of the component." The proposed rule defines component itself to mean "a distinct and identifiable element or constituent of a product." Minn. R. 7026.0010, Subpart 7. Grouping is allowed for similar components, where the PFAS chemicals, their concentration range and function are the same, and the products have the same basic form and function.

MPCA is to be commended for allowing the grouping of products and product components. It will somewhat lighten the reporting burden for manufacturers. Nonetheless, MPCA must make several changes to the product and component grouping requirements to reflect product realities.

MPCA needs to clarify the level of complexity within which products can be grouped, that is, what is meant by the "same." For example, the TSCA PFAS Reporting Rule allows grouping of complex products (e.g., automobiles and computers) and reporting of PFAS concentrations for the complex product. MPCA needs to confirm that it will allow grouping for complex products.

In addition, manufacturers often obtain components from multiple suppliers. The reporting system needs to accommodate the reality of variability of PFAS content in products within the same high-level product group. Grouping products for reporting should accommodate the range of PFAS that might be used within a product group. The reporting system needs to allow for variability in PFAS content between units product units under the same higher-level numerical product code due multi-sourcing of supplier components that may contain different types and concentrations of PFAS chemicals and differences in product configurations that may result in differences in the quantity and types of components or assemblies.

The reporting system needs to allow for the potential PFAS content of a product within a product group under a high-level numeric product code with the understanding a unit of product sold may or may not have all the PFAS listed in the report. The report would be a conservative estimate of the PFAS content that may be present, recognizing that not every listed PFAS would be necessarily present in any given unit of product sold under the same high-level numeric product code. The reportable concentration ranges need to allow for the understanding that the concentration is a conservative estimate that could be lower or even zero (not intentionally added) if certain supplier parts with unique PFAS chemicals are not used in individual units of product sold when there is an alternate supplier parts without that PFAS chemical was used in assembling the product.

In sum, MPCA should consider allowing grouping of products and components with functionally similar PFAS and not limit grouping to the same PFAS. While these components are interchangeable, functionally equivalent and identical to a customer, the specific PFAS chemical and concentration may vary from component to component. The manufacturer may often lack specific PFAS information for any particular components, although they may know that any

given components would have one of a discreet subset of PFAS. Accordingly, MPCA should allow grouping and reporting of these products and components even though the specific PFAS and concentration will vary.

Comment Summary: MPCA should allow grouping of similar products and components with functionally similar PFAS, not limit grouping to the same PFAS and allow reporting of potential PFAS under one product report instead of multiple reports.

4. Chemical Name and CAS No - Proposed Rule 7026.0030, Subpart 1.B

The proposed rule requires reporting on PFAS chemicals used in the product or its components as identified by the chemical name and the Chemical Abstracts Service Registry number (CASRN) or, if no CASRN exists, another chemical identifying number. It is possible that, despite their diligent efforts, manufacturers may be unable to obtain the required chemical identity information from suppliers because of supplier trade secret claims or non-responsiveness. To address such situations, MPCA should allow the reporting manufacturer to provide a generic name, description or class of the PFAS, as allowed under EPA's TSCA PFAS Reporting Rule**.**

Comment Summary: MPCA should allow reporting a generic name, description or class of the PFAS when one cannot otherwise be reasonably determined.

5. **PFAS Function - Proposed Rule 7026.0030, Subpart 1.D**

The proposed rule requires reporting on "the function that each PFAS chemical provides to the product or its components." MPCA needs to be aware that an individual PFAS chemical may provide multiple functions in a product. For example, PTFE may be present in multiple materials in the product and used as insulation in one material and a lubricant in another material. Accordingly, the reporting system needs to allow the reporting of multiple functions for each PFAS chemical used in a product.

***Comment Summary: MPCA should construct the reporting system to accommodate situations where an individual PFAS may provide multiple functions in a product*.**

6. **Report Update Time Period – Proposed Rule 7026.0040, Subpart 1.A**

The proposed rule requires that "By February 1 each year, a manufacturer or group of manufacturers must submit an update to the report submitted under part 7026.0030 if during the previous 12 months: (1) a significant change was made to a product; (2) new product information was provided to a manufacturer; or (3) a new product was sold, offered for sale, or distributed in or into the state."

As drafted, the timing provision is unclear. MPCA uses the phrase previous 12 months when it appears that the intent is to cover the previous calendar year. Further, MPCA should clearly indicate that the first reporting updates will be required starting February 1, 2027 for calendar year 2026**.**

Comment Summary: MPCA should revise Subpart 1.A as follows: "By February 1, 2027 and each year thereafter, a manufacturer or group of manufacturers must submit an

update to the report submitted under part 7026.0030 if during the previous ~~12 months~~ calendar year. …"

7. **Report Updates Significant Change– Proposed Rule 7026.0040, Subpart 1.A**

The proposed rule requires reporting when there is a **significant change** in information. The proposed rule defines a "significant change" to mean "when there has been a change in the composition of a product that results in the addition of a specific PFAS not previously reported in a product or component or a measurable change in the amount of a specific PFAS from the initial amount reported that would move the product into a different concentration range." Proposed rule 7026.0010, Subpart 18.

MPCA needs to clarify whether significant change reporting is required when a PFAS is entirely removed from a previously reported product. If so, MPCA should allow manufacturers to merely provide a simple notice when a PFAS is entirely removed from a previously reported product and exempt such reporting from fee requirements.

Comment Summary: MPCA should allow manufacturers to provide a simple notice when a PFAS is entirely removed from a previously reported product and exempt such reporting from fee requirements

8. **Report Updates New Product Information – Proposed Rule 7026.0040, Subpart 1.A**

It appears MPCA is requiring reporters to amend a previously submitted report when there is "new product information." An update based on "new product information" is not specifically authorized by the statute. In the SONAR, MPCA failed to identify what specific new information would trigger reporting. The proposed rule is vague and not well explained. It is unclear how this reporting differs from updates that would be provided under the significant change reporting requirement.

Comment Summary: MPCA should delete the reporting requirement for new product information.

9. **Annual Recertifications - Minn. R. 7026.0040, Subpart 2.**

The proposed rule creates an annual recertification requirement for previously submitted reports. This requirement is outside the scope of the statute. It is burdensome overreach, with no technical or economic value.

The proposed rule creates an annual recertification requirement for previously submitted reports. This requirement is outside the scope of statute. Other than the initial reporting due January 1, 2026, the statute authorizes reporting in three circumstance: (1) when a new product is sold, offered for sale, or distributed in the state; (2) when there is significant change in the information; or (3) when requested to do so by the commissioner. Minn. Stat. 116.943, subd. 2(c). The statute is silent regarding recertification.

Requiring recertification is burdensome overreach, with no technical or economic value. MPCA provides little justification, merely saying that it is "reasonable to require the manufacturer to verify that the information submitted in the initial report … is still correct to ensure that the MPCA has the most accurate data available for those products." SONAR p. 32.

MPCA mistakenly believe the statute authorized it to create a dynamic statewide PFAS product inventory, which is poor use of limited agency resources. MPCA claims this requirement "**reduces the reporting burden** for manufacturers that made changes by requiring them to only reverify that the information previously provided has not changed." SONAR p. 32. It does the opposite. It increases the reporting burden on manufacturers and collectively increases their financial burden as well.

To the extent MPCA would claim recertification is allowable under the provision that requires to report "whenever requested to do so by the commissioner" such a claim would be misplaced. First, the plain language of the statute indicates that this applies to case by case requests and not a blanket recertification requirement for all reporting manufacturers. Further, MPCA failed to raise such an argument in the SONAR.

***Comment Summary: MPCA should withdraw the recertification requirement*.**

10. Due Diligence - Chapter 7026.0080

The statute does not mandate a specific reporting standard. MPCA proposed an onerous "due diligence" standard which is both unclear and unreasonable. Minn. R. 7026.0080. It requires manufacturers to carry out a mandatory and apparently exhaustive request that their supply chain provide "detailed disclosure of information required in part 7026.0030" that must continue "until all required information is known." Minn. R. 7026.0080, Subpart 2

This requirement is both vague and goes beyond what might be required under typical due diligence (generally, a reasonable person standard). MPCA is requiring manufacturers "to actively engage with their supply chain" and requires a mandatory and apparently exhaustive request to the supply chain that must continue "until all required information is known." SONAR p. 37. The Agency asserts that this effort is required in the name of promoting accountability and transparency across the entire supply chain. Id. That is not the goal of the statute. MPCA overstates the usefulness of information it seeks and moreover, its ability to use and translate this information into policy and future regulations.

MPCA's proposed due diligence requirement is naïve and burdensome and ignores supply chain realities. By definition, the rule cannot impose requirements for the "entire supply chain" because the reach of the statute is limited to sales only in Minnesota.

Without any discussion in the SONAR, MPCA has apparently rejected using the "known to or reasonably ascertainable" reporting standard used by EPA under TSCA. EPA and companies have considerable experience with the known to or reasonably ascertainable reporting standard starting with the Chemical Data Reporting (CDR) rule. See 40 CFR Part 711. EPA has experience and issued guidance regarding known to or reasonably ascertainable reporting standard under the CDR. EPA has adopted this as the reporting standard for the TSCA 8(a)(7) PFAS Reporting Rule. 40 CFR Part 705. Further, EPA has issued guidance regarding known to or reasonably ascertainable reporting standard under the PFAS Reporting Rule. Moreover, many of the same companies subject to the Minnesota PFAS reporting requirements have already conducted their product due diligence of TSCA reporting following the known to or reasonably ascertainable reporting standard.

In contrast to the objective known to or reasonably ascertainable reporting standard under TSCA, the contours of MPCA's proposed due diligence requirements are unclear and subjective. Under the proposed rule, there are no explicit off ramps for situations where suppliers or others are non-responsive. Compare this to EPA's recognition that "if manufacturers do not know nor can reasonably make estimates for certain data elements, except for production volumes, they may indicate such information is Not Known or Reasonably Ascertainable (NKRA) to them. 88 FR 70516, 70521 (October 11, 2023).

Comment Summary: MPCA should adopt a reporting standard that is realistic and consistent with EPA's Known to or Reasonably Ascertainable reporting standard.

Closing Statement

In closing, on behalf of my client, we appreciate the opportunity to provide comments on the proposed PFAS Product Reporting and Fee rules. Our is hope that the agency will hear the concerns of my client and other commenters and honestly consider them.

We recognize that the legislature was well intentioned in passing Amara's Law. We believe and that MPCA made a good faith effort in drafting the proposed rules. Nonetheless, good intentions notwithstanding, the law and the proposed rules make it difficult and costly for companies of all sizes to comply. These pending requirements have already has resulted in some manufacturers of products that are critical to the successful functioning of Minnesota society to consider not selling products in Minnesota.

We look forward to a fruitful sharing of ideas that will result in improved rules that facilitate the reporting of practical information without burdening companies doing business in Minnesota. Such information might help inform public policy decisions regarding PFAS.

Best regards,

Jeffery Sepesi

RECEIVED
By: OAH on 5/21/2025

May 21, 2025

Comments and information on Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees (c-pfas-rule1-06)

https://www.pca.state.mn.us/get-engaged/pfas-in-products-reporting-and-fees

Name of the associations which make this input:
The Japanese electrical and electronic industrial associations:
JEITA (Japan Electronics & Information Technology Industries Association)
CIAJ (Communications and Information Network Association of Japan)
JBMIA (Japan Business Machine and Information System Industries Association)
JEMA (The Japan Electrical Manufacturers' Association)

With the endorsement of the following electric equipment manufacturers' coalition of medical devices, and analysis, measurement, test, control and monitoring instruments:
JAIMA (The Japan Analytical Instruments Manufacturers' Association),
JEMIMA (Japan Electric Measuring Instruments Manufacturers' Association),
JFMDA (The Japan Federation of Medical Devices Associations),
JIMA (Japan Inspection Instruments Manufacturers' Association),
JMIF (Japan Measuring Instruments Federation),
NECA (NIPPON ELECTRIC CONTROL EQUIPMENT INDUSTRIES ASSOCIATION),
SEAJ (Semiconductor Equipment Association of Japan).

Contact details of responsible person for this contribution:

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The four Japanese electrical and electronic industrial associations –JEITA, CIAJ, JBMIA and JEMA (hereinafter JP4EE) – and the endorsed associations hereby express gratitude to Minnesota Pollution Control Agency (MPCA) giving us the opportunity to comment on the Proposed Permanent Rules relating to PFAS in Products; Reporting and Fees.
We conduct our businesses in Minnesota State and all over the world and are firmly committed to protecting

human health and the environment and to complying with chemical substance legislations as defined by the countries and regions where we operate. Also, we support active prevention or minimizing chemical pollution. In this spirit, we have carefully and conscientiously examined these document, and would like to submit our comments and recommendations which support to make the future risk management feasible and balanced. We would highly appreciate it if the MPCA would carefully consider our input.

Table of Comments:

Appendices:

Our basic position is the same as that of the opinion we previously submitted regarding the following:

- "39507 Minnesota Pollution Control Agency Request for Comments on PFAS in Products Reporting Rule" in November 2023 (OAH Docket No. 65-9003-39507),
- "39506 Minnesota Pollution Control Agency Request for Comments on PFAS in Products Fee Rule" in November 2023 (OAH Docket No. 71-9003-39506), and
- "39667 Minnesota Pollution Control Agency Request for Comments on PFAS in Products Currently Unavoidable Use Rule" in February 2024 (OAH Docket No. 71-9003-39667).

Please note that our comments were submitted under the name of Ms. Emi Yamamoto.

The above opinions were accompanied by the following explanatory materials: If necessary, please feel free to contact us. We will be happy to resubmit those comments.
1: List A of PFAS essential uses in EEE
2: List B of EEE Functions needing PFAS
3: Explanation on EEE Functions in List B
4: Unfeasibility of "possible substitutes" in actual EEE

Our fundamental requests and concerns, particularly regarding reporting, are the same as those expressed in the comments submitted in November 2023 regarding "39506 Minnesota Pollution Control Agency Request for Comments on PFAS in Products Fee Rule."

1 Fundamental request: US states that broadly regulate PFAS should harmonize their operations.

If different US States require treating the same products in different way, especially for those distributed in the US wide and globally, such as EEE, it would hinder smooth product distribution to the detriment of Minnesota residents and retailers. Harmonisation among the States is important and at least, the exemptions set forth in Maine MRSA §1614 (4) should also be exempted in the Minnesota State.

We fully understand that this proposed rule is constructed on current Statute Section 116.943 - PRODUCTS CONTAINING PFAS[1], and we understand that the MPCA does not have the authority to amend the Minnesota Statutes.
On the other hand, the Minnesota Legislature is currently examining exemptions to its PFAS regulation, with some proposed amendments that would create exemptions similar to those in MRSA §1614(4) in the State of Maine.

We consider at least the same exemptions as MRSA §1614 (4) should be also added:

K. A semiconductor, including semiconductors incorporated in electronic equipment, and equipment and materials used in the manufacture of semiconductors;

L. Nonconsumer electronics and nonconsumer laboratory equipment not ordinarily used for personal, family or household purposes; and

M. Equipment directly used in the manufacture or development of the products described in paragraphs E to L.

The same exemption should be introduced in "PFAS in Products Reporting and Fee Rule" as well.

In addition, many countries and regions (such as the EU, Canada, and State of New Mexico) have recently been considering excluding fluoropolymers from the scope of PFAS regulations. PFAS reporting rules under US TSCA are also expected to be revised. Taking these situations into consideration, we would like to propose MPCA to consider further regulations that are truly necessary and beneficial for risk management.

2 Main requests to the proposed permanent rules

2.1 Based on our efforts and experience to date, for complex articles such as EEE, providing detailed reports on the basis of the proposed rule within the required time frame would impose a significant burden, and it would be virtually impossible to provide reports that fully satisfy the requirements. Therefore, we would like to request complex articles such as EEE be excluded from the reporting requirements. If the above request is not accepted, we would like the reporting to be limited to products recognized as CUU (Currently Unavoidable Use), which is the scope of the reporting subject to the PFAS Regulation preceded in the state of Maine. If none of the above is accepted, for complex articles such as EEE, we would like to request that MPCA simplifies reporting requirements similar to US TSCA section 8(a)7 PFAS reporting rule.
Specifically, these will be stated in 4. Other concerns and requests.

2.2 We would also like to request that the MPCA allows sufficient time for preparation of the report. Under the current timeline, the Minnesota State would become the first state in the world to mandate PFAS reporting. If possible, it would be desirable the mandatory date is at the same date as other States, or slightly later.

2.3 We would like to request that MPCA adopts EPA's "Known to or Reasonably Ascertainable By" Standard.

3 Basis and background of our requests

[1] https://www.revisor.mn.gov/statutes/cite/116.943

3.1 Basis and background of the request 2.1

Firstly, we would like to explain about Electrical and Electronic Equipment.

Electrical and Electronic Equipment (hereinafter, EEE) covers so many various product categories, but the technologies and materials and parts used in EEE are basically common. Therefore, we believe that EEE should be treated as one category in most cases [2].

In order to have MPCA understand EEE using PFAS, we would like to use the categories under EU RoHS Directive 2011/65/EU to show illustrative examples of EEE which may use PFAS.

Today, electric parts are widely used in not only EEE but also other product sectors. Products under other sectors such as automotive, military, space and aviation also need similar considerations as EEE if they use electric parts.
Also, please note that these categories include a mix of consumer and non-consumer products.

1. Large household appliances.
   Example: Refrigerators; Freezers; Other large appliances used for refrigeration, conservation and storage of food; Washing machines; Clothes dryers; Electric stoves; Other large appliances used for cooking and other processing of food; Electric heating appliances; Electric radiators; Other large appliances for heating rooms, beds, seating furniture; Electric fans; Air conditioner appliances; Other fanning, exhaust ventilation and conditioning equipment

2. Small household appliances.
   Example: Vacuum cleaners; Carpet sweepers; Other appliances for cleaning; Appliances used for sewing, knitting, weaving and other processing for textiles; Irons and other appliances for ironing, mangling and other care of clothing; Toasters; Fryers; Grinders, coffee machines and equipment for opening or sealing containers or packages; Electric knives; Appliances for hair cutting, hair drying, tooth brushing, shaving, massage and other body care appliances; Clocks, watches and equipment for the purpose of measuring, indicating or registering time; Scales

3. IT and telecommunications equipment.
   Example: Personal computers; Laptop computers; Notebook computers; Notepad computers; Printers; Copying equipment; Pocket and desk calculators; and other products and equipment for the collection, storage, processing, presentation or communication of information by electronic means; User terminals and systems; Facsimile; Telephones; Smartphone; Cellphone; Answering systems; and other products or equipment of transmitting sound, images or other information by telecommunications

4. Consumer equipment.
   Example: Radio sets; Television sets; Video cameras ; Video recorders; Hi fi recorders; Audio amplifiers; Musical instruments; And other products or equipment for the purpose of recording or reproducing sound or images, including signals or other technologies for the distribution of sound and image than by telecommunications

5. Lighting equipment.
   Example: Luminaires for fluorescent lamps with the exception of luminaires in households; All kinds of lamps; Other lighting or equipment for the purpose of spreading or controlling light

6. Electrical and electronic tools.
   Example: Drills; Saws; Sewing machines; Equipment for turning, milling, sanding, grinding, sawing, cutting, shearing, drilling, making holes, punching, folding, bending or similar processing of wood, metal and other materials; Tools for riveting, nailing or screwing or removing rivets, nails, screws or similar uses Tools for

[2] Some categories such as medical, measurement or manufacturing equipment may need additional applications in addition to those for the other EEE.

welding, soldering or similar use; Equipment for spraying, spreading, dispersing or other treatment of liquid or gaseous substances by other means; Tools for mowing or other gardening activities

7. Toys, leisure and sports equipment.
   Example: Electric trains or car racing sets; Hand held video game consoles; Video games; Computers for biking, diving, running, rowing, etc.; Sports equipment with electric or electronic components; Coin slot machines

8. Medical devices.
   Example: Radiotherapy equipment; Cardiology; Dialysis; Pulmonary ventilators; Nuclear medicine; Laboratory equipment for in vitro diagnosis; Analysers ; Freezers; Fertilization tests; Other appliances for detecting, preventing, monitoring, treating, alleviating illness, injury or disability

9. Monitoring and control instruments including industrial monitoring and control instruments.
   Example: Smoke detector; Heating regulators; Thermostats; Measuring, weighing or adjusting; appliances for household or as laboratory equipment; Other monitoring and control instruments used in industrial installations (e.g. in control panels)

10. Automatic dispensers.
    Example: Automatic dispensers for hot drinks; Automatic dispensers for hot or cold bottles or cans; Automatic dispensers for solid products; Automatic dispensers for money; All appliances which deliver automatically all kind of products

11. Other EEE not covered by any of the categories above.
    Example: 'large-scale stationary industrial tools' which are permanently installed and de-installed by professionals at a given place, and used and maintained by professionals in an industrial manufacturing facility or research and development facility; or 'large-scale fixed installation' which are a large-scale combination of several types of apparatus, intended to be used permanently in a pre-defined and dedicated location.

As for the examples of PFAS in Electrical and Electronic Equipment (EEE), please refer to Appendix1.

Secondly, we would like to state that it is not possible for the importers or the manufacturers of the complex manufactured items to satisfy requirements on identifying and reporting every PFAS as well as their volume. The reasons are as follows.

- Generally, what article manufactures have been doing is to specify main materials and/or necessary specifications of final products to be supplied and they hardly specify each substance contained in each article excepting for substances legally restricted.

- In most cases, manufacturers of final articles hardly use PFAS on their own or any mixtures including PFAS above SDS-reportable level. Additionally, user of chemicals in supply chain might be not the "first tier" or "second tier" supplier but be more upstream material manufacturers, where manufacturers of final manufactured items cannot directly reach out.

- In case of complex manufactured items, it is difficult to carry out PFAS investigation throughout entire supply chain. From our experience, even if an article manufacturer obtains information that a fluorinated substance is used for certain use, it was almost impossible to identify whether it was PFAS or not. For example, while we suppose substances used in articles as alternatives of PFOA might contain PFAS, none of our members were able to obtain tangible name of the substances from upstream supply chain.

- Especially for complex manufactured items like EEE, their supply chain spreads globally. Many suppliers might be located in countries/regions where this PFAS requirements are not applicable. Manufactures of final articles cannot oblige those suppliers (in case of not first tier suppliers, in particular) to provide

detailed information on very tiny amounts of substances beyond SDS requirements in their countries. Also, since SDS is a document to list hazard information of chemicals contained, not all chemicals contained are listed. Hence, even if an article manufacturer obtains SDS from upstream suppliers, what is listed there is only PFAS which are classified as hazardous.

- Specific chemical composition of functional materials, in many cases, is considered as trade secret and has never communicated to downstream users beyond the necessary level for safe use. In case of impurities and/or byproducts originated in manufacturing process, such information is not going to be transmitted to downstream users due to trade secret reason. In the case, it might be possible that even chemical manufacturers themselves do not know the information unless high precision measurement is carried out. For example, the fact is that even none of our member was able to obtain the concrete chemical name of PFOA-related substances which are covered under applicable derogations in the Stockholm Convention.

About the difficulties of information gathering for the importers and manufacturers of the complex manufactured items, we would like to give more detailed explanation, because we assume that the lawmakers, who have mainly covered chemicals, are not easy to correctly understand how the material investigation in the complex manufactured items conducted and how it is difficult.

Explanation of Difficulties in Obtaining Information on Chemical Substances Contained in EEE.

(i) Framework on Investigating Chemical Substances Contained in Products in the EEE Industry.

The EEE industry has developed an international standard, IEC62474 and conducts surveys of chemical substances in supply chain based on the standard. The Declarable Substance List (DSL), which is part of this standard, lists substances of concern that are subject to restrictions under the chemical substance regulations in countries and that may be contained in EEE with the knowledge of experts in each country. Substances that have not been found to be hazardous and are not restricted by the regulations in countries are usually not added to the DSL.

Usually, even for a few substances for which CAS has been identified, it takes at least months, or more than years if number of substances is large, that a survey initiated from the EEE manufacturers, which is placed at the bottom of the supply chain, can reach the chemical manufacturers at the top of the supply chain, and then will be back to the EEE manufacturers.

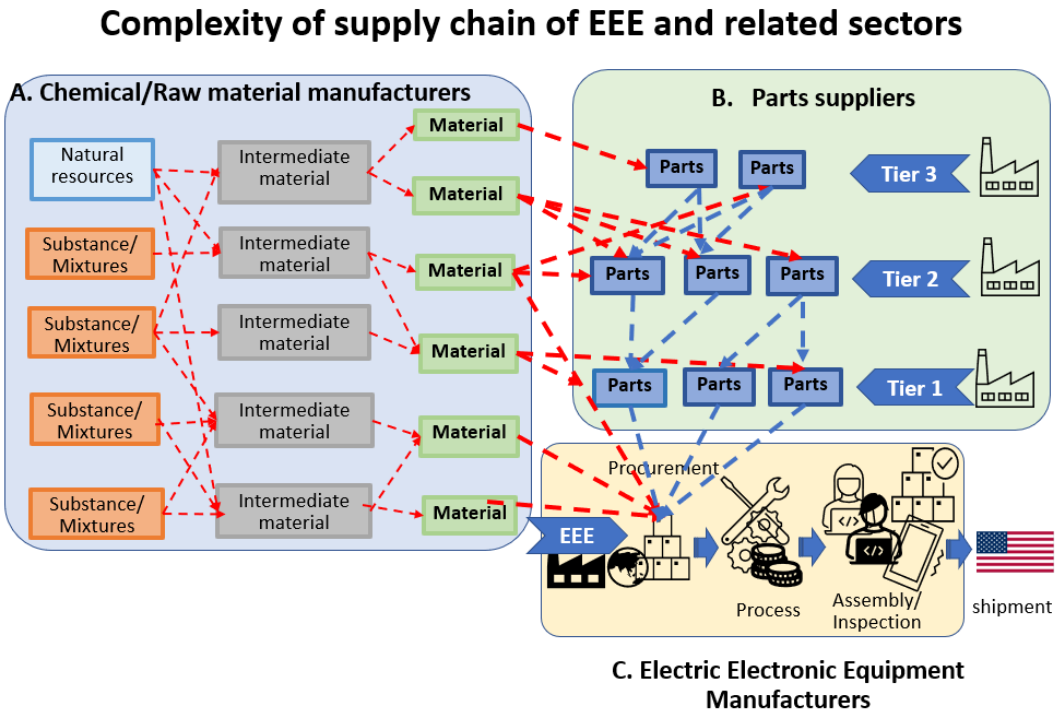
(ii) Adding PFASs to the DSL

With the promulgation of the laws requiring information of PFAS in products in the state of Maine, the EEE industry has begun to take actions as much as possible. Although most of PFAS have not been found to be hazardous, due to PFAS Law in the Maine, "PFAS" was added to the DSL on January 17, 2023. Nevertheless, since the laws do not specify the CAS numbers of specific target substances, the DSL does not specify specific PFAS substances. Instead, 629 PFAS substances (indicated as “not exhaustive list”) selected based on expert knowledge were added to the Reference Substance List (RSL).

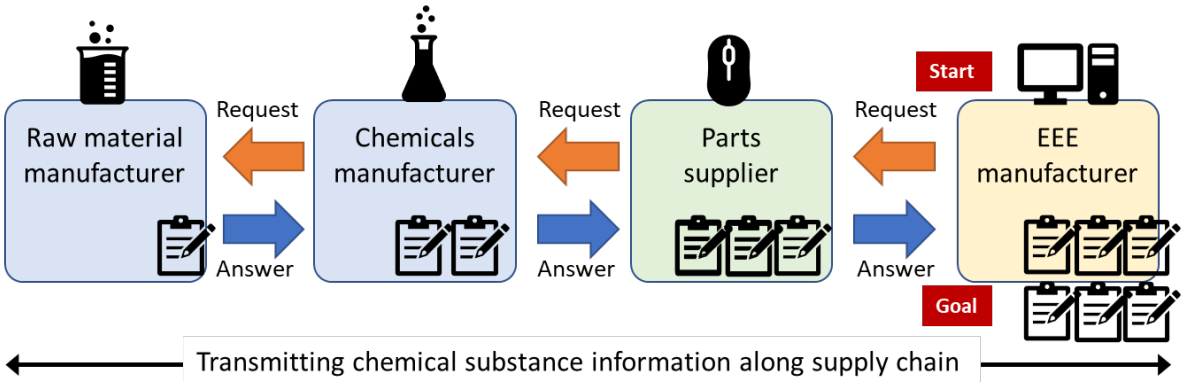
Anyway, this will enable future surveys of PFASs across the supply chain, but there are many obstacles to conducting such surveys, as described below.

(iii) Conducting complicated Surveys

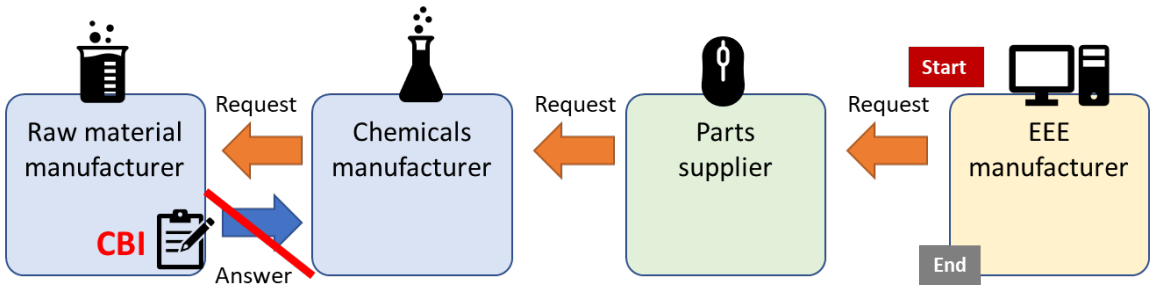
For complex manufactured items such as EEE, the supply chain is multiply layered and complex and spread globally.



In order for the final EEE manufacturer placed in downstream of the supply chain to obtain information about the chemicals contained in each part or component of the product, it is necessary to go up through the supply chain one-tier by one. On the other hand, normally, the suppliers which the final EEE manufacturer would be able to realistically reach out is two-tier upstream suppliers at the best.



The detailed chemical composition of the functional material in which the PFAS may be used is often considered a trade secret and is not communicated to the user beyond the level required for safe use. Furthermore, in the case of impurities or by-products generated during the manufacturing process, such information may not be communicated due to trade secret issues. In such cases, even the manufacturer of the chemicals may not know the information unless a highly accurate analysis is carried out. For example, as one of our members was not able to obtain specific chemical names from suppliers for PFOA-related substances covered by the PFOA exemptions prohibited under the Stockholm Convention.



CBI won't be transmitted to downstream → EEE manufacturer cannot obtain sufficient information

The longer and more complex the supply chain and the larger the number of substances surveyed, the longer the time will be needed to obtain response (months to years or longer).

If the substances subject to survey are not uniquely identified, the supplier who is asked for the survey has no way to verify whether or not their products, purchased parts, or materials contain PFAS (and which PFAS is how much contained,), making it more difficult for the surveyor (e.g. EEE manufacturer) to get a response and taking longer.

In fact, in our experience, even when an EEE manufacturer has information that certain fluorinated compounds (not necessarily PFAS) are used in certain applications, it was almost impossible for the manufacturer to know whether or not they are PFAS.

EEE manufacturers have hundreds or thousands of suppliers in Tier1 only, and it is not even possible to estimate how much time and effort it would take to obtain information on the content of more than 10,000 PFAS from their entire supply chain.

The EEE manufacturer usually directs its suppliers to the necessary specifications of the main material or finished product, but rarely identifies each substance in each article, except for legally restricted substance. Also, in most cases, finished article manufacturers rarely use PFAS themselves or as any mixture containing PFAS. Furthermore, in the supply chain, the user of the chemical itself is not the "first or second tier" supplier, but often the material manufacturer which is further upstream.

Therefore, the manufacturer has no option but to rely on information about the substance that is transmitted incrementally from further upstream in the supply chain and ultimately delivered to the manufacturer.

For the above reasons, the addition to the DSL allows PFAS investigations, and even if PFAS content information is transmitted to EEE manufacturers several years later, there is no certainty that EEE manufacturers know the exact PFAS content in the articles, and we cannot obtain thorough information even taking longer time.

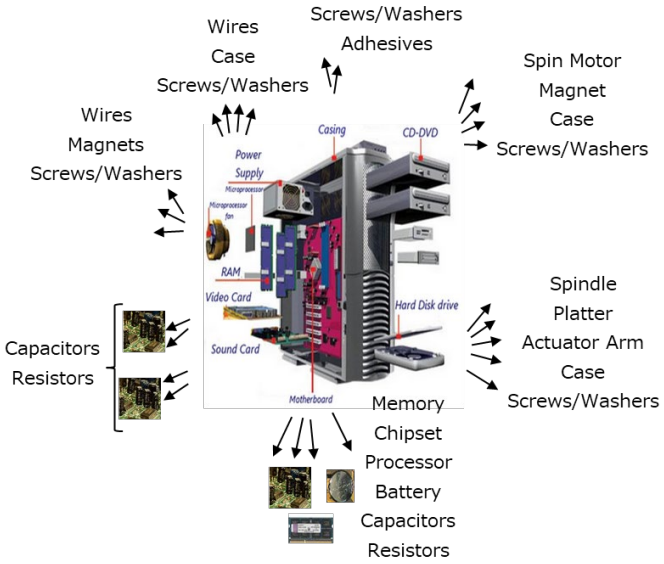
(iv) Difficulty of analysing PFAS in EEE.

Internationally recognized analytical methods have been established for only some PFASs, including those already internationally regulated. The EPA provides PFAS analysis methods but it does not list methods for analysing PFAS content in articles.

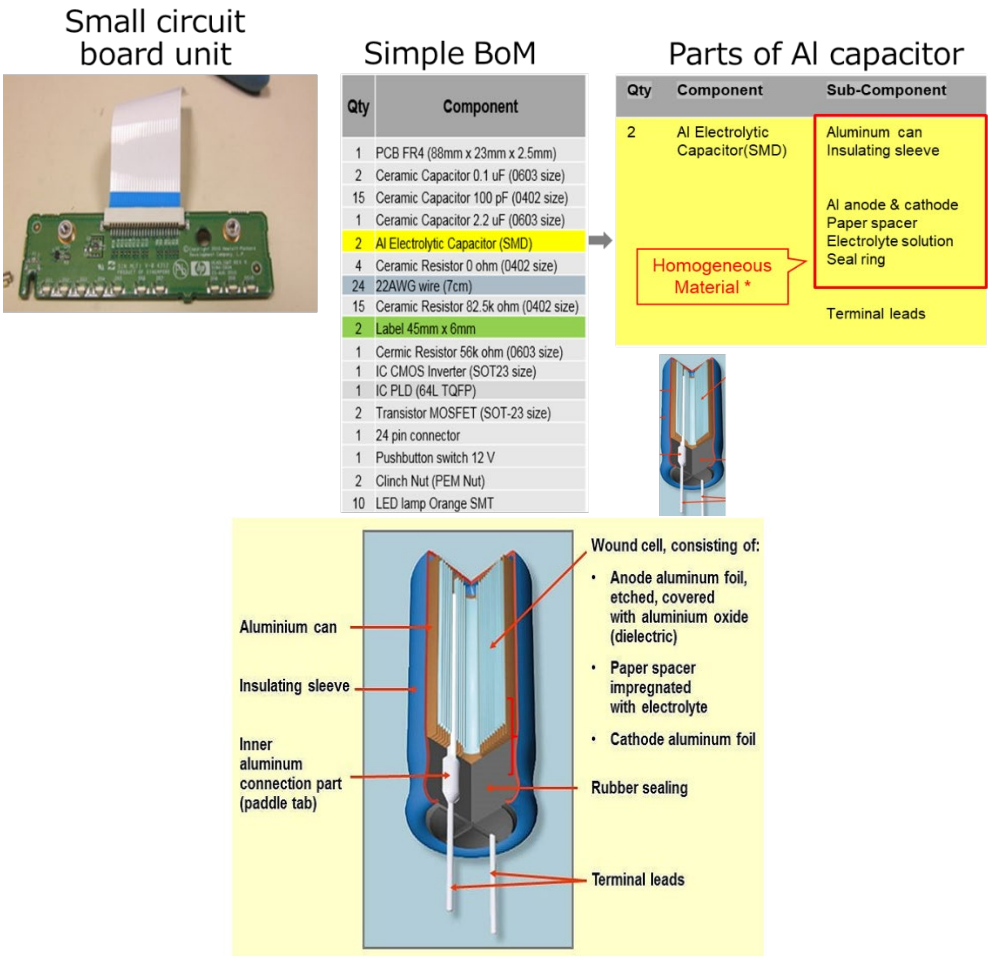
In addition, the Act allows the report as the total organic fluorine when individual PFASs cannot be identified. However, Combustion-Ion Chromatography (CIC), the commonly known analysis of fluorine, detects not limited to organic fluorine but also inorganic fluorine. Therefore, it is not possible to detect only total organic fluorine.

Even if an EEE manufacturer were to conduct an analysis, it would be impractical because the EEE consists of tens of thousands of parts, and it would take a tremendous amount of time and effort to analyse each of these parts to determine the PFAS content.

Here is an example. A computer consists of many parts as shown in the figure.



Each part consists of many tiny parts (a board unit is shown as an example).



In order to analyse, it is necessary to prepare the samples to be tested by decomposing to the material (homogeneous material) level constituting the tiny parts. However, no methods have not been established to prepare such a sample for which can be carried measurement of PFAS in a reproducible manner.

Even a very tiny part consists of multiple materials, it is hard to imagine how much time, effort and cost it would take to conduct analysis for each component of every EEE.

Based on the above, it is not practical for an EEE manufacturer as downstream of the supply chain to analyse and identify the type and content of PFAS contained.

This explains the difficulties in investigating materials in EEE.

Thirdly, we would like to explain that the amount of exposure to EEE is extremely small to begin with.
During the use of manufactured items like EEE, it is presumed that an exposure amount of PFAS is generally negligibly low compared with the exposure of the PFAS as chemicals own[3] [4]. For example, the U.S. Agency for Toxic Substances and Disease Registry (ATSDR) concluded that the route of human and environmental exposure to PFAS is mostly through ingestion of drinking water or food, and negligible exposure through consumer products. In articles, PFASs are firmly integrated into polymer matrix in most cases and are contained in very small amounts. Furthermore, due to an extremely low vapor pressure (about 10-4 Pa), PFASs are not emitted into the environment. Even if a very limited amount would be emitted or eluted from articles, it is not considered to be a level that affects humans or the environment.
It is also presumed that environment impact of PFAS from EEE (i.e. manufactured items) is extremely low since a significant part of EEE distributed to general consumers are properly managed in accordance with Minnesota Electronics Recycling Act.

In light of the above, since the risk of adverse effects on humans and the environment is extremely small, we request that complex articles such as EEE be exempt from reporting, or that the reporting requirements be at least simplified compared to those required by the proposed rule.

3.2 Background of the request 2.2

In order to avoid disruptions to the supply chain, final product manufacturers like us cannot take concrete investigation to the upstream supply chain until at least the draft rule is finalized and the requirements are clearly defined in detail. On the other hand, as mentioned above, investigations tracing back the supply chain can take at least several months or even several years, so if the investigation is started after the official adoption of this proposed rule, it will be impossible to submit the first report by January 1, 2026.

Even if the CAS-RN of the PFAS subject to the investigation has been identified under the rule, a minimum of two years is required from the time the rule is finalized. If CAS-RNs were not identified, as is currently proposed, the investigation alone would likely take four to five years, depending on what needs to be reported. Even in such cases, we believe that the level of information required in the current proposed rule would not be sufficient to completely identify PFAS that may be intentionally present in the products in question.

Additionally, under the current timeline, the Minnesota State would become the first state in the world to mandate PFAS reporting. In April 2024, the state of Maine passed "An Act to Amend the Laws Relating to the Prevention of Perfluoroalkyl and Polyfluoroalkyl Substances Pollution," which significantly expanded the list of products that are exempt from the law. For example, semiconductors and non-consumer electrical and electronic equipment are exempt; they are not subject to any restrictions and do not require reporting.

Furthermore, the Maine's reporting requirements are limited to "uses for which the agency or the Pesticide

[3] According to the U.S. ADSTR research, PFAS exposure routes to human and environment are mainly oral ingestion from PFAS-containing foods, food packaging and/or drinking water, exposure from consumer products is low.
https://www.atsdr.cdc.gov/pfas/health-effects/exposure.html

[4] According to Duke Nicholas School of the Environment, PFAS percutaneous exposure via skin contact is negligibly low although inhalation of PFAS absorbed to house dust migrated out from PFAS-containing carpets and/or furniture might be possible.
https://sites.nicholas.duke.edu/pfas/files/2020/08/Duke-NSOE-PFAS-Background.pdf

Enforcement Committee currently determines that PFAS is an unavoidable use (CUU)," and there is no longer any mention of when reporting should begin. In the State of Maine, a ban on all PFAS-containing products except for air conditioning refrigerants will take effect on January 1, 2032, and CUU applications must be submitted 18 months prior to that date. Therefore, under the Maine's current law, reporting on EEE would begin only for consumer electronics after the establishment of the CUU around 2030.

New Mexico's recently enacted law also exempts fluoropolymers in addition to the same exemptions as the State of Maine and harmonizes its schedule with Maine's law. US TSCA section 8(a)7 PFAS reporting requirements are much less stringent for articles than Minnesota's PFAS regulation, the reporting period has been postponed again from April 13 to October 13, 2026, and further amendments to the rules are also expected to be considered. That means that the Minnesota is likely to be the State to adopt the most rapid, broadest and most information-demanding requirements.

When examining the rule, we would also like to recommend that MPCA reference Maine's Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances[5]

3.3 Basis and background of the request 2.3

Even if we were to take sufficient time to investigate further up the supply chain, we may not be able to obtain the detailed information required by the proposed rule due to the difficulties of investigating substances in EEE as explained above.
Therefore, we would strongly like to request that in addition to providing a sufficient grace period, manufacturers will be permitted to report only what they “Known to or Reasonably Ascertainable By”.

Specifically, we believe that when the required information is beyond the knowledge or ability of a manufacturer to reasonably ascertain it, a required reporting option similar to TSCA § 705.18(a) should be provided.

If this is not accepted, a significant number of products will not be able to comply with the requirements, and as a result, huge amounts of EEE will not be able to be distributed within the Minnesota State, which could ultimately cause inconvenience to the Minnesota citizens and have a negative impact on the state's economy.

In addition to the comments above, we state specific concerns and requests regarding the reporting and fee requirements proposed in this proposed rule as follows.

4 Other concerns and requests

4.1 Parties responsible for reporting (7026.0020 PARTIES RESPONSIBLE FOR REPORTING.)

4.1.1 The proposed rule, 7026.0020 PARTIES RESPONSIBLE FOR REPORTING., subp. 2. Reporting on behalf of other manufacturers, would require all manufacturers in the same supply chain to be responsible for reporting unless they enter into an agreement establishing their respective reporting responsibilities. This statement may seem to assume that there are multiple “manufacturers” along the same supply chain. However, according to the definition of manufacturer in the proposed rule (7026.0010 DEFINITIONS. Subp. 14. Manufacturer.), for a product imported into the United States that is manufactured outside the United States, the manufacturer is either the importer of the product or the first domestic distributor, so there won’t be multiple manufacturers. In order to avoid confusion for reporters, subp. 2. Reporting on behalf of other manufacturers. in proposed rule 7026.0020 should be deleted.

[5] https://www.maine.gov/sos/sites/maine.gov.sos/files/inline-files/096c090.docx

4.2 Scope of the reporting (7026.0030 REPORT; REQUIRED INFORMATION.)

4.2.1 We request that the scope of the initial report by January 1, 2026 be limited to products that manufacturers may sell on or after January 1, 2026. It is possible that products that have already been discontinued and are no longer sold by manufacturers may remain in stock at retail stores after January 1, 2026, in which case the manufacturer cannot know whether those stocks are sold in Minnesota after January 1, 2026.

In addition, we request the derogation for service parts from reporting. Service parts mean the parts for repair (i.e. enabling to use the products longer) and consumables or replacing parts for EEE (i.e. being consumed during product use and need to be replaced or resupplied regularly). Normally, service parts are already reported as a part of products since they are the same with original parts. If service parts are separately reported from the products themselves, the part of service parts and their original parts will be duplicated and the report won't be correct.

4.2.2 In the proposed "HF1627[6]", the description "commercial or industrial" is deleted from the definition of (q) Product in Subdivision 1 Definitions of Section 1. Also, the description "a prosthetic or orthotic device or to any product that is a medical device or drug or that is otherwise used in a medical setting or in medicalapplications regulated by the United States Food and Drug Administration" in subdivision 8(b) of the proposal "HF1627A1[7]". If these proposals are approved, the decisions should be applied to the reporting proposal.

4.3 Timing of the reporting (7026.0030 REPORT; REQUIRED INFORMATION.)

4.3.1 Any new products marketed after the initial reporting period will require reporting prior to the product's first distribution in Minnesota. On the other hand, reporting is required again before every February to update the previous year's report. If a new product is released in December, the first report will need to be submitted in December, followed immediately by another update report in February next year. In order to avoid such duplicate reporting, it is reasonable to report new products after January 1, 2026 together at the time of annual renewal in the next year.

4.4 Contents of the reporting (7026.0030 REPORT; REQUIRED INFORMATION. etc.)

4.4.1 The conditions stipulated in 3. Notification C. of Maine "Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances" should be more relaxed. Especially, for grouping of products, we would like to request that the one of the conditions (iii) the PFAS chemicals in the products provide the same function in each product be deleted. PFAS are substances to show various functions at the same time and there are many variations which function is utilized. Hence, it is not feasible to recognize as the same group only in case of perfectly matching the functions.

For example, under 3. Notification C. of Maine "Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances", products covered by the same CUU will be able to include the same notification as follows.
C. A manufacturer may submit a single notification to the Department for multiple products if all of the products are covered by the same currently unavoidable use determination found in section 9(B).

[6] https://www.revisor.mn.gov/bills/text.php?number=HF1627&version=0&session_year=2025&session_number=0

[7] https://www.house.mn.gov/comm/docs/q9ypPcFoiUmJB5ENZsXvdQ.pdf

We believe the reporting requirements with the same granularity is feasible in Minnesota State as well.

Alternatively, PFAS reporting under US TSCA requires that reporting entities select a reporting type from Table 2 in § 705.15(c)(1), a Code for Reporting Industrial Sectors from Table 3 in § 705.15(c)(2), and a Code for Reporting Function Categories from Table 4 in § 705.15(c)(3) that best describes the use of PFAS in the product. Products with matching these codes should be reported as "similar products."

Under the current proposed rules in Minnesota State, EEE using IC are all subject to reporting. Both the Authorities in Minnesota State as well as industries will be exhausted by using cost and resources to handle huge amounts of date unless accepting grouping reporting.

4.4.2 7026.0030 Subpart 1.A(1)(a)

We request that the information about the product code assigned to the product to be optional, not mandatory.

If MPCA thinks it is absolutely necessary, we believe it is desirable that the list of codes is provided and manufactures can select the appropriate code. It is also beneficial from the viewpoint of data analysis and management after data collection. In that case, the code should harmonize with those under TSCA, not to create the original codes for reporting.

4.4.3 7026.0030 Subpart 1.B

As we commented in our previous comments, we would like to request that a list of CAS RN be provided for PFASs that are subject to reporting. EEE consists of many parts, and complex items can consist of tens of thousands of parts. Additionally, there are thousands of tier 1 suppliers that supply parts directly, and then there are complex, multi-tiered supply chains with tier 2, tier 3 and subsequent suppliers that supply components of those parts. PFAS is not a single substance but a large group of substances, and without identifiers such as CAS RN, it would be extremely difficult for EEE manufacturers to investigate complex, multi-layered supply chains and gather accurate answers.

4.4.4 7026.0030 Subpart 1.B

Suppliers may not be able to provide detailed information about the PFAS chemicals used in a product or its components, and they may only be able to report that "PFAS" is contained. We would like to request that manufacturers are allowed to report the chemical names as "PFAS".

For example, TSCA PFAS Reporting section 705.18(2) accepts following information. It is feasible to accept the same level of reporting in case of PFAS contained in articles.

(ii) If the specific chemical identity of the PFAS imported in an article is not known to or reasonably ascertainable to the submitter (e.g., if the chemical identity is claimed as confidential business information by the submitter's supplier, or if the submitter knows they have a PFAS but is unable to ascertain its specific chemical identity), the submitter may provide a generic name or description of the PFAS.

4.4.5 7026.0030 Subpart 1.C. the concentration of PFAS chemicals in a product or components of a product made up of homogenous material.

EEE consists of numerous parts, and complex items can contain tens of thousands of parts. For such complex articles, even if detailed data at the component level is submitted, we believe it is unlikely that the data will be effective in preventing PFAS contamination, which is the purpose of the law. Furthermore, as mentioned above, the amount of PFAS contained in EEE is extremely tiny, and the risk of adverse effects to humans and the environment is extremely low. Information on PFAS-containing parts at the homogeneous material level is a huge amount of data, and there are concerns that it will be an excessive burden for both

manufacturers and authorities to handle such huge amount of data. If the purpose of this proposed rule is to know the amount of PFAS used in products, MPCA should allow reporting of the consolidated PFAS content (by weight) at the finished product level, at least for complex articles such as EEE.

4.4.6 7026.0030 Subpart 1.D

We would like to request that the reporting requirement on the function that each PFAS chemical provides to a product or its components be optional. Normally, manufacturers of complex articles like EEE specify their suppliers specifications of parts they purchase, rather than identifying the substances contained in the parts. Even if any of PFAS is used in the parts, the article manufacturers do not have information which PFAS contributes to which function. If the supply chain were to be investigated including the functions of each PFAS, a further investigation period would be required. Furthermore, even if a thorough investigation is conducted over a long period of time, it is likely that complete information will not be obtained.

If MPCA thinks it is necessary to mandatory require the information on functionality, we think it is feasible to select one CODES FOR REPORTING FUNCTION CATEGORIES which describes the use of PFAS the best from Table 4 of TSCA PFAS Reporting§705.15(c)(3).

4.4.7 7026.0050 WAIVERS. Subpart 1. Waiver eligibility.

In order to avoid duplicate reporting, we would like to request that products that have already been reported under other programs, such as the PFAS reporting under US TSCA section 8(a)7, be recognized as having already been reported and that they do not need to be submitted again under this rule.

4.4.8 7026.0070 TRADE SECRET DATA REQUEST.

Due to confidentiality, upstream suppliers are reluctant to or may not be able to provide information about PFAS to their downstream supply chains. We would like to request that the MPCA will introduce a joint submission system similar to that is introduced in the U.S. TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, allowing suppliers having PFAS information can contact the MPCA directly.

4.5 Documentation and recordkeeping (7026.0080 DUE DILIGENCE. Subp. 3. Documentation and recordkeeping)

4.5.1 7026.0080 DUE DILIGENCE. Subp. 3. Documentation and recordkeeping, Section C, specifies that the date when PFAS are removed from the supply chain is the starting point for recordkeeping, but it is impossible for manufacturers to know when that date occurs. After a manufacturer has sold a distributor a product containing PFAS which was intentionally added, the manufacturer cannot know when the distributor has finished the sales of the product. We would like to request that record keeping begin from the "manufacturing date" of the product, which is controllable by the manufacturer.

4.5.2 MPCA should clarify the documents that need to be kept as records in Section A of 7026.0080 DUE DILIGENCE. Subp. 3. Documentation and recordkeeping. We would like to request that the scope of recordkeeping be limited to documents that prove the presence of PFAS selected by the manufacturer.

4.6 Fees (7026.0100 FEES.)

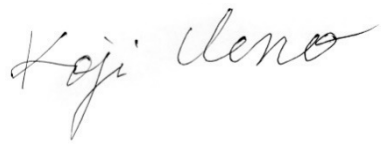
4.6.1 As mentioned above, we have requested that it is accepted to report all new products sold after the initial report at an annual renewal. If this is not permitted, we believe that we will need to report each time a new product is sold for the first time. We would like to ask for more clarification of the details of the fee required each time, concretely, we would ike to ask that no new fees will be required at the reporting the new product.

5 Conclusion

We hope our input would provide substantive information to ensure the smooth and practical implementation of PFAS management to realize a healthy environment and a sustainable economy for the present and future generation in Minnesota State.

If you have any questions, please do not hesitate to contact the JEITA secretariat.

Sincerely yours,



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About Japanese electrical and electronic (E&E) industrial associations:

About JEITA

JEITA aims to create digital technologies, improve the business environment, enhance industrial competitiveness, and, of course, to realize Society 5.0. To that end, we urgently need to accelerate society's digital transformation (DX). JEITA will work closely with member companies, the government, and related organizations to solve social issues and energize the Japanese economy, contributing to the society and lifestyles of the future.
https://www.jeita.or.jp/english/

About CIAJ

Mission of Communications and Information network Association of Japan (CIAJ). With the cooperation of member companies, CIAJ is committed to the healthy development of info-communication network industries through the promotion of info-communication technologies (ICT), and contributes to the realization of more enriched lives in Japan as well as the global community by supporting widespread and advanced uses of information in socio-economic and cultural activities.
https://www.ciaj.or.jp/en/

About JBMIA

Japan Business Machine and Information System Industries Association (JBMIA) is the industry organization which aims to contribute the development of the Japanese economy and the improvement of the office environment through the comprehensive development of the Japanese business machine and information system industries and rationalization thereof.
https://www.jbmia.or.jp/english/index.php

About JEMA

The Japan Electrical Manufacturers' Association (JEMA) consists of major Japanese companies in the electrical industry including: power & industrial systems, home appliances and related industries. JEMA will

contribute to sustainable global development through improvement and enhancement of social and living infrastructures by strengthening international competitiveness of Japanese electrical machinery equipment industry.
http://www.jema-net.or.jp/English/

About electric equipment manufacturers' coalition of medical devices, and analysis, measurement, test, control and monitoring instruments that have endorsed this paper:

About JAIMA

The Japan Analytical Instruments Manufacturers' Association (JAIMA) is a sole industry association of Analytical Instruments in Japan, which established under the Japanese law. JAIMA is to contribute to the development of the Japanese economy and the cultural lives of citizens in Japan through efforts to improve and advance technologies related to analytical instruments and the analytical instruments industry for the purpose of the advancement of science & technology.

About JEMIMA

Japan Electric Measuring Instruments Manufacturers' Association (JEMIMA) is the only one association representing this industry in Japan. Electric measuring instruments support all kinds of manufacturing industries as so-called "Mother tools" that support innovative activities for research, development, design and manufacturing.
JEMIMA has active committees that collect technical and market information of electric measuring instruments, and provide member companies with useful information for their businesses. Regarding regulations such as environmental, safety and EMC (Electro-Magnetic Compatibility) issues, JEMIMA has been investigating details and providing proposals to legislative organizations summarizing requirements from the industry in cooperation with international related organizations.
Through these activities, JEMIMA will continue to contribute to the steady growth of electric measuring instruments and related industries in Japan.

About JFMDA

The Japan Federation of Medical Devices Associations (JFMDA) was founded in February 1984 by medical device associations consisting of manufacturers and suppliers of medical and health-care devices, equipment, instruments and materials. Since then, JFMDA has been addressing various national and international issues related to all its member associations. By taking appropriate actions on these issues, and through the support of innovation and sustainable supply of medical devices and technologies to the world, JFMDA has contributed to the growth of the industries it represents and to the improvement of welfare and health care in Japan. JFMDA became a legal entity as of January 6th, 2014.

About JIMA

Japan Inspection Instruments Manufacturers' Association (JIMA) is a corporation aggregate of manufactures and sellers for non-destructive inspection instruments and systems. JIMA is the only industry group in Japan for non-destructive inspection instruments. JIMA would eventually contribute to the safety of social capital and facilities, and quality assurance in various productions through non-destructive inspection technology, and supports the safety and reassurance of people's lives.

About JMIF

Japan Measuring Instruments Federation (JMIF) is an industrial association for measuring instruments manufacturers and related organizations/companies in Japan. JMIF was established in 1952 to develop the whole measuring instruments industry through improvement of measuring instruments, aiming to contribute to the eventual development of the Japanese economy and society.
The main activities by JMIF include supporting new technology development, conducting demand trends survey, developing domestic and overseas markets, and enhancing global cooperation.

About NECA

NIPPON ELECTRIC CONTROL EQUIPMENT INDUSTRIES ASSOCIATION (NECA) was established in 1964 and promoting the growth of the electric control equipment fields such as Relays, Switches, Sensors, PLC/FA System Equipment and others, Safety Control Equipment. NECA has 30 companies as regular members and 33 companies as support members, and shipping amount of relevant products were 672.3billion Yen in FY2023. Our website provides further information on our recent news and activities:
https://www.neca.or.jp/en/

About SEAJ

Semiconductor Equipment Association of Japan (SEAJ), founded in March 1985, promoted by the major semiconductor equipment manufacturers, is a nationwide organization of semiconductor manufacturing equipment, flat panel display (FPD) manufacturing equipment and equipment manufacturers that applied their technology and related equipment manufacturers.
SEAJ had existed as an incorporated association from July in 1995. From April 1st in 2012, SEAJ has been authorized by Cabinet Office as a General Incorporated Association that related to the reform of the public-interest corporations system.
The Japanese semiconductor manufacturing equipment, FPD manufacturing equipment and equipment industries that applied their technology is playing great role in supporting the world's semiconductor industry due to the manufacture of semiconductors, FPDs that lay the foundation of the advanced information oriented industries by supplying manufacturing equipment and the indispensable producer goods to the semiconductor industry to Japan and abroad.
In order to promote the development of the semiconductor manufacturing equipment industry and other related industries and to contribute to the further development such as investigative research on production and distribution, proposing and indicating the direction of semiconductor equipment technologies, investigating and studying the area of Emerging Technology, the activities of popularization and enlightenment by conducting of various seminars and lectures, planning of project and promotion of standardization.

PFAS in Electrical and Electronic Equipment (EEE)

Four Electrical and Electronic Industry Associations in Japan (JP4EE)

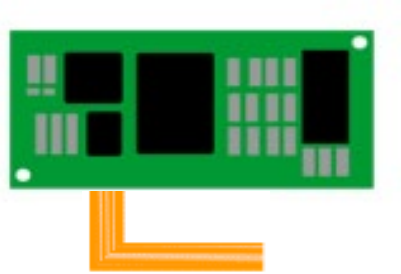
1. PFAS in Electrical and Electronic Equipment (EEE)

- **The use of PFAS remains unavoidable in a wide variety of EEE**
  - Due to the high cost of PFAS-based parts and materials, we only use them **only where the multi-functionality of PFAS is required to meet the performance requirements of EEE**, making it extremely challenging to find alternatives for current applications.
  - **When substituting chemicals in EEE, the performance of the finished product must be warranted**. **Performance matters**, even when there are potential alternatives with similar uses.
- The electronics and semiconductor sectors account for **less than 1% of PFAS uses and emissions.**
- **Many of waste EEE has been governed by Minnesota for over 10 years.**
- **Durable, high-performance EEE is essential to modern society** and requires close consideration from a socio-economic perspective, feasible and enforceable.

2. Main Points - Our concerns on the draft PFAS Management Plan

- EEE (complex articles) require a transition period of **at least 5 years** **after feasible alternatives become commercially available as substances or mixtures**.
  EEE for industrial and social infrastructure requires a longer period.
  - There are many different types of EEE and their supply chains are very long and complex, making it extremely challenging to collect data and find alternatives.
- **Exclusion from the restriction scope is needed for spare parts and pre-owned articles.** Finished complex articles cannot be redesigned retroactively. Spare parts prevent an increase in e-waste and contribute to sustainable circular economy.
- **PFAS are still essential in many applications of EEE**, and **derogations are necessary** for them.
  - **The high performance of PFASs is due to their multi-functionality** covering two or more properties at a time, such as durability, low friction, electrical properties, flexibility, resistance to heat, UV light and/or chemicals, etc. Such properties of PFAS allow EEE to set many functions in a compact unit, **resulting in high performance and energy and/or resource-efficient EEE**.
  - While there are chemicals that perform each function **there are currently no alternatives that offer similar multi-functionality and performance**.

3. Multi-functionality of PFAS (Not satisfied with a mixture of alternative materials)



e.g. Printed Circuit Board in a Mobile Phone System
The component needs
- Low dielectric constant
- Heat resistance
- Flame retardancy

There may be alternative materials that satisfy each specific property, but...
- Formulating a functional mixture of alternative materials is in most cases, extremely challenging in practice.

Depending on the property, it is the worst-case from the constituent materials that determines the final properties of the mixture.

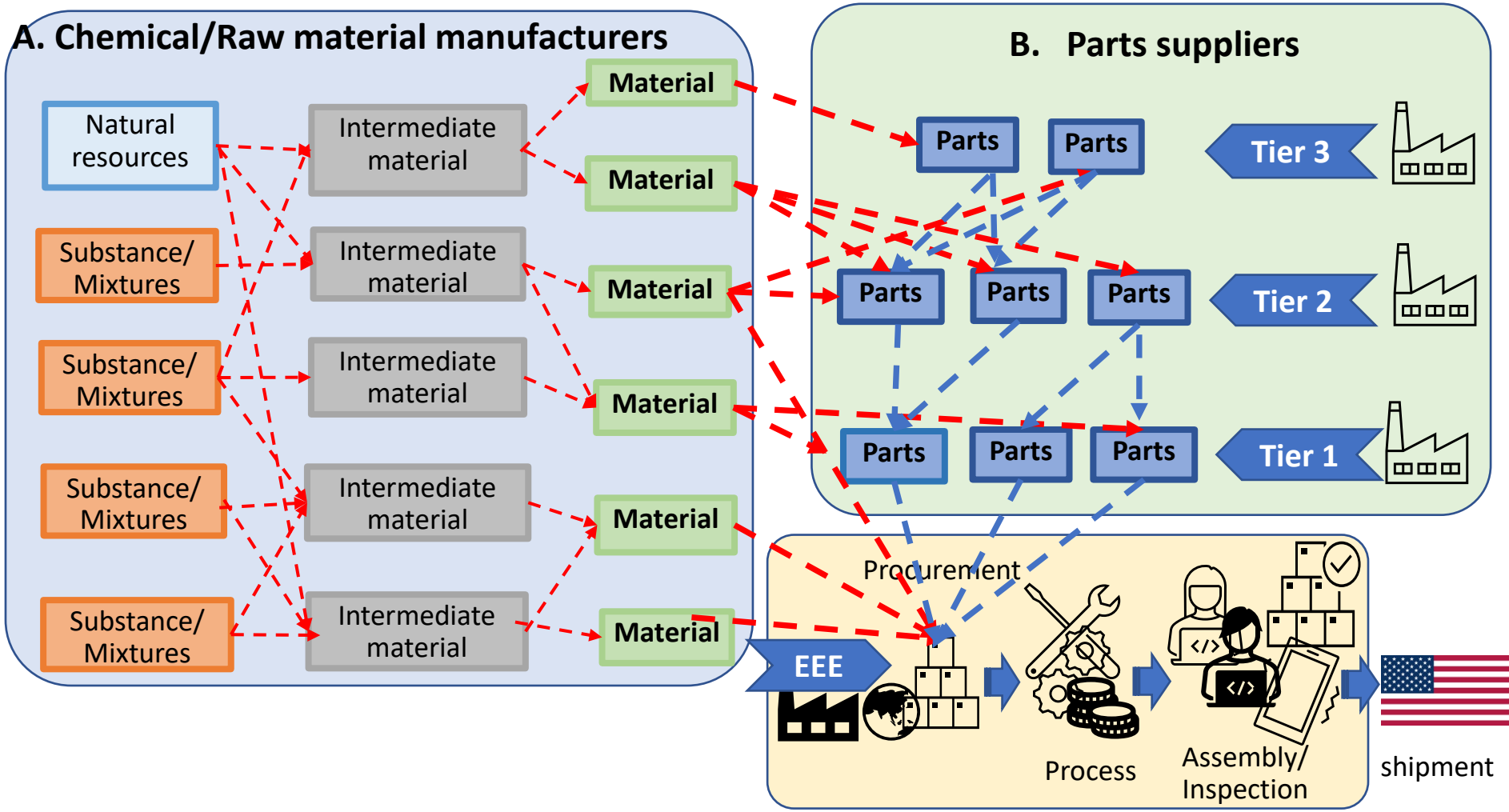
	Material A (e.g. PPE)	Material B (e.g. PI)	Material C (e.g. Br-based material)	Mixture of Material A/B/C
Low dielectric constant	○	△	×	△～×
Heat resistance	△	◎	—	△～×
Flame retardancy	×	×	◎	○

Fluorinated material
◎
○
◎

◎=Excellent; ○=good; △=not good; ×=bad

4. Complexity of the Supply Chain of EEE and Related Sectors

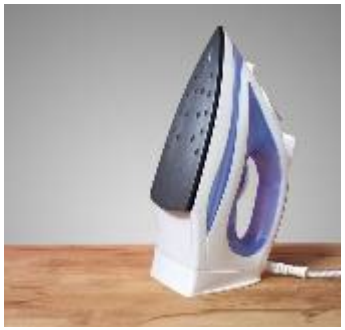
EEE consists of many components & parts, and **each component or part has its own supply chain as shown below**.



5. Wide Variety of EE products

A wide variety of EE products with different applications exists, many of which require the use of PFAS to achieve their essential functions. **A "One fits all" review of EEE is not feasible.**

1.Large household appliances

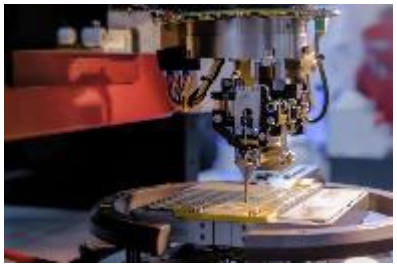


2.Small household appliances

3. IT and telecommunications equipment

4. Consumer equipment

5. Lighting equipment



6. Electrical and electronic tools

7. Toys, leisure and sports equipment

8. Medical devices

9. Monitoring and control instruments including industrial monitoring and control instruments

10. Automatic dispensers

11. Other EEE not covered by any other categories

7. Functions of PFAS required in EEE

PFAS's **multi-functionality** is the most important reason for their use in EEE.

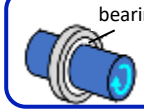
1. Safety functions


cable & connector

2. High-speed communication/transmission function


mobile phone

3. Sliding function in mechanical section


bearing


lubricant

4. Piezoelectric function


Pressure Sensor
(Smart watch)

5. Display function (Liquid crystal)

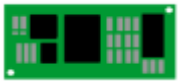

liquid crystal display
(Personal Computer)

6. Optical function


security camera

7. Functional surface


oven

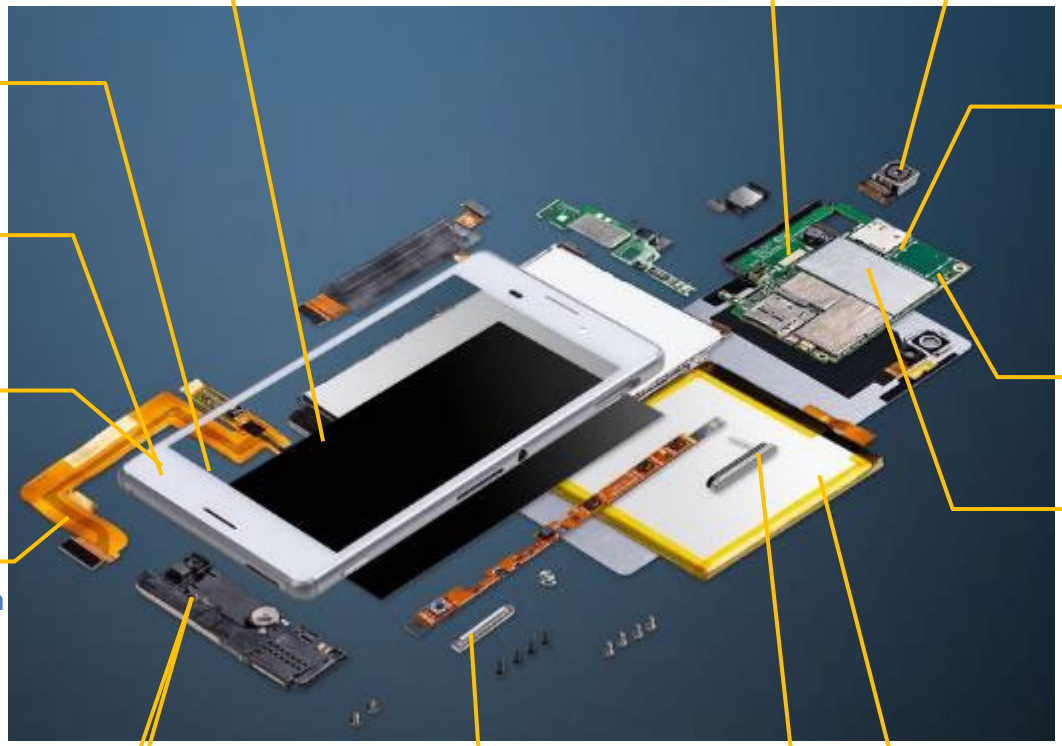

printed circuit board

8. Semiconductor
9. Thin film device production process
10. Energy supply (Battery)
11. Refrigerant function (Refrigerant gas)

8. Many uses of PFAS are currently unavoidable

Mobile phones contain a wide range of electronic parts.
Many of those parts contain PFAS as listed below.

The numbers are linked to the essential functions in "Functions of PFAS required for EEE" in the previous page of this presentation.



Antennas
2. High speed communication and transmission function

Liquid crystal panel or OLED
5. Display function

Touch screen
4. Piezoelectric function

Enclosure
1. Safety and safety functions

Coating of smartphone surfaces
7. Functional surface

Flexible substrate
2. High speed communication and transmission function

Speaker, Microphone
4. Piezoelectric function

Sealing material
1. Safety and safety functions

Optical Lens, Actuator, Image sensor, LEDs etc.
4. Piezoelectric function
6. Optical function
8. Semiconductor

Printed Circuit Board, Cable
1. Safety and safety functions
2. High speed communication and transmission function
8. Semiconductor

Coating of Electronic Components
7. Functional surface

Touch Sensor
Fingerprint sensor
Gyroscope
etc.
9. Thin-film device manufacturing process

Battery
10. Energy supply

Vibrator motor
3. Sliding function in mechanical section

Lubricant,
Sealing material (SIM/SD tray)
3. Sliding function in mechanical section

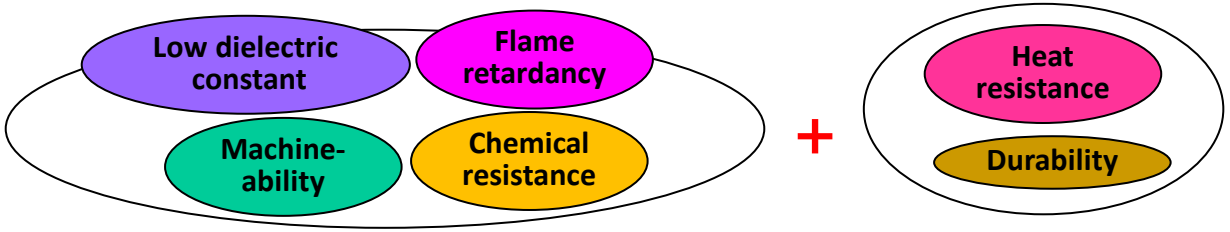
9. PFAS Contribute to Safety Functions

Insulating and anti-dripping materials require the multi-functionality of PFAS.

Required functions/properties of EEE: Electric insulation, drip-prevention, heat resistance, durability

Required functions for materials: Low dielectric constant, flame retardancy, chemical resistance, etc.

Examples of parts requiring use of PFAS

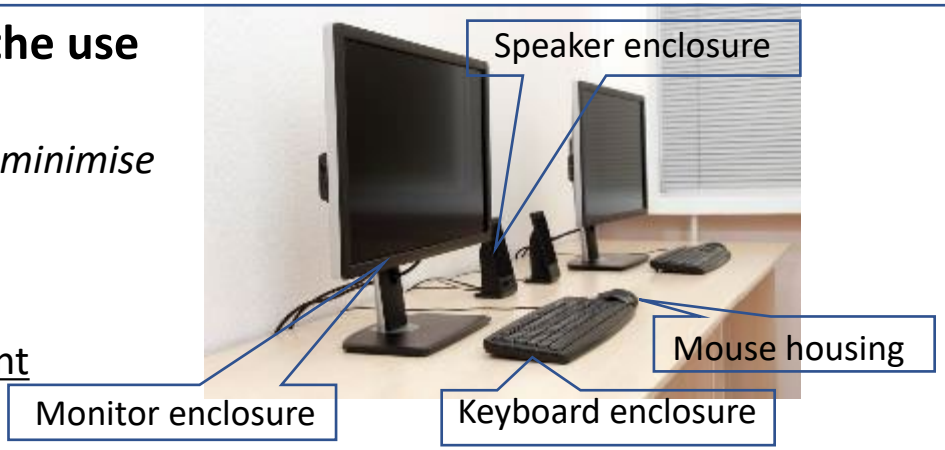


Anti-dripping material requires the use of PFAS

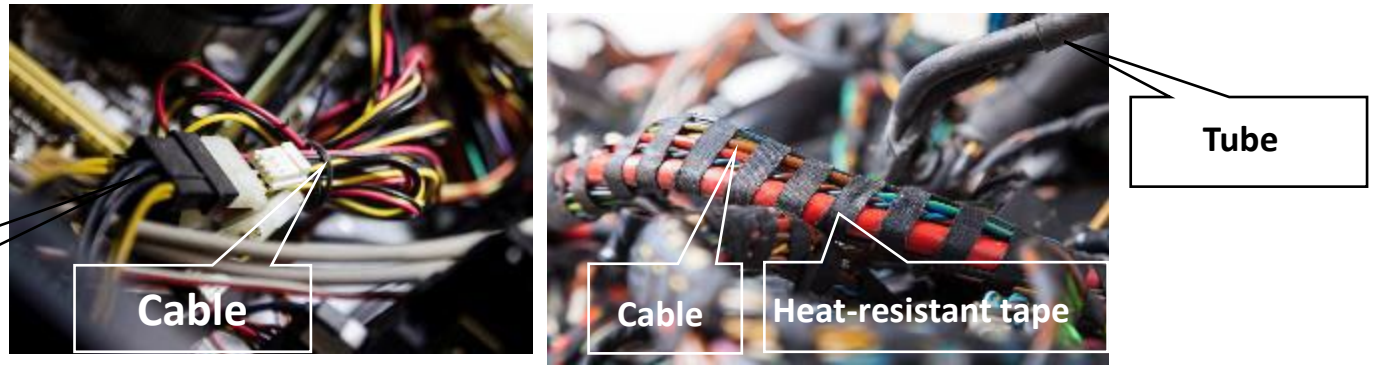
Preventing drip of resin components to minimise damage in the event of a fire.

- *PTFE as anti-dripping agent.*
- *Resin itself should be heat resistant.*

Example: Personal computer (equipment housing)



Wiring parts require PFAS for insulation

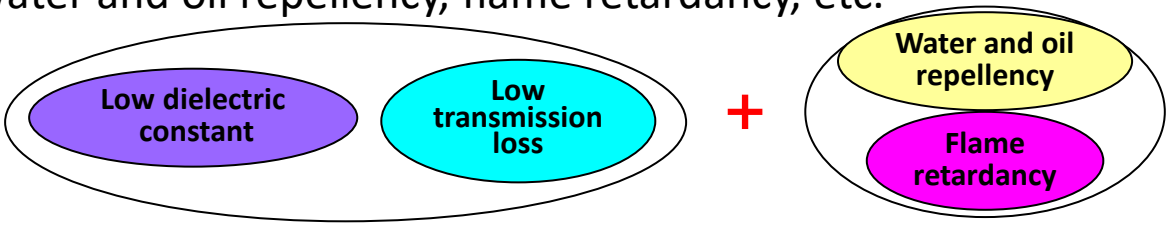


10. PFAS Contribute to High-speed Communication/Transmission Functions

PFAS are the only compounds that provide multi-functionality required by electronic parts for high-frequency applications as shown below:

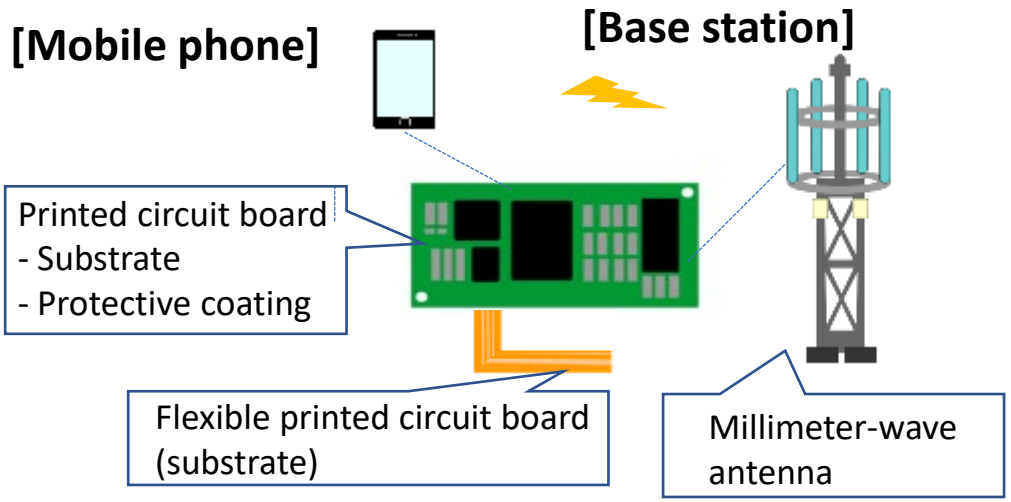
Required functions and properties of EEE : Low dielectric constant at high frequencies and low transmission loss

Required functions for materials : Water and oil repellency, flame retardancy, etc.



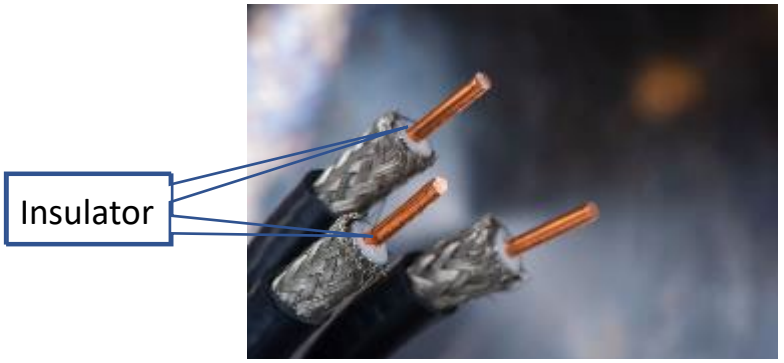
Examples of parts which require the use of PFAS:

Mobile Phone System



Millimeter Wave Band Apparatus

[Coaxial cables (high-frequency wires)]

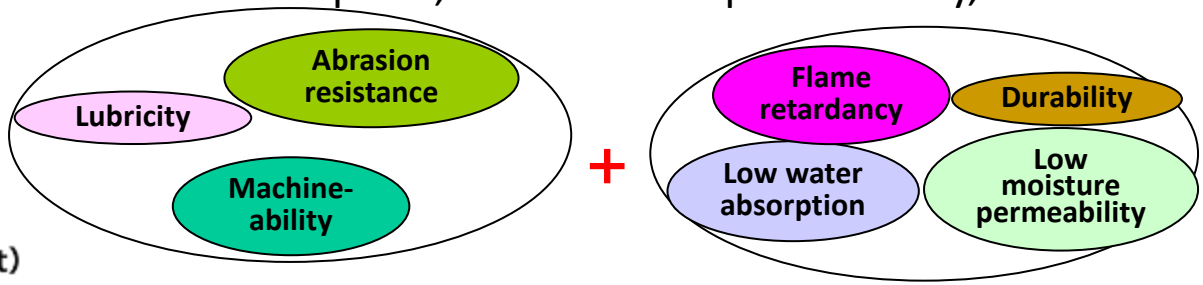


11. PFAS Contribute to the Sliding Function in Mechanical Sections

PFAS are the only compounds that can simultaneously provide multiple functions necessary for EEE as well as manufacturing equipment of components for such EEE **to properly work under various environments**.

Required functions and properties: Lubricity, abrasion resistance, machineability (elasticity)

Required functions for materials: Low water absorption, low moisture permeability, etc.

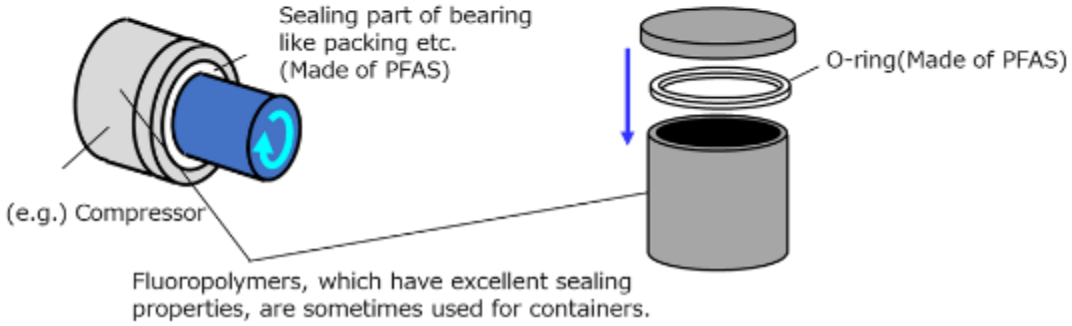


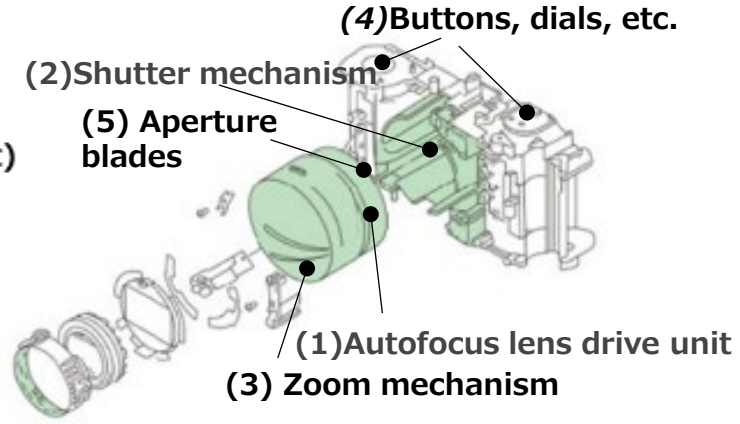
Examples of parts which require the use of PFAS:

1) Lubrication improvement (Sliding part)

2) Seal improvement (Sliding part)

3) Seal improvement (Fixed part)





Judah Prero Attachment

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May 23, 2025

Administrative Law Judge Jim Mortenson
Minnesota Office of Administrative Hearings
600 North Robert Street
PO Box 64620
St. Paul, MN 55164-0620

Re: In the Matter of Proposed New Rules Governing the Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per- and Polyfluoroalkyl substances (PFAS); Revisor's ID Number R-4828
OAH Docket 5-9003-40410

Dear ALJ Mortenson:

The Chemical Users Coalition (CUC) is providing comments in response to the Minnesota Pollution Control Agency's Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees.

CUC is an association of companies from diverse industries interested in chemical management policy from the perspective of those who use, rather than manufacture, chemical substances.[1] CUC encourages the development of chemical-regulatory policies that protect human health and the environment while simultaneously fostering the pursuit of technological innovation in the context of international markets and the global economy.

The CUC appreciates your consideration of these comments. If you have any questions relating to this submission, please feel free to contact me.

Sincerely,

Enc.

[1] The members of CUC are Airbus S.A.S., The Boeing Company, Carrier Corporation, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, the National Electrical Manufacturers Association, RTX Corporation, Sony Electronics, Inc., and TDK U.S.A. Corporation.

Before the Minnesota Office of Administrative Hearings
In the Matter of Proposed New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS),
Revisor's ID Number R-4828, OAH Docket No. 5-9003-40410

Comments of the Chemical Users Coalition

The Chemical Users Coalition ("CUC")[1] appreciates the opportunity to provide our comments on the Proposed Permanent Rules Relating to PFAS in Products: Reporting and Fees (the "Proposal"). CUC is an association of companies from diverse industries that are interested in chemical management policy from the perspective of those who use, rather than manufacture, chemical substances. CUC encourages the development of chemical regulatory policies that protect human health and the environment while simultaneously fostering the pursuit of technological innovation. Aligning these goals is particularly important in the context of chemical management policy in a global economy. CUC Members have been actively engaged with federal and state regulators on PFAS-related legislation and regulation, including other activities relating to the Minnesota Pollution Control Agency's ("MPCA") efforts to implement Amara's Law.

CUC appreciates MPCA's efforts to implement a balanced reporting requirement that would gather information and data on products that contain PFAS while not overburdening those who need to report. We are providing comments on a section-by-section basis in the more detailed comments below. We offer these initial general comments as well.

General Comments

In the Statement of Need and Reasonableness for the Proposal (the "SONAR"), MPCA states that the reports to be received containing PFAS-in-products information will have utility both for MPCA and consumers. Specifically, it notes that "Informed consumers are key to reducing PFAS exposure and pollution. By providing clear, accessible information on which products contain intentionally added PFAS, the proposed rule empowers consumers to make educated purchasing decisions."

CUC believes that the goal of educating and informing consumers to make educated purchasing decisions is not met with this reporting requirement. As discussed further below, the information to be gathered by the proposed reporting requirements will not provide the state, nor consumers, with information which is informative of the potential risks of the specific PFAS which might be present in products, nor the likelihood of PFAS being released in a meaningful way from a

[1] The members of CUC are Airbus S.A.S., The Boeing Company, Carrier Corporation, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, the National Electrical Manufacturers Association, RTX Corporation, Sony Electronics, Inc., and TDK U.S.A. Corporation.

product about which information is being gathered. Unfortunately, the regulations proposed will impose reporting burdens on submitters and administrative burdens on state government officials who will need to collect and process information being submitted.

The adoption of the class-wide approach to regulating PFAS reflected in this Proposal fails to recognize that (as defined) the term "PFAS" comprises a group of thousands of synthetic chemicals that are used widely throughout the world, in a broad range of applications. Chemically, toxicologically, and physically, PFAS differ widely. Included in the category as PFAS are substances in the solid (e.g., fluoropolymers), liquid (e.g., fluorotelomer alcohols), and gaseous (e.g., hydrofluorocarbon refrigerants) forms. The fundamental physical, chemical, and biological properties of solids, liquids, and gases are clearly different from one another. Furthermore, PFAS vary substantially in their physicochemical properties and may include polymers and non-polymers; solids, liquids, and gases; volatile and non-volatile compounds; and compounds that are water soluble and water insoluble.

The simple reporting of data on thousands of unique substances and the products in which they appear, even in some minute quantities, fails to inform the consumer that there are significant differences among the unique substances included within the broad definition of PFAS the legislation provides and that many PFAS may not pose any risk of harm to human health or the environment. Furthermore, there may be extremely limited to no exposure to consumers from the PFAS within reported products, as the PFAS may not be present on a product's surface nor migrate into the environment. The reporting requirement provides no scientific context for any of the information provided and will not truly inform or educate consumers in a meaningful way. The information being gathered will be subject to misinterpretation and will be likely to exaggerate risks.

CUC notes that the scope of the regulation is impractically large. CUC recommends that reporting should be implemented as a phased approach. Instead of requiring reporting on all products, whether for industrial or consumer use, and for all PFAS, at one time, the focus of an initial round of reporting could be limited. It could provide for reporting on both a specific subset of PFAS and product categories, namely those of highest concern, and the scope of subsequent reporting could be revisited thereafter. By limiting the initial scope and breadth of PFAS and products for which reporting requirements are initially imposed, MPCA can provide a more reasonable and practical opportunity for suppliers of products and components that are incorporated within complex articles to determine the presence of PFAS in their supply chain and to begin evaluating opportunities to phase out certain uses of PFAS where possible. This also will permit the development and submission of more accurate reporting.

Furthermore, CUC recommends that MPCA adopt a reporting threshold, similar to those Environment and Climate Change Canada adopted for their 71(b) PFAS reporting requirement.[2] This would ensure that the entities that are selling products with significant quantities of PFAS are those that report and would ease the burden on manufacturers whose PFAS use is negligible.

Our comments on specific provisions in the Proposed Rule follow.

[2] Canada Gazette, Part I, Volume 158, Number 30: SUPPLEMENT, July 27, 2024, *Notice with respect to certain per- and polyfluoroalkyl substances (PFAS)*

7026.0010 Definitions

Subp. 2. ***Authorized representative.*** *"Authorized representative" means a person designated by a manufacturer to report on behalf of the manufacturer.*

CUC requests clarification from MPCA as to the intent of this definition. For example, MPCA could simply intend for an individual who is a representative of the manufacturer to report, or MPCA could intend for someone who has more direct or intimate knowledge of the actual product composition to be the authorized representative for reporting. If MPCA has no preference, it would be helpful if MPCA could explicitly indicate such.

Subp. 7. ***Component.*** *"Component" means a distinct and identifiable element or constituent of a product. Component includes packaging only when the packaging is inseparable or integral to the final product's containment, dispensing, or preservation.*

Complex finished products may contain a multitude of individual and potentially integrated components. For example, a passenger automobile/vehicle could have an air conditioning system that is charged with a PFAS refrigerant or refrigerant blend. The system may also have PFAS-containing seals, gaskets, nuts, bolts, wires, and hoses that are all individual components, but would be difficult to identify as distinct unless the system was completely disassembled. CUC requests that MPCA clarify the meaning of a "distinct and identifiable element or constituent of a product." Ascertaining whether every small component of a complex manufactured good may be impossible, and at a minimum would impose a significant burden on manufacturers.

The definition of "Identifiable element" makes understanding the meaning of a component even more confusing. "Identifiable element" is defined as "*an element that can be recognized, distinguished, or discerned, even when not visually evident, as in the case of a mixture or formulation.*" This appears to indicate that literally everything and anything is considered a "component." It may be impossible to discern the various substances in a mixture or formulation once it is complete. To categorize an element as "identifiable" simply because at one point in time it was separate and distinct from others renders the definition meaningless. If MPCA truly means that a manufacturer must account for literally every molecule of a product, breaking down the constituent components of every single drop of adhesive, coating, lubricant, colorant, solder, regardless of how much of the substance is present in the product, MPCA is placing a mammoth compliance burden - assuming it can actually be achieved - on manufacturers. CUC requests that MPCA reconsider this definition in light of the significant burden it would impose contrasted with the limited utility of information that would likely be gleaned from requiring such an evaluation.

Subp. 14. ***Manufacturer*** *"Manufacturer" means the person that creates or produces a product, that has a product created or produced, or whose brand name is legally affixed to the product. In the case of a product that is imported into the United States when the person that created or produced the product or whose brand name is affixed to the product does not have a presence in the United States, manufacturer means either the importer or the first domestic distributor of the product, whichever is first to sell, offer for sale, or distribute for sale the product in the state.*

There are circumstances when two different entities meet that definition: one may manufacture the product and the other may legally affix their name to the product. In such a circumstance, it is not clear who the "manufacturer" is and therefore which entity has the compliance obligation. MPCA should clarify which entity has the primary obligation to report.

7026.0020 PARTIES RESPONSIBLE FOR REPORTING

Subpart 1. ***Scope.*** *A manufacturer or group of manufacturers of a product sold, offered for sale, or distributed in the state must submit a report for each product or component that contains intentionally added PFAS.*

- CUC appreciates MPCA's effort to lessen the reporting requirements by allowing for groups of manufacturers to report together. This is evidenced by the allowance made in 7026.0030 for reporting groupings of similar products. However, as currently drafted, with the specific criteria needed to allow for "grouped" reporting, these allowances will have limited applicability and utility.

  Different manufacturers will often have different numeric codes assigned to their products, even if they are similar. This alone creates complexity as the same code cannot be provided in a joint submission. Furthermore, even for what may seem to be identical products from different manufacturers, suppliers of component parts and the material composition can differ. This is often the case even for single products from the same manufacturer: the supplier of components may differ during the course of any given year due to supply chain and economic issues, in which case "identical" product from one manufacturer may not be exactly "identical" as there may be slight variations in material composition – whether it be in the PFAS used or the quantity of a PFAS used - even within the same product.

  In order to provide a substantive easing of the compliance burden on manufacturers, MPCA should consider allowing for greater latitude in whom and what could qualify for joint reporting. For example, for "similar" products, MPCA could allow a report to contain multiple entries for PFAS used or multiple concentration ranges to cover all permutations. The report would indicate that PFAS is present in the products, providing MPCA with this basic information, and the need for multiple reports would be eliminated, easing the compliance burden on manufacturers.

  Additionally, CUC believes that any "grouping" of reporting, whether of manufacturers or products, would reduce the burden on MPCA of reviewing and processing reports, as there will be fewer reports. It therefore would be product for MPCA to incentivize the use of the group reporting provisions. However, as mentioned above, it seems unlikely that manufacturers will be able to utilize group reporting. In fact, with the proposed provisions that penalize all manufacturers that report together for the failure of one of the parties, there is a significant disincentive for manufacturers to form a group to report. CUC believes that, as suggested above, greater flexibility should be added so that the efficiencies of group reporting can be realized by MPCA.

7026.0030 REPORT; REQUIRED INFORMATION

Subpart 1. Report Required

- The Proposal requires that a report be submitted on or before January 1, 2026. This date for reporting is not practical given that the reporting rules and information technology processes are not yet finalized. The initial reporting timeline should be delayed sufficiently to provide for *at least* 12 months after the Minnesota reporting rule and reporting process and platform have all been finalized.

- The Proposal provides that the report must be submitted before the product can be sold, offered for sale or distributed in commerce. It is likely that there will be products containing PFAS that were distributed to retailers or other entities operating in the state for months if not years prior to the effective date of the reporting requirement. The manufacture and placing of these products in the Minnesota market may have ceased. Such manufacturers may not even know that these products are still in stores. CUC requests clarification that in this scenario, manufacturers do not have any obligation to report despite the fact that the product may be sold, offered for sale or distributed to an end user after January 1, 2026.

- The Proposal is unclear on when the reporting obligation is triggered when a new product will be sold into Minnesota beginning after January 1, 2026. If a product will be sold into Minnesota starting June 2027, would a report be required at that time, or would the manufacturer wait to file until the beginning of 2028? Assuming they must notify in June 2027, would they still need to submit a certification in 2028, which is only a few months later? CUC requests that MPCA clarify the application of the reporting obligation.

- The Proposal provides that the report must be submitted before the product can be sold, offered for sale, or distributed in the state. CUC requests that MPCA clarify whether approval of the report is required prior to sale, offering for sale or distribution in the state, or simply that the report and accompanying fee be submitted and then sale can commence.

- For many products, there may be a lengthy manufacturing period once an order is placed by the customer. A customer may place the order, may tender a deposit, and manufacturing commences. During the time of manufacture, the composition of components varies due to available parts and suppliers. CUC requests that MPCA provide guidance on when the "sale" of such an item occurs and at what time the obligation to report is triggered. If the obligation to report is triggered when the order is placed, as that commences the "sale," it is possible that PFAS presence in a component may not be contemplated. CUC therefore recommends that MPCA only require reporting in such a scenario at the time of final delivery to the customer in Minnesota.

- The Proposal lists a number of specific pieces of information that must be reported, such as the specific PFAS used, its function and its concentration range. In many situations, it

will be challenging for a manufacturer to provide the exact PFAS (by name and CAS), its function, and the concentration range. Complex supply chains make this type of information challenging to obtain. For example, while PFAS are not typically on an SDS for formulations, identifying PFAS becomes even more challenging for manufacturers of complex goods. Furthermore, in complex supply chains, thousands of global suppliers provide hundreds of thousands of parts, and it may take many years to track down this information, if possible. CUC recommends that the MPCA allow for reporting of general information, such as simply that PFAS is present, as that will provide MPCA with the information that there is indeed PFAS in a specific product.

- The proposal provides that the concentration of PFAS chemicals in a product or components of a product made up of homogenous material must be provided within a range, or one can indicate PFAS is present but amount or concentration range is unknown, or the total organic fluorine (TOF) if the amount of PFAS is not known. It is unclear if MPCA is requiring that TOF testing be performed if the exact amounts cannot be ascertained, or that is an alternative to simply report~~ing~~ if it cannot be ascertained. CUC requests that this be clarified.

  Furthermore, the requirement for TOF testing is impossible in most scenarios. As discussed, if MPCA is requiring that every single "component" be accounted for, TOF testing cannot be performed on a finished product, particularly complex manufactured goods, to ascertain if any PFAS is present in any component. CUC requests that MPCA allow the reporting of TOF values as an alternative to PFAS concentration ranges, when feasible, and that if the concentration range/amount is unknown, that fact can be reported in satisfaction of the requirements.

- CUC recommends that reporting not be required for spare/replacement parts for existing products, and materials needed to maintain and repair existing products. These parts often are not newly manufactured. Rather, when a new product is manufactured, spare and replacement parts are manufactured and maintained in accordance with either contractual or regulatory requirements so that the product can be continuously used and need not be replaced solely because a replacement part is not available. If these parts are not newly manufactured, it may be difficult for the entity selling the parts to ascertain PFAS content due to the lapse of time since manufacture. A parts supplier, if required to report, may simply decide not to provide these parts to customers in Minnesota, due to the compliance burden. The availability of spare/replacement parts allows for the continued use and maintenance of existing products, thereby preventing the accumulation of unnecessary waste including e-waste.

7026.0040 REPORTING UPDATES.

The Proposal requires that by February 1 of each year, manufacturers must either update reports to reflect changes to information previously submitted or recertify the previously submitted report.

While CUC understands a need to update information when what MPCA has on record changes, the requirement to recertify is unnecessary and only serves to add a compliance burden, creating another opportunity to find a violation - and an opportunity to collect a fee – on those attempting to do business in Minnesota. Once there is an affirmative obligation to ensure that the information MPCA has been provided is (and remains) accurate, annual recertifications are not necessary. CUC requests that this requirement be eliminated and that updates be required only when a material change in a product's PFAS composition has occurred.

7026.0050 WAIVERS.

The Proposal allows for the commissioner to waive all, or part of the information required if substantially equivalent information is publicly available. As MPCA is aware, EPA will be moving forward with its own PFAS reporting under Section 8(a)(7) of the Toxic Substances Control Act. To ease the reporting burden and reduce duplication of effort, CUC recommends that MPCA issue a blanket waiver for all manufacturers that will be reporting information to EPA to comply with that reporting requirement.

7026.0070 TRADE SECRET DATA REQUEST.

The Proposal provides for procedures to maintain confidential business information, or "trade secret data," as "not public." However, the SONAR states that MPCA anticipates utilizing the Interstate Chemicals Clearinghouse (IC2) High Priority Chemicals Data System, an application that allows manufacturers to submit data on chemicals in products, and for participating states and the public to access that reported data from the required reporting. As this database is shared by multiple states, CUC requests that MPCA explain how information trade secret data submitted will indeed be protected when other jurisdictions will have access to this very information.

The procedures by which MPCA will process trade secret claims must be clearly stated and known to all manufacturers who will need to report. Substantiation standards and submission requirements must be articulated, and the review process must be transparent and predictable. Trade secret data is of vital importance to manufacturers, and CUC believes that MPCA must recognize this and make the efforts needed to ensure that the data protection system is robust.

7026.0080 DUE DILIGENCE.

The Proposal states that "(a) manufacturer or group of manufacturers must request detailed disclosure of information required in part 7026.0030 from their supply chain until all required information is known." The SONAR explains that "(i)t is reasonable to require manufacturers or a group of manufacturers to continue to request information from their supply chain until the reporting requirements can be fulfilled because PFAS can be present at various stages of product manufacturing and may be introduced at different points within the supply chain. By ensuring that manufacturers trace PFAS usage through multiple tiers of manufacturers in the supply chain, the MPCA can gather comprehensive and accurate data on PFAS in products, thereby preventing gaps in reporting that could undermine the rule's effectiveness."

CUC believes that such an approach fails to acknowledge the complexity of global supply chains, particularly for complex manufactured goods. As previously discussed, for complex manufactured goods, the number of components, and specifically using the definition for "components" in the Proposal, can be in the thousands. The number of companies involved in the manufacture of any constituent part can be numerous, difficult if not impossible to track, and even if they could be identified, many suppliers globally may simply refuse to cooperate. It is simply naïve to believe that repeated requests for information – assuming the parties can be identified - will actually result in the provision of information so that all required information is known.

In US EPA's Initial Regulatory Flexibility Analysis (IRFA) and Updated Economic Analysis for the TSCA 8(~~a~~)(7) PFAS Reporting Rule, EPA noted that there are "various challenges companies expect from contacting suppliers (e.g., foreign suppliers not responding or refusing to give information, suppliers going out of business, etc.)." Furthermore, it was EPA's understanding that "many PFAS are used in such a way that their use is a trade secret or there is no requirement that their use be stated in a specific application." EPA also recognized that article supply chains are complex, and for certain instances testing would be needed to determine the presence of PFAS. Because of these and other factors, EPA significantly revised the cost of compliance with the TSCA 8(a)(7) rule from $10.8 million to $876 million. This estimate was for compliance with a rule that required reporting data that was "known or reasonably ascertainable," not utilizing the unrealistic due diligence standard in the Proposal. It is evident that attempting to secure PFAS related information from suppliers is a costly and time intensive endeavor with no guarantee of success.

It behooves MPCA to use a familiar and accepted due diligence standard that has been used for decades by EPA for reporting – that information be "known to or reasonably ascertainable." "Known to or reasonably ascertainable by" is generally defined to mean "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know." This is a realistic standard with which industry is familiar and has been successfully used by EPA. Keeping the current due diligence standard will result in codification of an unachievable mandate and set manufacturers up for failure and non-compliance, even after valuable time and resources have been expended in efforts to comply.

To address the situation where PFAS content information cannot be obtained from a supplier due to trade secret or non-responsiveness concerns, CUC suggests that MPCA authorize and implement a joint submission system. Such a system would allow manufacturers to submit their suppliers' contact information when such suppliers were reluctant to provide chemical substance information to the customers due to confidentiality concerns. The system would directly contact the upstream suppliers so that those suppliers could submit the needed information directly to the state. The duty to report would then lie with the suppliers, and the reporting manufacturers would have fulfilled their reporting obligation by providing the supplier contact information.

7026.0100 FEES

The Proposal states that "*A manufacturer must pay a $1,000 fee to submit the initial report under part 7026.0030, subpart 1.*" As discussed above, 7026.0020 states that a manufacturer must submit a report for each product or component that contains intentionally added PFAS. The Proposal states further that "A manufacturer must pay a $500 flat fee for the annual update according to part 7026.0040, subpart 1, or annual certification update according to part 7026.0040, subpart 3."

Based on the plain read of the text, it is not clear if MPCA is requiring $1,000 per report or $1,000 per manufacturer, regardless of how many reports that manufacturer submits. The term "flat fee" is only used in connection with the annual update/recertification. That would imply that there is no flat fee for the initial report. Furthermore, the "initial report" is simply the first report submitted as opposed to the annual reporting. A manufacturer may need to submit numerous initial reports, as a report is needed for each product or component, and it appears that a $1,000 fee is required for each initial report.

The language in the SONAR addressing the requirement does not provide clarity. It states that "Subpart 2 establishes a $1000 flat fee per manufacturer for the initial report." The term "flat fee" is not used in the regulatory text. Furthermore, this language implies that MPCA is expecting a single initial report from a manufacturer, which is highly unlikely for many product manufacturers. If MPCA indeed is only requiring a single $1,000 fee for each manufacturer that reports, regardless of how many reports are submitted, MPCA must state that clearly and unequivocally.

CUC also requests clarification as to whether a manufacturer who has previously reported for a specific product needs to pay a fee if at some later point in time, a new product is introduced into commerce in Minnesota by that manufacturer. If indeed fees are imposed per manufacturer, fees would not need to accompany reports for new products introduced at later times.

7026.0090 REPORTING EXEMPTIONS.

The Proposal exempts a product for which federal law governs the presence of PFAS in the product in a manner that preempts state authority from the reporting requirements. CUC recommends that MPCA elaborate on this exemption and expand it by providing that the exemption would apply to products that are required to meet federal standards or requirements of the United States Department of Transportation, Federal Aviation Administration, the National Aeronautics and Space Administration, the United States Department of Defense or the United States Department of Homeland Security or are products that have been authorized or are subject to approvals issued by federal agencies such as the FDA (e.g., drugs and devices) and EPA.

Conclusion

CUC appreciates the opportunity to submit the foregoing comments. We would welcome the opportunity to meet with MPCA staff to address our comments and to assist in refining the proposal.

21st May, 2025

Minnesota Pollution Control Agency
520 Lafayette Road North
St. Paul, MN 55155

Re: Minnesota Pollution Control Agency's Notice of Intent to Adopt New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per and polyfluoroalkyl substances (PFAS), Revisor's ID Number R-4828, OAH docket number 5-9003-40410

Dear Members of the Minnesota Pollution Control Agency,

I am writing to resubmit the BioPhorum Response to PFAS consultations document for your ongoing consultation regarding the reporting and fee rule for PFAS in products. BioPhorum represents a global collaboration of biopharmaceutical manufacturers and suppliers, and our response aims to provide comprehensive insights into the critical role of PFAS in the biopharmaceutical industry.

The attached document outlines the critical and irreplaceable roles that PFAS play in biopharmaceutical manufacturing processes and products. It highlights the potential risks to patient safety, product quality, and supply chain continuity that could arise from restricting these substances. We strongly advocate for full exemptions or time-unlimited derogations for essential PFAS materials used in this sector, reflecting the industry's unwavering commitment to both patient health and environmental stewardship.

Furthermore, we encourage the review team to consider opportunities for regulatory alignment. Specifically, adopting an approach consistent with other state-level PFAS reporting frameworks, such as those implemented in Maine and New Mexico, would promote harmonization, reduce administrative burden, and support a more coherent strategy for managing PFAS in essential industries.

We believe that our response addresses several key points relevant to your consultation, including:

- The critical role of PFAS in ensuring the safety and efficacy of biopharmaceutical products.
- The challenges and feasibility of finding suitable alternatives to PFAS.
- The socio-economic impacts of PFAS restrictions on the biopharmaceutical industry.

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- The need for regulatory flexibility and collaboration to navigate PFAS-related challenges effectively.

While our document provides a global perspective and reflects our position from the initial Minnesota consultation, our stance remains unchanged. We recognize the importance of addressing state-specific regulations and requirements. However, gathering the additional information needed as outlined below:

- Specific reporting requirements: Detailing the procedural aspects of reporting PFAS in products as required by the Minnesota consultation.
- Fee structure: Addressing the financial aspects related to the reporting and administration of the PFAS program, which are not covered in our current document.
- Product-specific information: Providing granular details about individual products containing PFAS and their specific uses, which are required under the Minnesota consultation but are not included in our current document.

This would require significantly more time than the deadline of 21 May allows.

In addition to the response the consultation has raised several questions these include but are not limited to:

- We respectfully request further clarification regarding the proposed fee structure outlined in the Minnesota PFAS reporting requirements. Specifically, we seek clear definitions on whether the fees are assessed per individual product, per SKU, or by product family. Additionally, we ask for transparency on the structure and frequency of annual update fees, including whether there is a maximum cap to prevent disproportionate financial burden.

- It would also be beneficial to understand how company size factors into the fee calculation, particularly for small and medium enterprises that may face greater challenges in absorbing these costs. Greater clarity in these areas will support more accurate planning and compliance across the biopharmaceutical sector.

- We would appreciate further clarification regarding the rationale for requiring PFAS reporting for pharmaceutical and biopharmaceutical products that are otherwise exempt from the proposed bans. If these products are recognized as essential and granted exemptions due to their critical role in patient care and public health, what is the intended purpose of maintaining a reporting obligation? How will the reported data be used, and what benefits are anticipated from collecting this information from exempted sectors?

- Additionally, could the review team clarify whether the reporting requirement is intended to be temporary or ongoing, and how it aligns with the broader regulatory objectives? Addressing these questions would help ensure that the reporting framework is both purposeful and proportionate for our industry.

We hope that our detailed industry-specific insights and data will support informed decision-making in your legislative and regulatory processes concerning PFAS. This initial response for Minnesota is also included within the document attached: "**BioPhorum Response to PFAS consultations – Worldwide response to each consultation"**, specifically Appendix 3 (page 33)

We appreciate the opportunity to contribute to this important consultation and are committed to working collaboratively with the Minnesota Pollution Control Agency and other stakeholders to develop practical and protective strategies for managing PFAS-related challenges.

Please do not hesitate to contact us if you require any further information or clarification regarding our response.
Thank you for your consideration.

Kind regards

Victoria Mwanza
Senior BioPhorum Facilitator.

Victoria Mwanza Attachment 2

BioPhorum Response to PFAS consultations – Worldwide response to each consultation

Connect
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Contents

2.0 Abstract

This document provides a comprehensive overview of the potential impacts of prohibiting or restricting PFAS on the BioPharma industry. It aims to advocate for the industry and serve as an educational resource for regulatory and government bodies, ensuring that BioPharma is recognized as a significant user case in PFAS-related consultations. The paper highlights the critical role of PFAS in manufacturing processes and products within the BioPharma sector, emphasizing the potential consequences of restricting these substances. It underscores the importance of balancing environmental concerns with the need to maintain the supply of essential medicines to patients.

The document includes detailed reviews of country- or region-specific consultations, offering insights into how different regulatory environments might approach PFAS restrictions. It addresses the challenges of finding suitable alternatives to PFAS, the socio-economic risks associated with restrictions, and the necessity for exemptions or derogations to ensure the continuity of biopharmaceutical manufacturing. The paper also discusses the broader implications of PFAS restrictions on the sustainability of the supply chain and the importance of visibility across the larger supply chain.

BioPhorum's response advocates for full exemptions or time-unlimited derogations for essential PFAS materials used in biopharmaceutical manufacturing, highlighting the industry's commitment to patient safety and environmental integrity. The document serves as a crucial resource for informed decision-making in legislative and regulatory processes concerning PFAS.

3.0 About BioPhorum

We enable the global biopharmaceutical industry to connect, collaborate and accelerate progress for the benefit of all. Since its inception in 2004, BioPhorum has become the open and trusted environment where senior leaders of the biopharmaceutical industry come together to openly share and discuss the emerging trends and challenges facing their industry. Growing from an end-user group in 2008, BioPhorum’s membership now comprises top leaders and subject matter experts from global biopharmaceutical manufacturers and suppliers, working in both long-established and new Phorums. They articulate the industry’s technology roadmap, define the supply partner practices of the future, and develop and adopt best practices in drug substance, fill finish, process development and manufacturing IT. In each of these Phorums, BioPhorum facilitators bring leaders together to create future visions, mobilize teams of experts on the opportunities, create partnerships that enable change and provide the quickest route to implementation, so that the industry shares, learns and builds the best solutions together.

4.0 Glossary

Term	Definition
BioPharma	A sector of the pharmaceutical industry that includes biological therapies such as monoclonal antibodies, cell and gene therapies, mRNA, and vaccines.
BioPhorum	A global biopharmaceutical manufacturing industry collaboration comprising over 150 companies, representing more than 98% of all biopharmaceuticals manufactured worldwide.
CUU (Currently Unavoidable Use)	Uses of PFAS that are deemed essential and for which no viable alternatives currently exist.
ECHA (European Chemicals Agency)	An agency of the European Union responsible for the implementation of the EU's chemical legislation.
EPA (Environmental Protection Agency)	The United States federal agency responsible for protecting human health and the environment.
FDA (Food and Drug Administration)	The United States federal agency responsible for regulating food, drugs, medical devices, and other health-related products and services.
PFAS (Per- and Polyfluoroalkyl Substances)	A group of human-made chemicals that are resistant to water, grease, and stains, and are used in a variety of industrial and consumer products.
PVDF (Polyvinylidene Fluoride)	A highly non-reactive and pure thermoplastic fluoropolymer used in applications requiring the highest purity, strength, and resistance to solvents, acids, and heat.
PTFE (Polytetrafluoroethylene)	A synthetic fluoropolymer of tetrafluoroethylene known for its non-stick properties and resistance to heat and chemicals.
FKM (Fluoroelastomer Polymer)	A class of synthetic rubber designed for very high temperature operation and chemical resistance.
FPM (Perfluoroelastomers)	Elastomers that contain a high percentage of fluorine, providing exceptional resistance to chemicals, heat, and other harsh environments.
FEP (Fluorinated Ethylene Propylene)	A copolymer of hexafluoropropylene and tetrafluoroethylene that is highly resistant to chemicals and has a low coefficient of friction.
ETFE (Ethylene Tetrafluoroethylene)	A fluorine-based plastic designed to have high corrosion resistance and strength over a wide temperature range.

GMP (Good Manufacturing Practices)	Regulations that require manufacturers, processors, and packagers of drugs, medical devices, some food, and blood to take proactive steps to ensure that their products are safe, pure, and effective.
Annex XV	A part of the REACH regulation that deals with the restriction of the manufacture, placing on the market, or use of certain dangerous substances, mixtures, and articles.
Derogation	An exemption from or relaxation of a rule or law.
E&L (Extractables and Leachables)	Chemical compounds that can be extracted from a material under laboratory conditions or that leach into a drug product under normal conditions of use.
CAGR (Compound Annual Growth Rate)	The mean annual growth rate of an investment over a specified period of time longer than one year.
HTS (Harmonized Tariff System)	An internationally standardized system of names and numbers to classify traded products.
API (Active Pharmaceutical Ingredient)	The part of any drug that produces the intended effects.
mRNA (Messenger RNA)	A type of RNA that carries genetic information from DNA to the ribosome, where proteins are synthesized.
TFA (Trifluoroacetic Acid)	A strong organic acid used in the synthesis and purification of peptides and proteins.

5.0 Introduction

This document provides an overview of the potential impacts of prohibiting or restricting PFAS on the BioPharma industry. It is intended to advocate for the industry and serve as an educational resource for regulatory and government bodies, ensuring that BioPharma is recognized as a significant user case in any industry consultations regarding PFAS.

The document highlights the critical role of PFAS in the manufacturing processes and products within the BioPharma sector, emphasizing the potential consequences of restricting these substances. It underscores the importance of balancing environmental concerns with the need to maintain the supply of essential medicines to patients.

Furthermore, the appendix offers a detailed review of country- or region-specific consultations, providing insights into how different regulatory environments might approach PFAS restrictions. This section aims to inform stakeholders about the varied impacts and considerations across different jurisdictions, facilitating a more informed and collaborative approach to managing PFAS-related challenges.

The Biopharmaceutical (BioPharma) industry, represented by BioPhorum, acknowledges the concerns regarding the potential adverse effects of Per- and polyfluoroalkyl substances (PFAS) on human health and the environment. Efforts to minimize and mitigate the presence

of these and other potential substances of concern in manufacturing processes and products are fully supported. The industry shares a responsibility to collaborate with all relevant stakeholders to manage the transition away from materials of concern while ensuring the safety and wellbeing of patients and the communities in which operations take place. Any efforts to restrict the usage and production of these materials must be pragmatically considered; the risk of drug shortages and the consequent failure to supply medicines to patients must be weighed against the environmental risks posed by these materials.

BioPhorum is a global biopharmaceutical manufacturing industry collaboration comprising over 150 companies, representing more than 98% of all biopharmaceuticals manufactured worldwide.

Biopharmaceuticals (or biologics), a subsector of the pharmaceutical industry, include biological therapies such as monoclonal antibodies, cell and gene therapies, mRNA, and vaccines. These therapies treat a wide range of disease indications, including immunology, neurology, infectious diseases, diabetes, oncology, cardiovascular conditions, and more. Advancements in biomedical science hold vast potential for the growth of the BioPharma market, and the ability of these drugs to treat chronic diseases that were previously untreatable is driving enormous demand, with newer therapies increasingly falling into the biopharmaceutical category.

6. High level overview

6.1. Compatibility and Alternatives

The biopharma industry is required by legislation to use materials that are not reactive or additive to our product streams. Specific PFAS materials (PVDF, PTFE, FKM, FPM, FEP, etc.) have been chosen as they present negligible reactive properties and are particularly low risk in terms of adding anything to medicinal products either at drug substance or drug product manufacturing processes, including direct packaging. It should be noted that the BioPharma Industry acts as downstream users of PFAS materials and does not own the technical solution outside of qualifying end use applications.

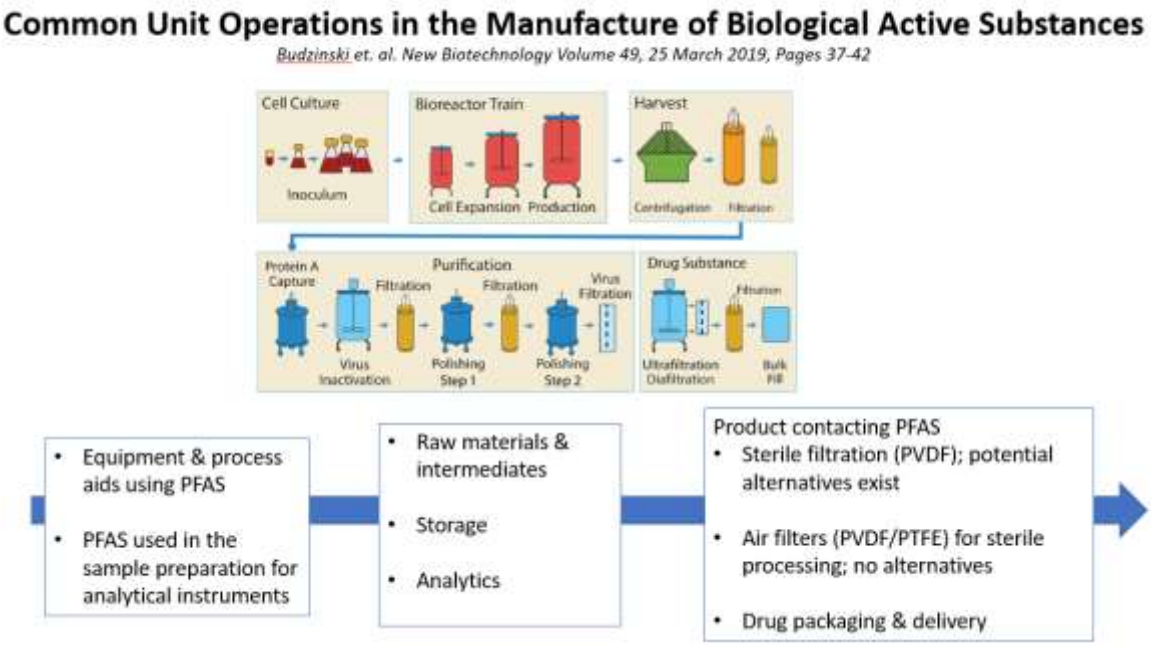
Within the BioPharma sector there are multiple sub-uses and applications of PFAS materials (mainly fluoropolymers) across the value chain, if not excluded in the relevant restriction report it is therefore assumed to be subject to any immediate ban or restrictions raised in the relevant proposal.

Proposed re write:

1. **Direct Uses**:
    - **Definition**: PFAS materials that come into direct contact with the drug substance and have a direct impact on drug product quality.
    - **Examples**: PTFE/PVDF liquid filters, bottles, packaging, films/coatings, tubing, connectors, starting materials.
2. **Indirect Uses**:
    - **Definition**: PFAS materials that do not come into direct contact with the drug product but are essential for the manufacturing process.
    - **Examples**: PTFE/PVDF air filters, gaskets, processing aids.
3. **Other Uses**:

- **Definition**: Miscellaneous components/materials that are not restricted to direct or indirect uses, including unintentional elements or particulates in the background environment.
- **Examples**: Supplier manufacturing precursors, intermediates, product testing and engineering components, refrigerants, electronics, stainless-steel vessels/skids.
- **Additional Note**: This category also includes contamination concerns, such as PFAS contamination in water, which is not an intentional use but a concern that needs to be addressed.

Figure 1:Common Unit Operations in the Manufacture of Biological Active Substances (1).



A non-exhaustive list of PFAS applications across the BioPharma industry with indication of possible alternatives and an analysis of the complexity and anticipated cost of substitution is included in Table 1: PFAS Applications in BioPharma (non-exhaustive list).

Note: Table 1 was prepared in collaboration with BioProcess Solutions Alliance (BPSA).

Table 1: PFAS Applications in BioPharma (non-exhaustive list)

Application	PFAS Type	Potential Alternatives	Feasibility of Replacement	Cost to replace	Patient safety/drug quality impact risk	Comments
Sterile Liquid filtration membranes	PVDF	(PES Nylon Cellulose) *	50%	Very high	High	*No alternative technology immediately available that would maintain product quality in all applications. This is a high-risk application area (particularly virus clearance filters): close proximity to patient, particularly of primary filling applications, dictates regulatory scrutiny and would require additional validation and regulatory approvals across multiple jurisdictions to support global supply chains of pharmaceuticals/API, diagnostics, and other controlled sectors. Cost of validation would be significant, capacity of 3rd party validation services would be a potential bottleneck; concern that current production volumes of PES are not adequate to meet demand and won't be available within the proposed derogation period. Alternatives have very high adsorption so overall yield may decrease and have cost implications (e.g., increased vaccine costs due to lower yield). Applications in Buffer/sterile filtration may be easier to switch.
	PTFE	PES Nylon	<10%	Very high	High	
Liquid filtration- virus clearance	PVDF	PES	80%	Extremely high	Moderate	
Application	**PFAS Type**	**Potential Alternatives**	**Feasibility of Replacement**	**Cost to replace**	**Patient safety/drug quality impact risk**	**Comments**

Films/plastics as primary contact material in manufacture and containment of drug intermediates (drug substance). • Containers/films/bottles • Single use processing bags • Single Use bioreactors • Probes/inserts	PVDF PTFE bottles FEP bags/bottles	†	TBD	TBD	TBD	This is a high-risk application area: close proximity to patient dictates regulatory scrutiny and requirement for extensive requalification, validation, and risk assessment. Changes must be submitted, reviewed, and approved by Regulatory Authorities.
Biopharma drug cryostorage bags and Cell culture cryostorage bags	PTFE FEP Custom fluoropolymer	ULDPE, EVA or EVA blends	<30%*	High	High	*For cell culture cryostorage bags feasibility of replacement is 75% with significant trade offs
Films/plastics (Primary contact material) for final drug product sterile packaging: • cap or stopper coatings/liners • Vial stoppers • Syringe stoppers • Seal linings	ETFE (cap or stopper coatings/liners) PTFE (coating for vial and syringe stoppers and seal linings)	no alternatives for drug product requiring barrier coating	0	N/A	High	This is a high-risk application area as the materials provide protection of the drugs throughout their shelf life. As of today, no alternative has been identified and would require development by the suppliers of containment solutions with subsequent testing, qualification at product level and submission for review and approved by Regulatory Authorities. They would also be subject to potentially lengthy stability studies. Removal of fluoropolymer barriers would also introduce a risk of occurrence of leachables and/or drug adsorption to the non-PFAS alternative.
Application	**PFAS Type**	**Potential Alternatives**	**Feasibility of Replacement**	**Cost to replace**	**Patient safety/drug quality impact risk**	**Comments**
Films/plastics (Primary contact material) for final drug product	PCTFE	Suggested alternatives	<5%	High	High	Blister packs confer protection to the Active Pharmaceutical ingredient in final drug products.

non-sterile packaging- blister packs		have been proposed but they do not confer sufficient protection				Feasibility of alternatives has not been demonstrated and the currently proposed 13.5-year time limited derogation will be insufficient to allow current blister packed products to remain on market. Manufacturers may not have capacity to qualify alternatives (if feasible) and this situation would place additional burden on regulatory authorities to approve
Intermediate, raw material or ancillary material used in manufacture, purification and testing of protein-based drugs	TFA (tri-fluoroacetic acid) or PFAS related compounds	No alternatives	0	N/A	High	This is a specific case not applicable to all biologic drugs however, where PFAS materials are used, any restrictions or removal of the PFAS material would result in an inability to manufacture the drug.
Vent and/or Gas Filtration (of bioreactors/carboys)- filter membranes	PVDF	No alternatives	<5%	Moderate	Moderate	This is a high-risk application area. There are no PFAS free alternatives for membranes used in Steam in Place filters. No PFAS free alternatives for membranes used in venting- and gas-filtration applications are available today. Restrictions in the availability of PFAS based air and vent filters would result in an inability to manufacture bio-pharmaceutical drug products.
	PTFE	No alternatives	<5%	N/A	Moderate	
Application	**PFAS Type**	**Potential Alternatives**	**Feasibility of Replacement**	**Cost to replace**	**Patient safety/drug quality impact risk**	**Comments**
	PVDF (tubing)	No alternatives	<5%	N/A	High	

Tubing & tube fittings, and filter components (manufacturing engineering systems and transfer of drug material intermediates and final product, lab testing applications, moulded parts, gaskets, and O-Rings)	PVDF (Fittings)	polycarbonate polypropylene polysulfone	<5%	Moderate	High	Used in bioproduction and technical applications such as chromatography, trace metal analysis, pollution sampling, highly reactive catalyst procedures, metallurgical corrosion testing, pharmaceutical work, dissolutions, and hot acid etchings where chemical compatibility and concerns over leaching is essential. Critical in fluid handling within analytical instrumentation. None of the alternatives match the inert properties of the PFAS materials
	PTFE	No PFAS free alternatives	<5%	N/A	High	
	FKM (tubing/O-rings / gaskets)					
	FEP					
	PFA					
	PTFA					
Hardware systems (lined pipes, TFF cassette seals/components/solvent exchange systems/lined valves/gaskets). Pumps & components (diaphragm)	PVDF PTFE FKM	No alternatives	<5%	N/A	High	None of the alternatives match the inert properties of the PFAS materials
Ultra-low temperature refrigerant (low boiling temp gases <-60ºC) for freezing drug intermediates or final product.	Multiple PFAS	CO_2: however energy consumption by alternatives is increased by 50%	100% but with energy pay-offs	High	N/A	PFAS materials were selected in this application to replace previously banned CFC materials. Alternatives may require substantial retrofitting or replacement of equipment (with subsequent qualification of the equipment to work with alternatives). To function as effectively as PFAS materials alternatives would require increased energy consumption.

Application	PFAS Type	Potential Alternatives	Feasibility of Replacement	Cost to replace	Patient safety/drug quality impact risk	Comments
Films/plastics (1º contact material) in laboratory reagents and standards	PTFE	No known universal alternative (use case specific)	<5%	TBD	TBD	Critical to research and development laboratory activities in pharmaceutical and API manufacture, life science and applied applications. Essential for preventing container leakage due to incompatibility-creating unwarranted hazards for chemical storage and shipping for many essential smaller (laboratory) scale reagents. Essential for high purity solvents and standards where minute quantities of leachable organics interfere with critical analysis (including High Performance Liquid Chromatography applications for detection of PFAS).
Laboratory Apparatus (funnels, flasks/containers, stirring bars etc)	FEP PTFE	Glass for some applications (compatibility dependant) but increased safety risks due to breakage.	<5%	TBD	TBD	Risk to research and development laboratory activities in pharmaceutical and API manufacture, life science and applied applications.

Applications not specific to BioPharma and which will also impact other industries.

Application	PFAS Type	Potential Alternatives	Feasibility of Replacement	Cost to replace	Patient safety/drug quality impact risk	Comments
Heat and/or chemical resistant, nonreactive coatings/insulation/lubricants used e.g. as components of electronics and stainless-steel vessels/skids.	Additive of PFAS origin	†	†	†	†	Impact to biopharma: not used directly in drug manufacture but are used in electronic components in system controllers/skids, PLCs s (Programmable Logic Controller) and stainless-steel equipment e.g. vessels and skids.

† Further assessment required; alternatives may be application specific; substitution with a particular non-PFAS material may not be suitable for all applications

Further details of PFAS applications in the BioPharma industry are detailed in individual response outlined within the Appendix. It should be noted here that if the BioPharma industry *is* granted regulatory relief and is permitted to utilise fluoropolymers/PFAS materials where no alternatives exist, there still remains a very serious concern that restrictions or removal of PFAS materials from the wider market will reduce or remove the availability of PFAS materials for BioPharma applications, resulting in a significant risk of disruption to the supply of critical medicines.

When evaluating the impact of the proposed ban on the BioPharma industry 4 core categories of change are important to consider:

1. Where no suitable alternative is available
2. Where alternatives are available but are not suitable/fit for purpose in every application
3. Where alternatives are available and fit for purpose but there is no stable, reliable supply chain
4. Where alternatives are available and fit for purpose, internal and external requirements to support the change will take several years (note this can be exacerbated further if the process of supplier of raw materials and biomanufacturers are ran in series). In addition, regulatory approvals could be delayed due to overload of the regulatory bodies who must evaluate and approve (or reject) every submitted change.

6.2 Social & Economic Risk

This section provides a comprehensive, high-level overview of the potential impacts of prohibiting or restricting PFAS on the BioPharma industry. It is intended to advocate for the industry and serve as an educational resource for regulatory and government bodies, ensuring that BioPharma is recognized as a significant user case in any industry consultations regarding PFAS.

6.2.1 Current Landscape

Today, 50% of the top 100 drugs sold globally are biopharmaceuticals, with predictions indicating this will increase to 55% of all innovative drug sales by 2027. The industry generates global annual revenues of USD 163 billion (2) (3) (4). Appendix demonstrates the region-specific economic impacts of these consultations.

6.2.2 Critical Role of PFAS

Biopharmaceutical products currently being developed or already licensed for sale utilize PFAS at some stage in their development, manufacture, testing, storage of intermediates, or drug delivery systems. If regulatory action is to be taken to ban or otherwise restrict the use of PFAS without an exemption for biopharmaceuticals and their manufacturing, access to these vital medicines and life-saving therapies would be compromised.

6.2.3 Economic and Operational Consequences

Proposed restrictions would directly affect companies that manufacture and sell their products in the affected regions. However, the impact would extend globally, affecting the export of medicines and the industries supplying materials to drug manufacturing facilities.

Companies importing and selling these products would also be impacted. The development of new drug therapies would be hindered, as PFAS materials are integral to drug discovery and preclinical development. For medicines still under patent or classified as orphan drugs, no alternatives are available if production is halted due to PFAS restrictions.

Significant investments have been made to build and resource state-of-the-art drug manufacturing facilities. An inability to manufacture products due to the unavailability of PFAS materials could result in the relocation of operations out of the affected regions, potentially leading to facility closures and significant economic damage. Restrictions on importing or placing both direct and indirect materials on the market would disrupt the entire global supply chain, potentially halting BioPharma manufacturing and the supply of critical drugs to patients within a short timeframe. Over time, this could lead to organizations outsourcing or relocating their manufacturing activities to regions without PFAS restrictions, impeding future investment plans and causing significant socioeconomic impacts.

6.2.4 Broader Implications

While this response focuses on the BioPharma sector, BioPhorum and its member companies recognize that the scope of PFAS use and the resulting impact of proposed restrictions extend far beyond the Pharmaceutical and Healthcare industries. It is crucial to consider the substantial impact on raw materials (from ground to supply) which are integral to the biopharma industry. These stages significantly influence the sustainability of the supply chain, necessitating a comprehensive understanding and visibility of the larger supply chain. Ensuring the integrity and availability of these materials is vital for maintaining the continuity and efficiency of biopharma operations, as well as for achieving broader sustainability goals.

The supply chain stages involve the production and procurement of precursor materials that are essential for the manufacturing processes in biopharma. Any disruption or restriction in the availability of these materials can lead to significant delays, increased costs, or at its most severe ability supply lifesaving medicines. This impacts the overall efficiency and reliability of the supply chain. Therefore, it is imperative to have a robust strategy in place to manage these materials, ensuring that there is minimal disruption and that the supply chain remains resilient.

The visibility of the larger supply chain is crucial for identifying potential risks and vulnerabilities that could affect the availability of raw materials. If biomanufacturers and suppliers were required to map the entire PFAS supply chain, from extraction /chemical companies to end users, the complexity may require significant derogation to be completed. Even if a supplier is granted a derogation and exception for the BioPharma industry, it may still be uneconomical to support or supply the material in small quantities once the primary use has been discontinued. Without identified and approved alternatives, this could pose a significant risk to the biopharma sector.

Even if our industry is given an exception, if the supply chain is destabilized, we may not have any materials to use anyway. By having a clear understanding of the entire supply chain, from the initial stages of raw material processing to the final stages of product delivery, companies can better anticipate and mitigate any potential issues. This holistic approach not only supports the sustainability of the biopharma industry but also aligns with broader

environmental and regulatory goals aimed at reducing the impact of PFAS and other harmful substances.

7. Conclusion:

The BioPhorum collaboration, representing suppliers and end users of PFAS materials within the biopharmaceutical industry, underscores the critical need for full exemptions or time-unlimited derogations for essential PFAS materials. These materials are indispensable for the safe and effective delivery of medicines, as well as for various manufacturing, quality control, and supply chain processes.

The document highlights the extensive use of PFAS in biopharmaceutical manufacturing due to their unique properties, which are not easily replicated by alternative materials. The potential restrictions on PFAS pose significant risks to the continuity of drug supply, patient safety, and the overall sustainability of the biopharma supply chain. The industry faces substantial challenges in identifying, validating, and implementing suitable alternatives, which could take decades to achieve.

The socio-economic implications of PFAS restrictions are profound, with potential disruptions to the global supply chain, increased costs, and delays in drug development and approval processes. The biopharma industry requires regulatory flexibility and collaboration with stakeholders to navigate these challenges effectively. Continuous research and development are essential to discover viable alternatives that do not compromise the quality, safety, and efficacy of pharmaceutical products.

In conclusion, the BioPhorum collaboration advocates for a balanced approach that considers both environmental concerns and the critical need to maintain the supply of life-saving medicines. By working together, industry stakeholders, regulatory bodies, and government agencies can develop practical and protective strategies to manage PFAS-related challenges, ensuring the sustainability and resilience of the biopharma industry.

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Appendix 1 ECHA Annex XV response

The response below pertains to the ECHA Annex XV submission (5) (6) which along with information in the body of the document was included as part of the formal process.

While the ECHA Annex XV report includes consideration of the use of various PFAS in medical devices and some limited pharmaceutical applications, the BioPharma industry has not been specifically considered as a sector in the framework of the current proposal (refer to Figure 2 Table A.1 from the Annex XV report) and needs to be appropriately evaluated due to the considerable impact the proposal will have on our ability to supply safe and effective therapies to patients suffering from life threatening/debilitating illnesses.

Figure 2 Table A.1 from the Annex XV report

Table A.1. Overview of PFAS applications and the level at which they were researched.

PFAS applications			
PFAS manufacture	Textile, upholstery, leather, apparel and carpets (TULAC)	Food contact materials and packaging	Metal plating and manufacture of metal products
Consumer mixtures	Cosmetics	Ski wax	Applications of fluorinated gases
Medical devices	Transport	Electronics and semiconductors	Energy sector
Construction products	Lubricants	Petroleum and mining	Waste stage PFAS applications
Laboratory equipment & filtration	Plant protection products and biocides	Chemical industry	Firefighting foam
Medicinal products	Plastics (other than packaging) and rubber/elastomer production (including flame retardants)	Pyrotechnics	Personal care products other than cosmetics
Fracking (currently hardly applicable in EEA)	Immersion cooling (currently hardly applicable in EEA)	Defence industry	Printing inks
Cement industry	Professional cleaning and polishing	Other niche applications	Uses (yet) unknown

- Green uses are researched in detail
- Blue uses are researched in general
- Orange uses not researched in detail
- Purple use: Separate restriction proposal

A significant proportion of that revenue is generated in Europe (**USD 48.19 billion** in 2022[2]) with the European Biopharmaceuticals market estimated to be growing at a CAGR of 8.89% to reach USD 73.78 billion by 2027 (7) (8).

While the proposed restriction is intended for enforcement in the EU which will directly affect companies who manufacture and sell their products in that region, it will also have significant and wide-reaching impact on the export of drugs manufactured in the EU and supplied to the rest of the world, on global industries supplying materials to drug manufacturing facilities in Europe and to companies who import and sell their products into the European market.

Significant investment has been made to build and resource state of the art drug manufacturing facilities; an inability to manufacture product due to unavailability of PFAS materials would result in movement out of the regions affected with potential closure of the facilities and

resultant impact on the people, workforces (according to a European Commission report in 2019 the biopharma industry employs 2.4 million people (9) however this does not take in to account all suppliers and their suppliers across the supply chain) and revenues currently generated in the region with irreversible damage to the economy. The restriction on importing or placing on the market of both direct and indirect materials will impact the entire global supply chain and has the potential to shut down BioPharma manufacturing in Europe and the supply of critical drugs to patients within a very short timeframe. In time, this could lead to organizations outsourcing/relocating their manufacturing activities to locations without PFAS restrictions and impede plans for future investment in the EU with significant detrimental socioeconomic impact.

Below is our collaboration's response to the request from ECHA for more information on Missing uses – Analysis of alternatives and socio-economic analysis (Q6):

a. ***The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use.***

With a multi-tier, complex supply chain that is nearly impossible to evaluate and quantify, any number we could suggest would be an estimate.

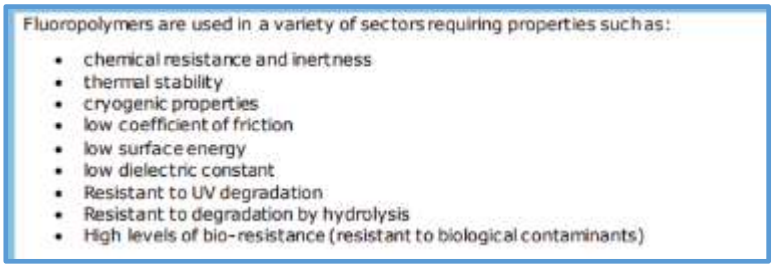
PFAS usage by the biopharma industry and subsequently their suppliers make a miniscule contribution to the total annual usage and emissions from other industries (around 45 million tonnes of PFAS is supplied to the EU market annually with a global figure likely to be at least 3 times this), the impact of a ban on our industry is disproportionate to the risk and would be very detrimental to the patient population as well as the European BioPharma manufacturers and suppliers.

Sector-based estimates, shared by the BioProcess Systems Alliance (BPSA), indicate that the single-use biotech/biopharma industry accounts for approximately 0.1% of PTFE production and 0.5% of PVDF production.

b. ***The key functionalities provided by PFAS for the relevant use.***

PFAS materials have been selected for use in the BioPharma industry for their core properties, some of which are listed in Annex A of the restriction report (refer Figure 3: Fluoropolymers sector uses copied from the report): inertness, chemical resistance, oleo- and hydro-phobicity, cleanliness, lack of chemical interaction with drug products, lubricant, and heat resistance/cryogenic properties etc.

Figure 3: Fluoropolymers sector uses



All these unique properties of PFAS provide key functionality in assuring integrity of drug product quality in the multiple applications they are used in across the end-to-end manufacture and supply of drugs. This includes ensuring quality of production

processes, assurance of sterility and stability throughout product shelf life, axenicity and safe delivery/dosage to the patient.

c. *The number of companies in the sector estimated to be affected by the restriction.*

100% of the approximately 830 BioPharma manufacturers in Europe, their global suppliers (and in turn their intermediate material suppliers) including 3rd party testing and validation service providers would be impacted across the complex and multi-tiered supply chain. This supply chain has yet to fully recover from the pandemic shortages.

Additionally, where alternatives to PFAS are available, any changes to drugs manufactured in Europe which are filed and distributed in Europe and/or in regions beyond must be submitted for approval to the European Medicines Agency and other global regulatory authorities; this is required to maintain license to operate and market authorisation. The volume of changes requiring review and approval resulting from the proposed restrictions will out-pace capacity of the authorities and put the supply of critical therapies at risk with drug stock-out situations becoming a reality.

The exact number of companies impacted is extremely difficult to quantify due to the complexity of the supply chain however there are at least 830 BioPharma companies with facilities in Europe alone. Every biologic drug currently licensed for sale in Europe and those in development but not yet licensed will be manufactured and packaged using PFAS materials somewhere in the process and will be impacted by these restrictions.

If drug manufacturing is moved out of the region to other geographies which do permit the use of PFAS, availability of these drugs may be impacted; an example of this is the current challenge in accessing some antibiotics in certain member states of the EU due to sourcing outside of the region. Movement to other less well-regulated regions where raw material quality is lower and regulatory compliance is less regulated may also impact drug quality resulting in a risk to patients. Any such external manufacturing locations will still require significant time to secure the appropriate licensing (as indicated for the case where alternatives exist).

d. *The availability, technical and economic feasibility, hazards, and risks of alternates for the relevant use, including information on the extent (in terms of market shares) to which alternative-based products are already offered on the EU market and whether any shortages in the supply of relevant alternatives are expected.*

The proposed timeline for consultation and implementation of the restrictions, if the proposal is accepted, has not permitted the biopharma industry sufficient time to fully identify, qualify and implement suitable non-PFAS alternatives for all applications. In this highly regulated industry sufficient time is required to perform several activities when making changes to the manufacturing process of drugs currently licensed for sale:

1. Research & development of potential alternatives with functional equivalence by the suppliers.
2. Perform development work to demonstrate “equivalence” of the products (characterization) to demonstrate **suitability** and **safety** of the materials in the specific biopharmaceutical processes. Note: a functionally equivalent product is not necessarily suitable in all end user applications.

3. **Validate** the biopharmaceutical product manufacturing process. One critical application of PFAS is in the filtration of drug intermediates to ensure sterility of final drug product using e.g., fluoropolymer (Polyvinylidene fluoride, PVDF) filter membranes. Factors such as different drug adsorption to different membrane materials can significantly affect yield and quality, and therefore availability of and cost to manufacture drugs. Exposure to solvents, surfactants and chemical mixtures throughout the drug manufacturing, packaging, and storage process (which will be specific to each drug) will have variable impact on the stability and durability of the materials and may result in leaching of substances during the manufacturing processes which pose a risk to patient safety if not fully tested and validated. Significant effort has been made during drug development to demonstrate that all materials currently used are safe and non-toxic for patients, switching to new non-PFAS materials would require significant time and cost investment to ensure no new risks are introduced. Currently, there are few (if any) alternatives to PFAS that encapsulate the required chemical and physical properties to fully emulate the performance of the components currently in use.
4. Generate stability data for the drug substance/product for its required shelf-life – this is a critical rate limiting step and will vary from product to product.
5. Update product licences for review and approval by regulatory authorities in every country that the product is marketed in (likely 3-6 years after time taken to complete steps 1-4). This is also a critical, rate limiting step-

   Regulatory authorities are likely to be overwhelmed by applications for license updates therefore the time required to complete this step is currently unknown and entirely unpredictable; every drug manufacturer globally is likely to be submitting additional license updates (1:1 submission for every biologic drug currently licensed for sale in the EU market). This will be applicable to licenses held for drug substance and drug product, without an exemption or at least an appropriate derogation this restriction will cause drug shortages in countries where the alternative material has not yet been approved.

   Note: This does not account for drugs currently being developed and not yet licensed. Therefore, availability of new drugs will also be critically impacted by the proposed restrictions. Nor does it reflect the severe disruptions placed on supply chains that would be observed during any future pandemic situation; the BioPharma supply chain is still recovering from the impact of Covid and has not yet established pre-Covid stability.

Even if the industry were granted the current maximum derogation of 12 years (plus 18-month transition) there is no guarantee that alternatives could be sourced, tested, and approved in that timeframe; if PFAS materials are removed from the supply chain while alternatives (where they are available) are being sourced there is a significant risk of interruption to the supply of critical drugs.

Mapping of PFAS use applications across the biopharma value chain (both direct and indirect uses) and indication of known, available alternatives is described in Table 1: PFAS Applications in BioPharma (non-exhaustive list). Note: this information was prepared in collaboration with Bio-Process Solutions Alliance (BPSA).

We must also be cognisant of another dimension to finding alternatives to PFAS, they have been chosen in drug manufacturing processes because of their unique properties provided by their chemical composition and there is a risk of regrettable substitution i.e., replacing PFAS components with alternative materials which have properties that may impact the quality of the drug.

e. For cases in which alternatives are not yet available, information on the status of R&D processes for finding suitable alternatives, including the extent of R&D initiatives in terms of time and/or financial investments, the likelihood of successful completion, the time expected to be required for substitution (including any relevant certification or regulatory approvals) and the major challenges encountered with alternatives which were considered but subsequently discarded.

The sourcing of and switching to non-PFAS alternatives needs to be considered from four critical perspectives- the design and manufacture of novel chemistries, adoption into plastic resin and intermediate articles, incorporation into Bioproduction equipment and processes including qualification and validation of the alternative material in its specific application (including safety evaluation to protect the ultimate user, the patient) and finally the regulatory review and approvals.

For suppliers to develop non-PFAS alternatives (if alternatives can be identified and developed), it will take up to or possibly more than 20 years of Research & Development followed by 2-3 years of validations to get to commercial availability for use in biopharmaceutical processes. However this is just the start of the substitution journey for biopharmaceutical end users who must then complete their own evaluation and validation in every application plus submit any changes under regulatory filings and await approval before implementation post-approval of the impacted licenses (refer to point d).

Drug product packaging such as PFAS lined closures for glass vials/syringes and vial stoppers (drug delivery systems) are likely the most difficult materials to change due to the lack of suitable alternatives in this application. The manufacturers of certain primary drug product packaging systems have failed to identify any viable alternatives. Fluoropolymers (such as ETFE) laminates on rubber closures provides the best protection to sensitive drugs and no suitable alternatives have been identified or become commercially available over the last 20 years.

Vent and gas filtration in equipment requiring in-place steaming/sterilization is performed using PVDF/PTFE based filters for which no robust alternatives were developed over the last 20 years either. The fluoropolymer membranes exhibit unique characteristics providing resistance to the chemical and thermal environment that other membranes could not so far sustainably provide. No PFAS free alternatives for membranes used in venting and gas-filtration applications are available today. Restrictions in the availability of PFAS based air- and vent filters would result in an inability to manufacture biopharmaceutical drug products.

Alternatives with the necessary specific properties that PFAS fulfil in drug packaging applications (such as high purity solvent resistance), are not currently available.

f. For cases in which substitution is technically and economically feasible but more time is required to substitute:

The biggest risk is the time required to a) develop alternatives, b) test alternatives and then c) obtain regulatory approval to switch to new materials in every single country where each product is marketed (refer to point d above). This process will take several years (easily beyond 20 years) for each change and each product under consideration. Without a sufficiently long derogation for the industry and the health authorities to adapt (beyond 20 years), this legislation could cause drug shortages in countries where the new material has not yet been approved.

For drug manufacturing processes which utilise PFAS at multiple stages and in multiple applications across the end-to-end value chain (essentially all drug manufacturing processes) there are two possible scenarios:

1. Best Case: every component part or ingredient which contains PFAS has an alternative which can be "dragged and dropped" into the process and where comparability studies show that the substitution does not impact product quality and Regulatory Authorities have no additional barriers to change.

2. Worst Case: any or all identified alternatives fail the comparability studies and cannot be substituted thus requiring continued use of the current PFAS material- if PFAS is removed from the market under the current proposal the ability to manufacture that drug would be at significant risk.
   There is no regulatory alignment with the change and every asset needs to be approved (essentially the process detailed above would be multiplied by the number of drugs and countries impacted).

   In both cases the exercise in completing the required studies will require significant investment in resource, materials and time and would be required for every drug manufactured by each company in both development efforts and in commercial production. If critical resources are diverted to address the multiple changes resulting from a ban this will compete for vital and limited R&D resources, thus delaying introduction of new life saving technology and therapeutics.

   A specific example of substitution requiring more time is for viral filters used in recombinant therapeutic protein purification processes, where demonstration of viral retention must be executed today for each process/product synthesised in mammalian/insect cell lines and be conducted in facilities that are accredited for virus manipulation. The availability of such facilities is low and conducting an industry wide change of viral filtration technology will result in a huge bottleneck and delay of the availability of support data to submit to regulatory authorities.

   The supply and qualification of the fluoropolymer materials currently used in the biopharma industry has been evolving over the last 30 years to fully support their safe and effective use in drug manufacture, it is not inconceivable that finding and transitioning to alternatives (if they can be found and safely and sustainably produced) could take another 30 years.

i. The type and magnitude of costs (at company level and, if available, at sector level) associated with substitution (e.g., costs for new equipment or changes in operating costs).

For pharma/biotech manufacturers, the biggest impact is the time, cost and (human) resources required to a) test alternatives and then b) obtain regulatory approval to switch to new materials in every single country where each product is marketed. This process can take several years for each change and product under consideration.

When determining the cost of substituting PFAS materials with alternatives there are multiple factors to consider: the time and resource for research and development, qualification and validation of their use in existing manufacturing processes (studies which may ultimately fail and require sourcing and testing of another alternative), the capacity of 3rd party test labs to evaluate extractables and leachables of the alternatives and which could quickly become a bottleneck at industry level, the resource required within health authorities to review and approve changes (again this is not a guaranteed process and may result in

rejection of changes). This applies to all impacted drugs and registrations around the globe which would result in additional burden on resources at suppliers, biomanufacturer and regulatory authorities to complete all required activities. In the proposal there is no derogation for the Biopharma industry, and we would be subject to an immediate ban.

A key consideration is also the capacity of the suppliers to support increased demand for the alternative materials, there are currently still some supply issues with existing materials following a rapid increase in demand during Covid, is the supply chain in place and robust enough to support new demand for new materials?

The cost of completing all the above noted points is anticipated to be vastly disproportionate to the impact of the small quantity of stable fluoropolymers sent for incineration (consumable parts) or retained as components of long-life instrumentation. It is difficult to estimate due to the complex, multi-tier supply chain and the requirement for regulatory scrutiny of changes within our highly regulated industry.

ii. The time required for completing the substitution process (including any relevant certification or regulatory approvals).

In the best-case scenario where an alternative is known, it is functionally equivalent and commercially available, requiring only process validation by the drug manufacturer and assessment and approval by regulatory authorities – estimated 5-8 years.

In the worst-case scenario-a full cycle of material identification and functionality assessment at the supplier, process validation in specific processes and assessment and approval by regulatory authorities- will take an estimated 20+ years. A non-exhaustive summary of key steps and timelines for finding and approving alternatives is described in Table 2: Anticipated steps for substitution if alternatives are available.

Table 2: Anticipated steps for substitution if alternatives are available.

Step	Activity	Estimated Timeline
Develop a new, suitable disposable	Selection of small scale for small scale studies	Min 6 months
Establish new disposable in GMP environment	Change request, inventory system update, review of certificates & documents, ordering, initial E&L assessment. Development of release testing method	1-2 months 2-6 months
Ordering of GMP/full scale	Procurement, supplier lead time	3-12 months
Release of disposable	Certificate/document check Release testing	Up to 3 months
Supplier/Manufacturer Qualification	Staged concept, Audit	6 months
Validation (late phase/commercial)	Validation in several batches (compatibility, functionality…), process validation (if required), comparability exercise for resulting DS/DP (release testing, stability studies…), Leachable studies	6-12 months + stability (multiple years)
Regulatory filing of changes / Amendments/Approvals	Update of TRDs, submission to relevant Health Authorities, approval by Health Authorities	Multiple Years

iii. Information on possible differences in functionality and the consequences for downstream users and consumers (e.g., estimations of expected early replacement needs or expected additional energy consumption).

In many cases, alternative materials may be available however the alternatives may be suitable/applicable for some applications but not others.

Consequences of substitution of PFAS components are increased extractable risk for the patient and may include reduced stability of biopharmaceuticals and other unforeseen consequences.

Reduction in microbial/bacterial contamination of drugs is a critical step in assuring product and therefore patient safety, and biologic drugs are typically sterilized by filtration using membranes commonly constructed from the fluoropolymer PVDF. The membrane material is highly durable, and the drug does not adsorb to the surface; alternative non-PFAS materials are constructed from cellulose acetate (CA), Nylon and polyether sulphone (PES), which constitute different limitations e.g. PES is also highly durable but shows higher adsorption for certain drugs and constituents such as excipients and surfactants in the drug formulation which could impact stability of the medicine. Switching

to alternatives could result in lower product yield thereby increasing production costs and reducing availability of the drug on the market.

iv. Information on the benefits for alternative providers.

On the basis that our industry has not identified suitable alternatives in most of the applications no further comment is appropriate.

g. For cases in which substitution is not technically or economically feasible, information on what the socio-economic impacts would be for companies, consumers, and other affected actors. If available, please provide the annual value of EU sales and profits of the relevant sector, and employment numbers for the sector.

The European Biopharmaceuticals Market is projected at USD 48.19 billion in 2022 and estimated to be growing at a CAGR of 8.89%, to reach USD 73.78 billion by 2027 (9).

As detailed in the response above there are many applications of PFAS across the Biopharma industry where no technically suitable alternatives exist; if alternatives do exist there is a risk that the time required to qualify and approve those alternatives would exceed any maximum derogation period currently proposed by ECHA.

Removal of the impacted drugs from the market (either to allow for qualification and approval where alternatives exist or complete removal when no alternatives with comparable performance attributes are available) would result in significant economic impact to the global manufacturers of these drugs and their suppliers resulting in facility closure, loss of employment and reduced revenue in Europe. Those organizations with alternate manufacturing provisions outside the EU would likely move manufacturing to that region with detrimental impact on future investment within the EU and potentially delaying the supply of therapies (including those in development) due to lack of capacity in the alternative facilities.

It is also important to note that the non-EEA production capacity would not be able to cope with the current EEA demand. There is negligible readily available production capacity at biotechnology manufacturing facilities outside of EU-27. If global capacity is not available, shortages in life saving and life prolonging medicines would become a realistic possibility.

Indeed, the most critical impact would be to the patients who would have no access to current and developing lifesaving and life prolonging therapies resulting in needless suffering and potential mortality.

Appendix 2: BioPhorum Response to request for identification of Currently Unavoidable Use (CUU) of PFAS by the US State of Maine Department of Environmental Protection

The response below pertains to the Request for identification of Currently Unavoidable Use (CUU) of PFAS by the US State of Maine Department of Environmental Protection (10) which along with information in the body of the document was included as part of the formal process.

Executive Summary

This response has been prepared by a collaboration of BioPhorum members in response to requests to facilitate identification of Currently Unavoidable Uses (CUU) of PFAS.

- The contents of this document and response are intended to identify, and provide context and rationale for, a non-exhaustive list of Currently Unavoidable Uses (CUU) of PFAS in the manufacture and supply of biopharmaceutical drugs plus the drug product delivery devices necessary for the dosing of these medicines. **The identified CUU of PFAS, the vast majority of which are non-hazardous fluoropolymers, are listed in**
-
- Table 3: PFAS Applications in Biopharmaceutical Manufacture, Supply, and delivery/dosage (a non exhaustive list) which includes the brick codes and Harmonized Tariff System (HTS) codes where known. Currently there are no viable alternatives that can be readily substituted for these identified CUU.

Further technical information is detailed in the main document.

- Biopharmaceutical drugs (biologics) are not themselves typically classed as PFAS however we acknowledge that prescription drug products (chemical Active Pharmaceutical Ingredients or small molecules) that have been classified as PFAS by the State will not have a comparable substitute, as removing the fluorinated carbon will alter the chemistry in a manner that will create a new substance with unknown properties for treating the intended medical condition, or the safety of the substance and is therefore essential for health, safety or the functioning of society.
- The State of Maine has defined a PFAS substance to include any member of the class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom. This definition includes medications. Any PFAS that is designated a pharmaceutical product should be considered as essential for the health of society. Medical devices used for the delivery of medications have already been identified to

be “Essential for health, safety or the functioning of society.” This is key as precise medication delivery would not be possible without such delivery devices.

- Medical Devices for the delivery of medicines has been defined as “Essential” by the State of Maine, and are essential for the health, safety and functioning of society; however, the medicines that are considered PFAS by the State definition of PFAS were not listed under this description. Medications considered to be PFAS by the State and the manufacturing of these medications should also be considered “Essential”. It was reported that approximately 68% (11) of US adults over the age of 18 were prescribed a medication in 2022.

- Removal of PFAS from the dose delivery devices that are used to administer biological medicines may cause them to become contaminated and/or alter the performance or have another detrimental impact on the quality of the medicine being administered.

Further comments in this submission are written from the perspective of manufacture and supply of drug and combination drug dosing devices manufactured using biopharmaceutical methods only (the biopharmaceutical sector) and do not include information related to any medicines or other medical devices currently included in PFAS definitions.

The Brick codes and Harmonized Tariff System Code classifications may not adequately identify all impacted products and it is **therefore recommended that all PFAS used in the manufacture and supply of biopharmaceuticals and associated medical and dosing devices approved by the US Food and Drug Administration be considered “Currently Unavoidable Uses” and “essential for the health safety and functioning of society”**. This should be also applied to medical and dosing devices and pharmaceutical products currently in development and clinical trials.

Brick and Harmonized Tariff Codes

Each of the PFAS containing components listed in

Table 3: PFAS Applications in Biopharmaceutical Manufacture, Supply, and delivery/dosage (a non exhaustive list) are used in the manufacture, supply, and dosage/delivery of our sector’s overall “products” i.e. pharmaceutical drugs (identified as Brick code 10005845) and medical devices (Brick code 10005845) however it has not been possible to identify an appropriate GPC/Brick code for each of the components listed. Harmonized Tariff System (HTS) codes have therefore been provided for the PFAS materials used in the manufacture and supply of biopharmaceuticals/medical devices where they are known.

A PFAS containing component can be present in a product that is placed on the market in multiple different ways due to the complexity of the products they are used in. For example, an FKM based O-Ring could be imported as a stand-alone spare part or accessory, in a complex item used as a replacement part in a pump, in a pump itself, in a hardware system containing a pump or in a larger installation containing a hardware system. This level of complexity in the ways these materials may be placed on the market makes it impossible to provide an exhaustive list of potential GPC or tariff codes impacted.

PFAS that are Essential to the Biopharmaceutical Industry

Today, 50% of the top 100 drugs sold globally are biopharmaceuticals, with predications that this will increase to 55% of all innovative drug sales by 2027 (12), and the industry generates global annual revenues of USD 163 billion.

100% of the biopharmaceutical products currently being developed or already licensed for sale in the US utilize CUU PFAS somewhere in the development, manufacture, testing, storage of intermediates, drug substance or drug product or in the drug delivery systems. If PFAS used in these processes are not classified as CUU and thus banned, these drugs would be removed from the market until PFAS alternatives (if they exist) could be developed, sourced, validated, and approved for use, thus preventing access to life saving therapies.

It would also limit the ability to develop new drug therapies since PFAS materials are also utilized directly and indirectly in drug discovery & preclinical development. For medicines which are still under patent or are orphan drugs there are no alternative drugs available for use if their production is prevented due to PFAS restrictions.

The biopharmaceutical industry is required by US Federal Food and Drug Administration to follow Good Manufacturing Practices (GMP) to use materials that are not reactive or additive to our product streams. Specific PFAS materials (PVDF, PTFE, FKM, FPM, FEP*, etc.) are preferred as they are proven to present negligible reactive properties. They are particularly beneficial in terms of not adding anything unintentional to medicinal products during drug substance or drug product manufacturing processes (i.e., they best meet the GMP requirements of being non-additive or reactive with the medicine – per 21 CFR 211.65).

It should be noted that the **BioPharma Industry acts as downstream users of PFAS materials and does not own the technical solution outside of end-application qualification.**

*PVDF (Polyvinylidene fluoride), PTFE (Polytetrafluoroethylene), FKM (Fluoroelastomer Polymer), FPM (perfluoro elastomers), FEP (fluorinated ethylene propylene), ETFE (ethylene tetrafluoroethylene)

Any PFAS materials utilized in biopharma manufacturing processes and by healthcare providers are disposed of at end-of-life by thermal oxidation and do not, therefore persist in the environment.

Table 3: PFAS Applications in Biopharmaceutical Manufacture, Supply, and delivery/dosage (a non exhaustive list)

			Industry Application (final product brick reference)						US Harmonized tariff code for PFAS material/component where known Note: products may also be included as part of more complex items, see product type explanation in document
Product containing PFAS / Application	PFAS Type	Function of product	Manufacture of Pharmaceutical drug (10005845)	Manufacture of combination product pharmaceutical drug (10005845) plus medical device (10005844)	Potential Alternatives	Feasibility of replacement	Cost to replace	Patient safety/drug quality impact risk	
Sterile Liquid filtration membranes	PVDF	Ensures patient safety, ensures sterility of final product and safety of patient during drug delivery	x		(PES Nylon Cellulose)	50%	Very high	High	8421990180
	PTFE			x	PES Nylon	<10%	Very high	High	
Liquid filtration- virus clearance	PVDF	Ensures patient safety - removal of viral contaminants from drug product	x		PES	80%	Extremely high	Moderate	8421990180
Films/plastics as primary contact material in manufacture and containment of drug intermediates (drug substance). • Containers/films/bottles • Single use processing bags • Single Use bioreactors • Probes/inserts	PVDF	Protects and maintains stability and quality of drug intermediates e.g. prevents contamination from bioburden/endotoxin/pyrogens.	x		†	TBD	TBD	TBD	3921190000
	PTFE bags/bottles			x					
	FEP bags/bottles			x					
Biopharma drug cryostorage bags and cell culture cryostorage bags and bottles	PTFE	Protects and maintains stability of drug intermediates	x		ULDPE, EVA or EVA blends	<30%*	High	High	3921190000
	FEP								
	custom fluoropolymer								

† Further assessment required; alternatives may be application specific; substitution with a particular non-PFAS material may not be suitable for all applications

Colour coding indicates where the same PFAS materials are used across multiple applications.

Table 3 PFAS Applications in Biopharmaceutical Manufacture, Supply, and delivery/dosage (a non exhaustive list) cont.

			Industry Application (final product brick reference)						US Harmonized tariff code for PFAS material/component where known Note: products may also be included as part of more complex items, see product type explanation in document
Product containing PFAS / Application	PFAS Type	Function of product	Manufacture of Pharmaceutical drug (10005845)	Manufacture of combination product pharmaceutical drug (10005845) plus medical device (10005844)	Potential Alternatives	Feasibility of replacement	Cost to replace	Patient safety/drug quality impact risk	
Films/plastics (Primary contact material) for final drug product sterile packaging: • cap or stopper coatings/liners • Vial stoppers • Syringe stoppers • Seal linings	ETFE (cap or stopper coatings/liners) PTFE (coating for vial and syringe stoppers and seal linings)	Ensures patient safety, maintains sterility and stability of final drug products		x	No alternatives for drug product requiring barrier coating	0	n/a	High	3921190000
Films/plastics (Primary contact material) for final drug product non-sterile packaging- multi layer blister packs intended for final solid oral dosage.	PCTFE	Ensures patient safety, protects stability and quality of final drug products	x		Suggested alternatives have been proposed but they do not confer sufficient protection	<5%	High	High	3921190000
Intermediate, raw material or ancillary material used in manufacture, purification and testing of protein based drugs	TFA (tri-fluoroacetic acid) or PFAS related compounds	Used in manufacture, purification and testing of protein based drugs	x		No alternatives	0	N/A	High	2915905050 2915901050 29159050 2915901800
Vent and/or Gas Filtration (of bioreactors/carboys) - filter membranes	PVDF	Maintains axenic boundary - prevents microbial contamination of bioreactor	x		No alternatives	<5%	Moderate	Moderate	8421290065
	PTFE				No alternatives	<5%	N/A	Moderate	

† Further assessment required; alternatives may be application specific; substitution with a particular non-PFAS material may not be suitable for all applications

Table 3 PFAS Applications in Biopharmaceutical Manufacture, Supply, and delivery/dosage (a non exhaustive list) cont.

			Industry Application (final product brick reference)						US Harmonized tariff code for PFAS material/component where known Note: products may also be included as part of more complex items, see product type explanation in document
Product containing PFAS / Application	PFAS Type	Function of product	Manufacture of Pharmaceutical drug (10005845)	Manufacture of combination product pharmaceutical drug (10005845) plus medical device (10005844)	Potential Alternatives	Feasibility of replacement	Cost to replace	Patient safety/drug quality impact risk	
Tubing & tube fittings (manufacturing engineering systems and transfer of drug material intermediates and final product, lab testing applications) incl gaskets & O-rings, sensors	PVDF (tubing)	Protection of drug intermediates and personnel during manufacturing process. Inert materials prevent chemical contamination of drug during manufacture and drug delivery to patient..		x	No alternatives	<5%	N/A	High	3917330000 3926904510
	PVDF (Fittings)				Polycarbonate, polypropylene, polysulfone	<5%	Moderate	High	
	PTFE				No PFAS free alternatives	<5%	N/A	High	
	FKM (tubing/O-rings / gaskets)								
	FEP								
	PFA								
	PTFA								
Hardware systems (lined pipes, TFF cassette seals/components/solvent exchange systems/lined valves/gaskets). Pumps & components (diaphragm)	PVDF	Protection of drug intermediates and personnel during manufacturing process. Inert materials prevent chemical contamination of drug during manufacture	x		No alternatives	<5%	n/a	High	8413500050 8421990180 9027905650
	PTFE								
	FKM								
Ultra low temperature refrigerant (low boiling temp gases <-60°C) for freezing drug intermediates or final product.	multiple PFAS	Provide required temperature for long term storage of intermediates, drug substance and drug products	x		CO_2 : however energy consumption by alternatives is increased by 50%	100% but with energy pay-offs	High	N/A	2705000000
Laboratory Apparatus (funnels, flasks/containers, stirring bars etc)	FEP	Utilized in preparation of small scale solutions to be added to process stream	x		Glass for some applications (compatibility dependant) but increased safety risks due to breakage.	<5%	TBD	TBD	9027905650
	PTFE								
Heat and/or chemical resistant, non reactive coatings/insulation/lubricants used e.g. as components of electronics and stainless steel vessels/skids.	Additive of PFAS origin	Utilized as components of electronics and stainless steel vessels and skids.		x	†	†	†	†	8413500050 9027905650

† Further assessment required; alternatives may be application specific; substitution with a particular non-PFAS material may not be suitable for all applications

Appendix 3 BioPhorum response to commentary on planned new rules governing determinations of currently unavoidable uses (CUU) of PFAS by the US State of Minnesota Pollution Control Agency.

The response below pertains to the Request for commentary on planned new rules governing determinations of currently unavoidable uses (CUU) of PFAS by the US State of Minnesota Pollution Control Agency (13) which along with information in the body of the document was included as part of the formal process submission.

This document has been prepared by a collaboration of BioPhorum members who appreciate the opportunity to respond to questions 1-9 below as requested by the Minnesota Pollution Control Agency.

BioPhorum is a global biopharmaceutical manufacturing industry collaboration comprising all major manufacturers and their key suppliers (over 150+ companies, representing > 98% of all biopharmaceuticals manufactured worldwide).

The Biopharmaceutical industry, represented here by BioPhorum, acknowledge the concerns raised regarding the potential adverse effects of various per- and polyfluoroalkyl substances (PFAS) materials on human health and the environment, and fully support efforts to minimise and mitigate the presence of these, and other potential substances of concern in our manufacturing processes and products. Our industry sector shares a responsibility to work with all relevant stakeholders to manage the transition away from materials of concern while maintaining our ability to ensure the safety and wellbeing of patients and the communities in which we operate. Any efforts to restrict usage and production of materials of concern by our industry must be pragmatically considered; the risk of drug shortages and therefore failure to supply medicines to patients must be evaluated against the risk the materials pose to the environment and to that very same population.

Biopharmaceutical drugs (biologics), a subsector of the pharmaceutical industry, include therapies such as monoclonal antibodies, antibody drug conjugates, therapeutic proteins, cell and gene therapies, mRNA and vaccines which treat a wide range of disease indications including immunology, neurology, infectious diseases, diabetes, oncology, cardiovascular conditions, and others. Advancements in biomedical science hold vast potential for growth of the biopharmaceutical market and the ability of these drugs to treat chronic diseases that were previously untreatable is increasing biologics demand enormously with newer therapies under development increasingly being in the biopharmaceutical category.

Today, 50% of the top 100 drugs sold globally are biopharmaceuticals, with predications that this will increase to 55% of all innovative drug sales by 2027 (12) , and the industry generates global annual revenues of USD 163 billion.

While this specific response is focussed on the biopharmaceutical sector, BioPhorum and its member companies recognise that the scope of PFAS use and resulting impact of proposed restrictions on other industries is far wider across the Pharmaceutical and Healthcare

industries and beyond. It should also be noted that while this submission on unavoidable uses has been prepared in response to the State of Minnesota, any restrictions on the use of PFAS within the biopharmaceutical industry will impact the supply of drugs to the whole of the US (and rest of world).

1. **Should criteria be defined for "essential for health, safety, or the functioning of society"? If so, what should those criteria be?**

   In the case of regulating PFAS as a broadly defined group of substances, the specific hazards, if any, for an individual substance are unknown; therefore, defining criteria for "essential for health, safety, or functioning of society" requires multiple risk-based analyses, a complex task.

   The reasoning is that the hazard profile of an individual PFAS substance by itself may differ from the hazards associated with use of that PFAS substance by a downstream user in a specific medicinal application.

   Any PFAS use required for manufacture, packaging and safe delivery of medicines or medicinal product to patients should be considered **essential for health, safety, or the functioning of society.**

2. **Should costs of PFAS alternatives be considered in the definition of "reasonably available"? What is a "reasonable" cost threshold?**

   If costs are considered in this context, then consider the full scope of activities that drive monetary costs. For example, consider monetary and economic constraints such as time to substitute (feasibility, product performance, and implementation), raw material availability, logistics, regulatory authority approvals, etc.

   The costs of any substitution, where feasible, are currently unknown but will be significant. Timelines from concept through to final qualification and regulatory approval of alternatives is likely to take a minimum of 20 years.

3. **Should unique considerations be made for small businesses with regards to economic feasibility?**

   Considerations regarding small businesses should include the ability to support niche markets that a supply chain may be dependent upon. Small businesses may not have adequate resources to drive innovation in the Research and Development space and to qualify alternatives.

4. **What criteria should be used to determine the safety of potential PFAS alternatives?**

   The biopharmaceutical industry is required by US Federal Food and Drug Administration to follow Good Manufacturing Practices (GMP) to use materials that are not reactive or additive to our product streams and assure patient safety. The specific PFAS materials utilized by our sector are non-hazardous fluoropolymers (PVDF, PTFE, FKM, FPM, FEP*, etc.) and are proven to present negligible reactive properties. They are particularly beneficial in terms of not adding anything unintentional to medicinal products during drug substance or drug product manufacturing processes (i.e., they best meet the GMP requirements of being non-additive or reactive with the medicine – per 21 CFR 211.65). With any change to materials there is a risk of regrettable substitution (i.e., replacing PFAS

components with alternative materials which have properties that have unintended detrimental impact to the quality of the drug).

*PVDF (Polyvinylidene fluoride), PTFE (Polytetrafluoroethylene), FKM (Fluoroelastomer Polymer), FPM (perfluoro elastomers), FEP (fluorinated ethylene propylene), ETFE (ethylene tetrafluoroethylene)

Any PFAS materials utilized in biopharma manufacturing processes and by healthcare providers are disposed of at end-of-life by thermal oxidation and do not, therefore persist in the environment.

5. **How long should PFAS currently unavoidable use determinations be good for? How should the length of the currently unavoidable use determination be decided. Should significant changes in available information about alternatives trigger a re-evaluation?**

   Due to end-of-life destruction by thermal oxidation diverting any waste from landfill, permanent CUU determination would be most appropriate for PFAS materials used in biopharmaceutical manufacturing.

   Periodically reviewing the status of a Currently Unavoidable Use of a PFAS substance would continue to drive innovation, seeking alternates to be identified and applied in products. In any product category designated as a CUU, the progress toward alternates should be anticipated and therefore a periodic review may be assigned.

   This should be also applied to medical and dosing devices and pharmaceutical products in development and clinical trials since these processes will continue to use PFAS materials until suitable alternatives are identified.

6. **How should stakeholders request to have a PFAS use be considered for currently unavoidable use determination by the MPCA? Conversely, could stakeholders request a PFAS use not be determined to be currently unavoidable? What information should be submitted in support of such requests?**

The MPCA should consider uses identified in this response to

Table 3: PFAS Applications in Biopharmaceutical Manufacture, Supply, and delivery/dosage (a non exhaustive list) as CUU (essential for health safety and functioning of society in general, and for patient safety specifically).

7. **In order to get a sense of what type of and how many products may seek a currently unavoidable uses determination, please share what uses and products you may submit a request for in the future and briefly why. There will be a future opportunity to present your full argument and supporting information for a possible currently unavoidable uses determination.**

   Dosing delivery devices, biopharmaceutical products and the equipment necessary to research, develop, manufacture, and bring these products to market are included in our response.

100% of the biopharmaceutical products currently being developed or already licensed for sale in the US utilize PFAS somewhere in the development, manufacture, testing, storage of intermediates, drug substance or drug product or in the drug delivery systems. If PFAS used in these processes are not classified as CUU and thus banned, the drugs would be removed from the market until PFAS alternatives (if they exist) could be developed, sourced, validated, and approved for use, thus preventing patient access to life saving therapies.

A PFAS containing component can be present in a product that is placed on the market in multiple different ways due to the complexity of the products they are used in. For example, an FKM based O-Ring could be imported as a stand-alone spare part or accessory, in a complex item used as a replacement part in a pump, in a pump itself, in a hardware system containing a pump or in a larger installation containing a hardware system. This level of complexity in the ways these materials may be placed on the market makes it impossible to provide an exhaustive list of potential GPC or tariff codes impacted.

The biopharmaceutical industry is required by US Federal Food and Drug Administration to follow Good Manufacturing Practices (GMP) to use materials that are not reactive or additive to our product streams. Specific PFAS materials (PVDF, PTFE, FKM, FPM, FEP*, etc.) are required as they are proven to present negligible reactive properties. They are particularly beneficial in terms of not adding anything unintentional to medicinal products during drug substance or drug product manufacturing processes (i.e., they best meet the GMP requirements of being non-additive or reactive with the medicine – per 21 CFR 211.65). It should be noted that the **BioPharma Industry acts as downstream users of PFAS materials and does not own the technical solution outside of end-application qualification.**

Refer to

Table 3: PFAS Applications in Biopharmaceutical Manufacture, Supply, and delivery/dosage (a non exhaustive list) for a non-exhaustive list of identified CUUs.

8. Should MPCA make some initial currently unavoidable use determinations as part of this rulemaking using the proposed criteria?

The MPCA should initially consider the CUU identified in this response in

Table 3: PFAS Applications in Biopharmaceutical Manufacture, Supply, and delivery/dosage (a non exhaustive list) (essential for health safety and functioning of society in general, and for patient safety specifically).

Would the rulemaking process allow impacted stakeholders to provide additional clarifying information to further the rulemaking process? If so, then it is reasonable for the MPCA to propose initial CUU determinations for select categories and solicit stakeholder engagement.

9. Other questions or comments relating to defining currently unavoidable use criteria and the process MPCA uses to make currently unavoidable use determination

No further comment.

Appendix 4. S.4187 - Forever Chemical Regulation and Accountability Act of 2024

The response below pertains to S.4187 - Forever Chemical Regulation and Accountability Act of 2024 (14) which was proposed to the 118th Congress. The below details the advocacy work the team conducted to provide information and overview of the implications the bill may have and opportunities to identify areas of focus to support the journey to removing these harmful chemicals.

Background

The S.4187 - Forever Chemical Regulation and Accountability Act of 2024 aimed to address the environmental and health impacts of perfluoroalkyl and polyfluoroalkyl substances (PFAS). Key provisions of the act included:

1. Phaseout of Nonessential Uses: The act proposed the gradual elimination of nonessential uses of PFAS, focusing on reducing their presence in consumer products and industrial applications.
2. Prohibition of Releases: It sought to prohibit the release of PFAS into the environment, aiming to prevent further contamination of water, soil, and air.
3. Research and Development: The act supported research into alternative substances and technologies that could replace PFAS in various applications.
4. Enforcement and Monitoring: It included measures for inspections, monitoring, and enforcement to ensure compliance with the proposed regulations.
5. Citizen Suits: The act aimed to allow citizens to file lawsuits against violators, empowering communities to take action against PFAS pollution.

However, the bill did not pass and therefore did not become law. As a result, the proposed measures were not implemented, and the efforts to reduce PFAS contamination and promote safer alternatives were not realized through this legislative initiative.

Meeting with Congress Woman Betty McCollum Team

The team provided a high-level overview of the content of the main body of this document: The full set of meeting minutes can be obtained by BioPhorum members here : BioPhorum meeting Congress Woman McCollum team Forever Chemical Regulation 10th July.pdf (15).

The meeting highlighted the critical role of PFAS in biopharma and the challenges associated with finding alternatives. The discussion underscored the need for regulatory flexibility, continued research, and collaboration to ensure the sustainability of the biopharma supply chain while addressing environmental concerns. The congress team emphasized the importance of phasing out PFAS and exploring exemptions if no alternatives are available they plan to explore BioPhorum's response to the ECHA Annex XV report (16) and consider further research funding for PFAS alternatives.

Meeting with Senator Dick Durbin's Team

Again, the team provided a high-level overview of the content of the main body of this document: The team did not give approval for the meeting minutes to be formally published however were happy to publish an overview. The content of the presentation was the same as the meeting for: BioPhorum meeting Congress Woman McCollum team Forever Chemical Regulation 10th July.pdf (15).

The meeting underscored the critical need for proactive management of materials of concern, such as PFAS, within the biopharma industry. Proactive management involves anticipating regulatory changes and potential risks associated with harmful substances, allowing the industry to prepare and adapt in advance. This approach helps mitigate disruptions to the supply chain and ensures the continued availability of essential medicines.

Regulatory flexibility is equally important, as it allows the biopharma industry to navigate complex and evolving regulations without compromising the supply of critical vaccines and biotherapeutics. Exemptions and derogations are necessary to provide the industry with the time and resources needed to find, test, and validate alternative materials. These measures ensure that the transition away from PFAS and other harmful substances does not jeopardize patient access to life-saving treatments.

Collaboration between industry stakeholders, regulatory bodies, and government agencies is essential to address the challenges posed by PFAS and other harmful substances. By working together, these entities can develop and implement effective strategies for managing materials of concern, ensuring that regulations are both practical and protective of public health and the environment.

Continuous research and development are vital for identifying and developing viable alternatives to PFAS. Investing in R&D helps the biopharma industry discover new materials that can replace PFAS without compromising the quality, safety, and efficacy of pharmaceutical products. This ongoing innovation is crucial for the sustainability and resilience of the biopharma supply chain, enabling the industry to adapt to regulatory changes and maintain the supply of essential medicines.

In summary, the meeting highlighted the importance of a multifaceted approach that includes proactive management, regulatory flexibility, collaboration, and continuous research and

development. These elements are essential for addressing the challenges posed by PFAS and ensuring the biopharma industry's ability to provide critical vaccines and biotherapeutics to patients worldwide.

Appendix 5 Canada published State of Per- and Polyfluoroalkyl Substances (PFAS) Report and proposed Risk Management Approach

The Government of Canada published State of Per- and Polyfluoroalkyl Substances (PFAS) Report and proposed Risk Management Approach (17), assessing the environmental and health impacts of PFAS, a class of over 15,000 human-made substances known for their persistence and widespread use. The report concluded that PFAS, excluding fluoropolymers, are toxic under the Canadian Environmental Protection Act, 1999 (CEPA). Consequently, the government proposes adding PFAS to Part 2 of Schedule 1 to CEPA, enabling targeted risk management approaches to safeguard public health and the environment.

To address these impacts, the Canadian government plans to phase out non-polymeric PFAS, starting with firefighting foams, followed by consumer goods, and finally industrial uses. Interested parties have until May 7, 2025, to provide input. Additionally, 163 PFAS substances will be added to the National Pollutant Release Inventory in 2025, requiring reporting if used or released above 1kg/year. While phase-out timelines remain unclear, BioPharmaceutical manufacturers wish to be a recognized user case as some uses involving non-polymeric PFAS, such as PFAS-coated materials are critical in biopharma manufacturing processes. Additionally, if certain PFAS chemical required as starting materials to produce PFAS polymers such as PVDF and PTFE are limited in availability or even become unavailable, this will have a significant impact on the ability of the biopharmaceutical industry to produce lifesaving drugs. As laid out in the body of this document the ramifications of unstable supply chains can have devastating effects on the industry ability to provide life-saving drugs.

The State of Per- and Polyfluoroalkyl Substances (PFAS) Report primarily addresses food and environmental concerns, with less emphasis on biomanufacturers, but updates to regulations on LC-PFCAs and other small molecule PFAS are relevant.

As an industry we can provide the unique insights detailed in this response. We request to be a recognized industry in any industry consultations and evaluations.

BioPhorum exist in a unique landscape and role is to be an advocate for the biopharmaceutical industry serving to educate and share information to allow government body and regulatory information to make informed choices. This document is aimed to provide a resource and support any legislative decision making.

Canadian Regulatory Provisions

Any changes to registered drug manufacturing must be approved by healthcare regulatory authorities, which could lead to a significant increase in change approval submissions, posing a risk of supply chain disruptions for drugs. Industry experts predict that the volume of filings and license updates to regulatory agencies, such as Health Canada, could be substantial; numerous Health Canada-licensed drugs and medical devices could be affected by any changes. Based on available data, Health Canada oversees the registration of a

substantial number of drugs and medical devices. While exact numbers can vary, it is estimated that Health Canada manages the registration of over 10,000 licensed drugs and approximately 5,000 licensed medical devices (18) (19) (20).

Socioeconomic risk

The proposed legislation could negatively impact Canadian citizens' access to biopharmaceutical therapies and the wider local economy. Currently, it is unclear to what extent this may be as all user cases as well as the n-1 to n-3 components of the supply chains are not easily assessed or understood. Biopharmaceutical manufacturing in Canada is estimated to have produced approximately 500-700 million units of biologic drugs in 2024 (21) (22). This includes a wide range of biologics such as monoclonal antibodies, vaccines, and biosimilars, reflecting the growing demand and advancements in biomanufacturing technologies.

In 2024, the economic value of biologic drugs to the Canadian economy was substantial, contributing approximately CAD $75 billion to the economy (21) (23) (24). This value reflects the significant role biologics play in healthcare in Canada and further afield, driven by advancements in biotechnology and the increasing demand for innovative treatments.

BioPhorum members believe that the proposed changes could pose a significant risk to patient safety. There is substantial concern about the impact these changes could have due to the availability of alternatives to bridge this gap. As a result, patients may at significant risk or not receiving lifesaving medications, including treatments such as preventive and therapeutic biologics, metabolic and hormonal biologics, immunotherapy and targeted therapy, advanced cellular and genetic therapies, and other essential drugs that are required to be reassessed by regulatory agencies.

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By: OAH on 5/21/2025

Fredric Andes Attachment

PFAS REGULATORY COALITION

May 21, 2025

via electronic submission

Office of Administrative Hearings Rulemaking eComments webpage

https://minnesotaoah.granicusideas.com

Re: Comments of The PFAS Regulatory Coalition on the Minnesota Pollution Control Agency's Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees
Revisor's ID Number R-4828

Dear Sir or Madam:

The PFAS Regulatory Coalition (the "Coalition") appreciates the opportunity to file the following comments regarding the Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees ("Proposed Rules") issued by the Minnesota Pollution Control Agency ("MPCA"). MPCA is accepting comments on the Proposed Rules until 4:30 p.m. on Wednesday, May 21, 2025.

I. The Coalition's Interest

The Coalition is a group of industrial companies, municipal entities, agricultural parties, aviation representatives and trade associations, each of which has members or facilities that are directly affected by the development of policies and regulations related to per- and poly-fluoroalkyl substances (PFAS). Coalition membership includes entities in the automobile, airport, coke and coal chemicals, food and feed ingredient, iron and steel, municipal, paper, petroleum, and other sectors.

Coalition members, for purposes of these comments, include: Airports Council International – North America; American Coke and Coal Chemicals Institute; American Forest & Paper Association: American Fuel and Petrochemical Manufacturers; American Petroleum Institute; Brown & Caldwell; City of Pueblo, CO; Coalition of Recyclers of Residual Organics by Practitioners of Sustainability; ENFINITE, The Industrial Liquid Recyclers Association; GEI; Gary Sanitary District (IN); HDR; Haley & Aldrich; National Oilseed Processors Association; Portland Cement Association; Recycled Materials Association; Salt River Project; TRS Group; Trihydro; and Western States Petroleum Association. None of the Coalition members manufacture PFAS compounds.

PFAS Regulatory Coalition member entities or their members own and operate facilities located in Minnesota or sell products within the State. Because the Proposed Rules, if finalized by MPCA, would impose potentially enormous costs and liabilities on Coalition members, the Coalition and its members have a direct interest in the Proposed Rules. Further, because this proposed action poses important and complex issues concerning regulation of PFAS, and could serve as a precedent in PFAS regulation beyond Minnesota, all Coalition members have an interest in the Proposed Rules. Beyond the issues raised in these comments, individual members of the Coalition may have other concerns with various aspects of the Proposed Rules and may file additional comments separately.

II. Coalition Analysis and Recommendations

The Coalition has serious concerns about several provisions of the Proposed Rules. Those concerns, and our recommendations, are provided below.

A. Standard for Obtaining Information

Section 7026.0080, Subp. 2 requires manufacturers to request detailed disclosure of information from their supply chain "until all required information is known." This standard is unreasonable; it seems to impose an absolute obligation to obtain information, even if suppliers refuse to disclose it or do not have it available, despite their own good faith efforts to obtain the information from other parties in the supply chain. The lack of any reasonable limitation on this obligation risks imposing a heavy ongoing burden on regulated parties for little benefit. Instead, MPCA should use the "known or reasonably ascertainable" standard that is applied by USEPA under the Toxic Substances Control Act in similar situations. USEPA defines this test to cover "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know." 40 CFR 704.3. The emphasis in this USEPA test on reasonable efforts avoids the impractical, infeasible and never-ending obligations that are imposed in the Proposed Rules. MPCA should use the USEPA test.

B. Reporting Fees

Section 7026.0100 imposes fees that must be included with reports when submitted. These fees, $1,000 for initial reports, $500 for updates, and $300 for extension requests, are unreasonable. A separate report needs to be submitted for each product, and for a company that has to submit multiple reports, the costs could be substantial. In an age of electronic submittals, these fees bear no relation to the actual costs of processing the reports. Further, they impose a burden that small

businesses may find difficult to bear. The lack of justification for these fees is made clearer by the fact that if a group of manufacturers reports together, each member of the group has to pay the relevant fee on its own. Obviously, it costs less for the agency to process a multiple-entry submittal, than it would if the parties each submitted their own report, but this fee system ignores that fact. The fee system also fails to promote parties making group submittals, which is a goal that MPCA should promote. The fees should be lowered, at least for small businesses, and the fees for group submittals should be discounted, to encourage group submittals.

C. Waivers

In addition to the circumstances provided in the Proposed Rules where waivers of the reporting requirement are allowed, MPCA should consider allowing waivers where a specific use of a PFAS is required by applicable product certification standards. It is often the case that a product cannot be marketed for a particular use – for example, fire protection or other safety uses – unless it has certification from National Fire Protection Association, Underwriters Laboratories, or another applicable certification agency. If the applicable certification standard requires the use of PFAS, or if the standard cannot currently be met without the use of PFAS, then the manufacturer has no choice but to include PFAS in the product. In these circumstances, the manufacturer should be eligible for a waiver of the MPCA reporting requirements.

D. Total Organic Fluorine Testing

Section 7026.0030, Subp. 1.C.(2) specifies that if the party does not know the amount of each PFAS in a product, it must conduct total organic fluorine (TOF) testing and provide those results. That requirement is unjustified, and will provide misleading and irrelevant information to the agency and the public. TOF testing shows only the overall amount of total organic fluorine, which can indicate the presence of multiple substances that are classified as PFAS, plus many other substances that are not classified as PFAS. A TOF result tells one nothing about which specific PFAS might be present and in what amounts. Also, it can create an impression that there is a significant issue, simply by showing high TOF levels, when the actual levels of any specific PFAS might be quite low. Instead, MPCA should simply provide that if the amount of a PFAS is not known, the manufacturer should provide an estimate and explain the basis.

E. Reporting of PFAS Concentrations

Section 7026.0030, Subp. 1.C requires the report to specify "the concentration of PFAS chemicals in a product or components of a product made up of homogenous material," and requires that concentration to be provided within certain ranges. The Proposed Rules do not explain how that obligation applies when there are multiple PFAS in a product. Is the company required to report separately for each PFAS? Or does the report have to add all of the PFAS together to come up with a concentration range? Adding them together would provide a meaningless and misleading concentration number. MPCA should clarify the requirement.

III. Conclusion

MPCA should address each of the issues set forth above before it finalizes its PFAS-in-products reporting and fees rule. The PFAS Coalition looks forward to continuing to engage with MCPA on these issues as the agency moves forward. Please feel free to contact us if you have any questions or would like any additional information concerning the issues raised in this letter.

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Coordinators

HARDI HEATING AIR-CONDITIONING REFRIGERATION DISTRIBUTORS INTERNATIONAL

Commissioner Katrina Kessler
Minnesota Pollution Control Agency
520 Lafayette Road
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news.MPCA@state.mn.us

May 15, 2025

RE: HARDI Comment Letter for Pollution Control Agency Notice of Hearing on PFAS in Products Reporting and Fee Rule.

Dear Commissioner Kessler,

Minnesota has been a leader on the issue of banning harmful per- and poly-fluoroalkyl substances (PFAS); however, the Minnesota Pollution Control Agency's (MPCA) PFAS in Products Reporting and Fees would create an unnecessary reporting requirement for the cooling, heating, ventilation, air-conditioning, and refrigeration (HVACR) industry that would increase a business's workload but provide no benefit to the MPCA. HARDI opposes MPCA's PFAS in Products Reporting and Fees as presented unless amended to add an exemption under section 7026.0090 for HVACR equipment and refrigerants approved under the Environmental Protection Agency's (EPA) Significant New Alternative Policy (SNAP) program. Exemptions for HVACR have been adopted in PFAS prohibition policies in New Hampshire, New Mexico, and Maine, and are under consideration in the Connecticut and New Jersey legislatures.

HARDI is a trade association comprised of more than 1,150 member companies, more than 490 of which are U.S.–based wholesale distribution companies. These include 20 wholesaler-distributor members in Minnesota, with 80 locations serving HVACR contractors and technicians in the state. Over 80 percent of HARDI's distributor members are classified as small businesses that collectively employ more than 60,000 U.S. workers, representing an estimated 75 percent of the U.S. wholesale distribution market for HVACR equipment, supplies, and controls.

HVACR refrigerants are not a danger to human health and should be exempt from PFAS reporting requirements.

Minnesota is justified in seeking to reduce and, if possible, eliminate the use of harmful PFAS, and HARDI understands that reporting is a step in that process. However, it is important to note that not all PFAS should be considered a danger to human health that needs reporting. According to a systematic review of chemicals by NIH, the three factors that create a danger are "[p]ersistent, bioaccumulative, and toxic substances … that can subsist for decades in human tissues and the environment."[i] This letter outlines the available science to show why hydrofluorocarbons (HFCs) approved for use in HVACR by the EPA, through the SNAP program, do not meet the three requirements to classify them as dangerous PFAS and urge the addition of exemptions when a separate state or federal regulation or code prohibits PFAS alternatives, such as the EPA's SNAP program.

Persistent

Many PFAS are rightly called "forever chemicals" because of their persistence in the environment for "thousands of years."[ii] A persistent PFAS will enter the environment and not degrade over time. Typically, these dangerous PFAS either stay in the soil or become mobile, moving to water where they can enter streams, rivers, aquifers, and lakes. On the other hand, refrigerant HFCs are gases at ambient temperature; because of this, HFCs cannot be absorbed into the soil and are not water-soluble. Additionally, HFCs have a shorter life span than other PFAS, breaking down in the atmosphere after an average of 15 years.[iii] With such a short lifespan in the atmosphere, HFC refrigerants are not considered persistent compared to other PFAS.

Bioaccumulative

"Humans, as the final link in numerous food chains, are subjected to PFAS uptake primarily through food and drinking water."[iv] As mentioned, PFAS often enters streams, rivers, and lakes, where fish and other animals ingest them. Additionally, plants can absorb PFAS from contaminated soil or irrigation water.[v] The ability of dangerous PFAS to be absorbed in human tissue and remain there for the rest of a person's life is a concern. However, toxicology reviews have found that R-32 and R-125 are not considered bioaccumulative.[vi] R-32 and R-125 are the components used to create R-410A, the most common refrigerant gas primarily used in air conditioners and heat pumps. In addition, as a gas, the ability of HFC refrigerants to enter the food chain is nearly impossible without first degrading from their original molecule. The most significant byproduct of refrigerant degradation in the atmosphere is trifluoroacetic acid (TFA). This substance has been extensively studied by the United Nations Environment Programme (UNEP) Environmental Effects Assessment Panel (EEAP). According to the UNEP findings, TFA is not classified as a PFAS and is not bioaccumulative. This conclusion is based on naturally occurring principles that, even under high concentrations of TFA, create no harm to biological life.

Additionally, bioaccumulation factsheets are available on other HFC refrigerants like R-134a[vii] and R-143a.[viii] R-23, R-125, R-134a, and R-143a are the components used to make the majority of HFC refrigerant blends used in HVACR. HARDI has found no safety data sheets showing an HFC refrigerant listed as bioaccumulative.

Toxicity

The American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) classifies all refrigerants as "higher toxicity" or "lower toxicity."[ix] Common HFC refrigerants and blends like R-410A are classified as lower toxicity. However, even non-HFC refrigerants, like ammonia, are rated "higher toxicity, lower flammability" by ASHRAE or "higher flammability" like propane; even CO_2 is listed as "lower toxicity." Refrigerants are designed to stay in the closed loop of an air conditioner, heat pump, or refrigerating machine; only when they leak out of the machine in an enclosed space does toxicity become a concern. CO_2 creates dangerous conditions at concentrations as low as 5,000 ppm;[x] R-32, on the other hand, required 350,000 ppm before adverse

effects were observed.[xi] In addition, some HFCs used as refrigerants, like R-134a, are also used as propellants in metered-dose inhalers because of their short serum half-life of between 4 and 11 minutes; this is considered a low human toxicity risk.[xii] HFC refrigerants have low human toxicity and are lower toxicity compared to some non-HFC refrigerants.

According to REACH, the European Union regulation for protecting human health, HFC refrigerants do not meet the persistent, bioaccumulative, or toxicity factors necessary to make them dangerous PFAS.[xiii] No refrigerant is 100 percent safe; however, HFC refrigerants pose a physical and environmental hazard rather than a health hazard like the PFAS that Minnesota intends to regulate. Because of this physical and environmental hazard, HFCs are already highly regulated. Unfortunately, the same proponents of eliminating HFCs faster than the Kigali Amendment to the Montreal Protocol often try to include HFCs in the definition of PFAS as an end-run around federal and international policy. The HVACR industry has worked with the international community to move to environmentally safer refrigerants. However, advocates falsely claim health hazards that do not exist to circumvent these industry agreements. HARDI has fully supported the phase-down of HFC refrigerants and is actively working with the EPA to reduce emissions of these refrigerants into the atmosphere.

HVACR refrigerants should be exempt from reporting requirements because they are currently heavily regulated, and federal regulations already require reporting all refrigerants sold in the United States.

The EPA regulates the life cycle of HFC refrigerants through the Clean Air Act and the American Innovation and Manufacturing Act. Knowingly releasing HFC refrigerant gases into the atmosphere is a crime. Refrigerants within systems do not wear out like oil in a car engine; with proper tools, refrigerants can be purified back to their original quality, an action required by the EPA. Federal and Minnesota regulations require HVACR technicians to recover refrigerants from equipment at the end of life; this refrigerant is then sent to an EPA-certified reclaimer to purify or destroy the refrigerant. Using reclaimed refrigerant reduces the environmental impact of HFCs by ensuring they are not released into the atmosphere. This process is vital as HFC production and imports are reduced over the next 11 years, and the industry reduces consumption by 85 percent from the baseline. To further reduce the impact of HFCs, the HVACR industry is moving to other refrigerants with lower global warming potential listed under the SNAP program.

Additionally, refrigerants produced in and imported into the United States are currently monitored by the federal government through reporting requirements. This federal reporting provides the same information that would be gained from the Minnesota PFAS reporting requirements being considered. Which essentially means the proposed Minnesota PFAS reporting requirement is only an unnecessary administrative and financial burden on businesses and the MPCA, that provides no real substantive benefit.

The reporting fee and additional administrative workload will increase the cost of all HVACR products for Minnesota businesses and consumers.

An HVACR industry business operates as a lean company, with dedicated staff fulfilling specific roles to create the most affordable products possible for consumers. However, to comply with the proposed reporting requirements, every HVACR business will need to hire additional staff to manage the administrative burdens of MPCA PFAS reporting. Like how companies have had to expand their workforce to handle the administrative tasks associated with properly filing for rebates and incentives. This forced hiring will lead to an increase in operational costs. As a result, each company will have to raise product prices, passing these increased costs on to consumers and consequently making products more expensive.

Additionally, the reporting fee of $1,000, along with any adjustments for inflation, will also be transferred through the supply chain to the consumer, further contributing to price increases. These cost hikes are unnecessary and will not provide any significant benefits for Minnesota's efforts to eliminate PFAS from the environment.

HVACR refrigerants should be exempt since every other state does not include HVACR in their prohibitions or reporting requirements.

In the U.S., 30 out of the 31 states that have adopted PFAS policies have purposely chosen not to include or exempt the HVACR industry. The states of Alaska, Arizona, Minnesota, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oregon, Pennsylvania, Rhode Island, Vermont, Virginia, Washington, West Virginia, and Wisconsin chose not to include or exempt the HVACR industry from their prohibitions. New Hampshire, New Mexico, and Maine legislatures adopted explicit exemptions for the HVACR industry from their PFAS prohibition policies. The Connecticut and New Jersey legislatures have their own PFAS prohibition currently under consideration, which adopts an HVACR exemption.

Conclusion

HARDI believes that the HVACR industry should be exempt from PFAS product reporting requirements based on the lack of danger to human health, the increase in costs to businesses and consumers, other state precedents, and current federal reporting requirements for refrigerants sold. This request is justified due to the science proving the lack of danger to human health, other states' PFAS prohibition exemption language, the enacted federal phasedown on the HVACR industry, the extensive administrative workload PFAS reporting requires, the reporting fees cost, and the current federal requirements for reporting all refrigerants sold. Exempting SNAP program-approved refrigerants from reporting under section 7026.0090 would save businesses and the MPCA time and funds, allowing them to focus on removing the most harmful substances from the environment.

Sincerely,

Todd Titus
Director of State and Public Affairs
Heating, Air-conditioning, & Refrigeration Distributors International

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[i] Fernández-Martínez, N. F., Ching-López, A., Olry de Labry Lima, A., Salamanca-Fernández, E., Pérez-Gómez, B., Jiménez-Moleón, J. J., Sánchez, M. J., & Rodríguez-Barranco, M. (2020). Relationship between exposure to mixtures of persistent, bioaccumulative, and toxic chemicals and cancer risk: A systematic review. Environmental research, 188, 109787. https://doi.org/10.1016/j.envres.2020.109787

[ii] Washington Department of Ecology, Per- and polyfluoroalkyl substances (PFAS), https://ecology.wa.gov/waste-toxics/reducing-toxic-chemicals/addressing-priority-toxic-chemicals/pfas

[iii] Climate & Clean Air Coalition, Hydrofluorocarbons (HFCs), https://www.ccacoalition.org/short-lived-climate-pollutants/hydrofluorocarbons-hfcs

[iv] Brunn, H., Arnold, G., Körner, W. *et al.* Correction: PFAS: forever chemicals—persistent, bioaccumulative and mobile. Reviewing the status and the need for their phase out and remediation of contaminated sites. *Environ Sci Eur* 35, 30 (2023). https://doi.org/10.1186/s12302-023-00730-7

[v] Ghisi, R., Vamerali, T., & Manzetti, S. (2019). Accumulation of perfluorinated alkyl substances (PFAS) in agricultural plants: A review. Environmental research, 169, 326–341. https://doi.org/10.1016/j.envres.2018.10.023

[vi] George M. Rusch (2018) The development of environmentally acceptable fluorocarbons, Critical Reviews in Toxicology, 48:8, 615-665, DOI: 10.1080/10408444.2018.1504276

[vii] Safety Data Sheet – R-134a, A-Gas, https://dimplexthermal.com/wp-content/uploads/2016/05/SDS_R-134a_V01.pdf

[viii] Safety Data Sheet – R-143a, National Refrigerants, https://nationalref.com/wp-content/uploads/2019/05/SDS_R143a_CLP.pdf

[ix] ASHRAE, Update on New Refrigerants Designations and Safety Classification, https://www.ashrae.org/file%20library/technical%20resources/bookstore/factsheet_ashrae_english_november2022.pdf

[x] Occupational Safety and Health Administration, OSHA Hazard Information Bulletins
Potential Carbon Dioxide (CO2) Asphyxiation Hazard When Filling Stationary Low Pressure CO2 Supply Systems, https://www.osha.gov/publications/hib19960605

[xi] Safety Data Sheet – R-32, Chemours, https://hdsupplysolutions.com/wcsstore/ExtendedSitesCatalogAssetStore/product/fm/additional/15/150110_MSDS-PDF.pdf

[xii] Ritchie, G. D., Kimmel, E. C., Bowen, L. E., Reboulet, J. E., & Rossi, J., 3rd (2001). Acute neurobehavioral effects in rats from exposure to HFC 134a or CFC 12. Neurotoxicology, 22(2), 233–248. https://doi.org/10.1016/s0161-813x(01)00011-0

[xiii] REACH Online, Annex XIII: Criteria for The Identification of Persistent, Bioaccumulative and Toxic Substances, and Very Persistent and Very Bioaccumulative Substances, https://reachonline.eu/reach/en/annex-xiii.html

Craig Tangren Attachment

LEECH LAKE BAND OF OJIBWE
DIVISION OF RESOURCE MANAGEMENT

Via Web Submission:
The Honorable Jim Mortenson
Minnesota Office of Administrative Hearings
600 North Robert Street
PO Box 64620
St. Paul, Minnesota 55164-0620

May 21, 2025

RE: Notice of Intent to Adopt New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS), Revisor's ID Number R-4828, OAH docket number 5-9003-40410

As a sovereign Tribal government located in Northern Minnesota, the Leech Lake Band of Ojibwe (LLBO) is taking this opportunity to comment on proposed new rules governing reporting and fees for products containing PFAS. This proposed rule, and the legislation which has prompted its creation, is of great importance to the Leech Lake Band of Ojibwe.

The continued production, use, and distribution of PFAS are an immediate threat to the Leech Lake Band of Ojibwe, our treaty-guaranteed rights to hunt, fish, and gather, our lifeways, our health, and the health of the environment. Although there are no manufacturers or other facilities known to be producing, or discharging PFAS within our Reservation, PFAS have been found in the drinking water of our Tribal school, in our lakes, and in the fish we eat, and are surely present in other parts of the environment we have not yet analyzed.

Deadline and Extensions

The deadline of January 1, 2026 for the reporting requirements in this rule in Section 7026.0030 Subpart 1 should be maintained. Although Minnesota is one of the first states to begin implementing reporting requirements for PFAS, this action should not come as a surprise to industry. The state of Maine passed a similar law governing PFAS reporting and restrictions in 2021, and Minnesota's "Amara's Law" which directed the creation of this rule, was passed in 2023. Manufacturers have previously been required by other states to report the PFAS contents of their products, and will need to eliminate those PFAS by 2032 in order to comply with Amara's Law; extending the deadline for reporting beyond January 1, 2026 is unnecessary due to existing requirements in other jurisdictions and may leave manufacturers unprepared for future regulations. For these reasons, the reporting deadline of January 1, 2026 per Section 7026.0030 and extensions per Section 7026.0060 should remain limited to 90 days from the deadline.

Required Information

The information required to be reported in Section 7026.0030 Subpart 1. C. requires that the **concentration** of PFAS in a product or component be reported. This requirement is inadequate and fails to meet the requirement of Minnesota Statute 116.943 Subdivision 2 Item

(3), which states that "the **amount** of each PFAS, identified by its chemical abstracts service registry number, in the product, reported as an exact quantity determined using commercially available analytical methods or as falling within a range approved for reporting purposes by the commissioner" (emphasis added.) The Leech Lake Band of Ojibwe does not object to reporting the concentration of PFAS, but we request that Section 7026.0030 Subpart 1. C. be amended to include the mass of individual PFAS components and the total mass of all PFAS compounds present in a product.

Additionally, Section 7026.0030 Subpart 1. C. (i) allows manufacturers to report that PFAS is "present but the amount or concentration range is unknown." We believe this creates a loophole for inadequate reporting which undermines the rule and enacting legislation. This would be remedied by amending Section 7026.0040 to require that any manufacture who has previously reported PFAS concentrations as unknown be required to submit an updated report including the mass of individual PFAS components and the total mass of all PFAS compounds, as well as the concentration of PFAS per Section 7026.0030 Subpart 1. C. (a-h). This would allow manufacturers to provide an initial report of PFAS compounds in compliance with the rule while providing additional time to determine the amount of PFAS in their products.

Trade Secrets

Section 7026.0070 discusses trade secret data requests and would allow a) chemical name b) chemical identifying number and c) supply chain information to be maintained as not public information. Minnesota Statutes, section 13.37 subdivision 1 (b) (2) defines "trade secret information" as, in part, "government data, including a formula, pattern, compilation, program, device, method, technique or process…that is the subject of efforts by the individual or organization that are reasonable under the circumstances to maintain its secrecy." In drafting and passing Amara's Law, the legislature has determined that PFAS pose a grave risk to human health and the environment and that disclosure and prohibition are required to remedy this threat. Recognizing the language of Minnesota Statutes section 13.37 defining "trade secret information" and the legislation behind this rule, it would be unreasonable to maintain the secrecy of any PFAS. As a result of this conflict between the legislative intent behind Amara's Law and Section 7026.0070 of the proposed rule, this section should be removed in its entirety.

Conclusion

The Leech Lake Band of Ojibwe would like to express our appreciation for the review and consideration of our comments on the Proposed New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS) (Revisor's ID Number R-4828). If you have any questions or require clarification please do not hesitate to contact me at (218) 335-7429 or at craig.tangren@llojibwe.net.

Sincerely,

Craig Tangren
Environmental Deputy Director, Leech Lake Band of Ojibwe

AMERICAN APPAREL & FOOTWEAR ASSOCIATION

Advocacy that fits.

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May 21, 2025

Hon. James Mortenson, Administrative Law Judge
Office of Administrative Hearings
600 North Robert St, P.O. Box 64620
St. Paul, Minnesota 55164-0620

Judge Mortenson:

On behalf of the American Apparel & Footwear Association (AAFA), I am providing comments on the proposed PFAS in Products: Reporting and Fees Rule issued by the Minnesota Pollution Control Agency (MPCA).

AAFA is the national trade association representing apparel, footwear and other sewn products companies, and their suppliers, and is the trusted public policy and political voice of the apparel and footwear industry, its management and shareholders, its more than 3.5 million U.S. workers, and its contribution of $509 billion in annual U.S. retail sales, and represents more than 1,100 world famous name brands, including several brands and retailers in Minnesota. AAFA approaches all of its work through the lens of purpose-driven leadership in a manner that supports each member's ability to build and sustain inclusive and diverse cultures, meet and advance ESG goals, and draw upon the latest technology.

With our members engaged in the production and sale of clothing and footwear, we are on the front lines of product safety. It is our members who design and execute the quality and compliance programs that stitch product safety into every garment and shoe we make. In fact, our members are actively phasing out the avoidable use of intentionally added PFAS and our open-industry Restricted Substances List has included PFAS as a class of chemicals for more than two years.

AAFA and our members are proud advocates for regulatory requirements that can effectively protect human health and the environment. Regulation plays a critical role in furthering our industry's efforts to ensure products are manufactured to the highest of compliance standards. However, this can only work if regulations are well designed, purposeful, and properly enforced. In that spirit, we provide the following comments.

Scope of Reporting

The proposed Rule requires that manufacturers report on each product, or group of similar products, containing intentionally added PFAS, including separate product components, by product code(s), specific PFAS chemicals by name and CAS number, concentration by PFAS chemical, the function of each PFAS chemical, and various manufacturer information. Such a requirement fails to acknowledge that products and product components for the apparel and footwear industry, as well as for many other industries, are often purchased without knowledge of which of the nearly 15,000 different PFAS chemicals are added to the product, nor the intended function at the individual PFAS chemical level. Moreover, the requirement to report on such a granular level about PFAS additions is complicated by the volume of product components inherent in the apparel and footwear industry across various iterations of similar product types (e.g. across outsoles, midsoles, linings, laces, eyelets, etc.). Such reporting is difficult, if not impossible, to accomplish and will be unwieldy for MPCA to review, with limited public benefit.

As acknowledged within the section on proposed concentration reporting, manufacturers must be able to report PFAS concentration via total organic fluorine (TOF) testing. Testing for each PFAS chemical is neither possible nor desirable and it has become industry standard to use TOF tests to determine overall PFAS concentrations. We recommend, therefore, that MPCA, in acknowledgement of the impracticability of

reporting across almost 15,000 different PFAS chemicals, allow for the reporting of PFAS in products via TOF concentration. We additionally ask that MPCA allow for the reporting of product components used across multiple product applications (e.g. zips, laces, eyelets) through consolidated reporting not tied to individual products.

We are also concerned by the requirement to conduct due diligence "until all required information is known". As outlined above, apparel and footwear products are composed of multiple different product components that are sourced from hundreds of suppliers. Such an open-ended requirement to obtain information from supply chain partners is concerning and beyond the scope of what MPCA is seeking to regulate. Such concerns would be obviated by limiting the reporting requirement to TOF testing, which would not require such complicated supply chain due diligence.

Insufficient Timelines

The proposed reporting rules would require the initial PFAS reporting be submitted on or before January 1 of next year. We are extremely concerned that such a deadline does not give covered producers sufficient time to adequately perform the required due diligence to comply with the proposed reporting rules. This condensed timeline for reporting into a system that does not yet exist is both unreasonable and near impossible to comply with. We recommend, therefore, the use of enforcement discretion for the first year of reporting as our brands continue to prioritize chemical management in the products they sell.

Trade Secret Data Process

Regarding the protection of "trade secret data", the proposed Rule limits the scope of data eligible to be considered not public information to chemical name, chemical identifying number, and specific supply chain information, as defined in the Rule. Given the detailed information needed to provide the level of reporting specificity required by the Rule, it seems probable that manufacturers will be disclosing proprietary information to MPCA. The proposed informational elements eligible for confidential treatment are too narrow and risk the dissemination of commercially sensitive information to the public. The supply chain information eligible for confidentiality is underspecified and leaves manufacturers unsure of which business information will be made publicly available. Additionally, the Rule does not specify the relevant timeline for reviewing trade secret data requests, nor what will happen if MPCA ultimately determines that submitted information does not constitute trade secret data. We recommend, therefore, that MPCA clarify the process for trade secret data requests and expand the scope of trade secret data.

We look forward to continuing to work with Minnesota on the regulation of substances in consumer products for the benefit of consumer product safety and public health. In the meantime, our members continue to design and execute the quality and compliance programs that emphasize product safety for every individual who steps into our apparel and footwear products.

Thank you for your consideration of these requests.

Respectfully,

Chelsea Murtha
Senior Director, Sustainability
American Apparel & Footwear Association

May 21, 2025

Office of Administrative Hearings
Attn: William Moore, OAH
600 North Robert Street
P.O. Box 64620, St. Paul, Minnesota
55164-0620

Submitted to the Office of Administrative Hearings via Rulemaking eComments:
https://minnesotaoah.granicusideas.com/

RE: Notice of Intent to Adopt New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS), Revisor's ID Number R-4828, OAH docket number 5-9003-40410; Proposed New Rules Governing PFAS in Products, Minnesota Rules, chapter 7026

The Honorable James Mortenson:

The RV Industry Association (RVIA) appreciates this opportunity to comment on the Minnesota Pollution Control Agency (MPCA) Request for Comment on the PFAS in Products Reporting and Fee Rule. This rule will require manufacturers to report information to MPCA on products sold, offered for sale, or distributed in the state which contain intentionally added PFAS, and would establish a fee structure for required reporters.

RVIA is the national trade association representing over 500 manufacturers and component and aftermarket suppliers who together build more than 98 percent of all RVs produced in the United States—including motorhomes, travel trailers, fifth-wheel travel trailers, folding camping trailers, park model RVs, and truck campers. The RV industry contributes more than $140 billion annually to the national economy and $3 billion to the Minnesota state economy each year. The RV industry is an American-made industry that supports 680,000 jobs paying more than $48 billion in wages[1]. In Minnesota the RV industry supports 15,120 jobs and $827 million in wages.

The RV Industry and Complex Durable Goods

Unlike traditional consumer product manufacturers that produce items in-house, RV manufacturers function more as complex assemblers, sourcing thousands of individual components from original equipment manufacturers (OEMs) and a wide array of upstream

[1] The Association is the unifying force for promoting safety and professionalism within the RV industry, and works with policymakers, government agencies, as well as recognized national standards-setting bodies, to promote and protect the RV industry.

suppliers. The average RV consists of thousands of parts—ranging from flooring and upholstery to electronics, mechanical systems, adhesives, and sealants—many of which are sourced from domestic and international suppliers across diverse industries. RV manufacturers do not typically manufacture these components themselves, which creates an exceptionally complex supply chain with over a million unique parts or stock-keeping units (SKUs) managed across the sector. This highly decentralized structure poses significant challenges when attempting to trace or verify the presence of intentionally added PFAS at the component level, especially when upstream suppliers may be foreign sources with no PFAS disclosure or testing requirements. As such, any regulatory reporting framework must accommodate the realities of complex durable goods manufacturing and recognize the limitations faced by downstream product manufacturers in accessing upstream chemical composition data.

With the above context, the RVIA will address each of the following issues in more detail and offer recommendations for change in the proposed rule:

- **MPCA should use a Risk-Based approach**
    - Internal Components
- **Chapter 7026.0030. "Information Required in Report"**
    - Aggregate Reporting at the Total Product (Vehicle) Level
    - Ability to Report the Volume of Information required by January 2026
- **Chapter 7026.0080. "Due Diligence Reporting"**
- **Questions and Clarifications for the Agency**

MPCA Should Use a Risk-Based Approach

MPCA should prioritize reporting requirements for PFAS substances that have demonstrated potential for consumer exposure or environmental impact, based on currently available science and data. For example, the US Environmental Protection Agency (EPA) uses a narrower definition of PFAS that focuses on substances that have a known human health risk.

RVIA recommends that MPCA aligns its PFAS program to be consistent with Federal requirements where feasible. Therefore, RVIA recommends that MPCA adopt the Federal definition of PFAS as follows:

"PFAS" is a nonpolymeric perfluoroalkyl and polyfluoroalkyl substances that are a group of man-made chemicals that contain at least 2 fully fluorinated carbon atoms, excluding gases and volatile liquids. "PFAS" includes PFOA and PFOS.

This would focus the MPCA program on PFAS substances that present the highest risk to consumers. MPCA should exclude substances with low-risk profiles, including fluoropolymers[2] These types of chemicals have high-molecular weight, low levels of residual monomer, and do not degrade easily under normal conditions of use. In 2023, the EPA's Risk Evaluation framework excluded certain high-molecular weight polymers from extensive evaluation due to their low bioavailability. This exclusion was based on the understanding that the physical characteristics of these polymers, specifically their insolubility and high molecular weight, would limit their ability to be absorbed into the body and therefore pose a lower risk[3]. MPCA should also consider exemptions for refrigerants and for components containing PFAS at de minimis levels, where the presence of PFAS is incidental.

Internal Components

Within RV manufacturing, many components that may contain PFAS are fully integrated into vehicle systems and are not typically accessible during routine use or handling. This includes electronic modules, internal wiring, sealed gaskets, refrigeration units, insulation foams, lithium-ion batteries, and chemical- or temperature-resistant hoses and seals. These components are engineered for durability and function and are not designed for consumer interaction. Accordingly, these parts may present limited consumer exposure potential and should be considered for categorical exclusion from reporting obligations.

RVIA recommends that MPCA use a risk-based approach to reporting by excluding certain low-risk substances and components, as discussed above. This would allow the agency to focus its resources on meaningful exposure pathways while avoiding undue reporting burdens on manufacturers of complex durable goods. As more data becomes available, MPCA can expand the program over time.

Chapter 7026.0030. "Information Required in Report"

While RVIA supports the goal of Minn. Stat. § 116.943 Subd.2 for collecting information on products sold in the state that contain intentionally added PFAS, the most effective way to obtain the necessary information is to focus on upstream manufacturers of the specific items/articles that contain intentionally added PFAS. For example, RV manufacturers purchase thousands of individual parts, components, and subassemblies from third parties that are assembled at the RV manufacturing facility to develop a final product, a recreational vehicle.

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[2] Stephanie Jacobs, David S. Kosson, Assessment of Fluoropolymer Production and Use with Analysis of Alternative Replacement Materials (January 2024), https://www.osti.gov/biblio/2370520.

[3] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/polymer-exemption-new-chemicals#:~:text=reactants%20for%20polyesters.-,Exclusions,CF3%2D%20or%20longer%20chain%20length

Each RV contains at least 10,000 individual parts and in some cases over 100,000 per unit for larger, more complex units.

RVIA recommends that MPCA adopt the following definition of complex durable goods, which is similar to that outlined in Section 6 of the Toxic Substances Control Act (TSCA) and is being considered in other jurisdictions. This would provide better consistency with other jurisdictions.

"Complex durable goods" means a consumer product that is a manufactured good composed of 100 or more manufactured components, with an intended useful life of 5 or more years, where the product is typically not consumed, destroyed, or discarded after a single use, including its component parts and service items."

Further, due to the complex and unique nature of RV manufacturing and the RV supply chain, RV manufacturers are not the best positioned to provide the required information. As manufacturers of "complex durable goods:"

RVIA recommends that MPCA strongly consider excluding RV manufacturers from reporting under the proposed Minnesota reporting rule if they themselves have not intentionally added PFAS as part of the final product.

<u>Aggregate Reporting at the Total Product (Vehicle) Level</u>

If MPCA requires RV manufacturers to report, we strongly urge the agency to permit aggregate reporting at the total product level (i.e., the vehicle itself). RVs are highly customizable, low-volume products—each unit can differ significantly based on the buyer's selected floor plan, finishes, furnishings, and optional features. As a result, components used in each vehicle can vary substantially even within the same model line. This level of customization creates a moving target for reporting, making it exceedingly difficult to track PFAS content at the individual component level.

Compounding this challenge is the structure of our industry: many RV manufacturers are small, family-run businesses that do not have in-house legal teams, chemical experts, dedicated compliance staff, or the infrastructure to conduct chemical testing or collect detailed supplier data on thousands of SKUs. These manufacturers operate at tight margins and build relatively small production runs, which means that uniform reporting obligations—without flexibility or scalability—could impose disproportionate compliance costs and jeopardize the economic viability of businesses that form the backbone of this industry.

RVIA recommends that MPCA permit aggregate reporting at the total product (vehicle) level. It would enable manufacturers to disclose PFAS content in a meaningful way while reducing burden and preserving the integrity of small businesses. MPCA would still receive valuable data on the presence of PFAS in consumer goods without requiring a level of granularity that is

unreasonable, not necessary and is neither technically feasible nor economically sustainable for much of our sector.

Ability to Report the Volume of Information required by January 2026

RVIA is highly concerned there will not be a reasonable amount of time for RV manufacturers to collect, validate, and report information about their products that have intentionally added PFAS. As stated earlier, RVs are complex products that contain thousands of individual parts, components and assemblies that are sourced throughout a highly complex supply chain that is international in scope. Given the volume of chemical composition information being requested by MPCA, it will be nearly impossible for RV manufacturers to meet the current reporting deadline of January 2026. This is further exacerbated by the extreme due diligence standard that requires all information requested in total. Given the delays in this rulemaking, it is unclear when a final rule may be issued. We hope that the MPCA will do its due diligence and conduct a complete and thorough review of all stakeholder comments and testimony.

Additionally, it is essential that manufacturers have clear, practical steps for submission of data into the reporting system. This cannot happen until the reporting system's functional capabilities are fully tested and established. This is especially true for a manufacturer who is reporting on behalf of multiple manufacturers. Manufacturers will need detailed guidance on how reporting entities can submit on behalf of multiple manufacturers and to put in place formal relationships to do such.

We understand that detailed guidance will be included in the reporting system instructions or in a supplemental guidance document. However, this information will not become available until the reporting system's functional capabilities are fully established. This is critical for ensuring that entities have clear, practical steps for submission of data on behalf of multiple manufacturers.

RVIA recommends that MPCA delay the current reporting deadline from January 1, 2026, to January 1, 2027. RVIA believes this is quite reasonable, given the complexity of the reporting process and the numerous steps and related systems that need to be in place, tested, and validated prior to actual reporting.

Chapter 7026.0080. "Due Diligence Reporting"

The proposed requirement for a manufacturer to request detailed disclosure of information required from their supply chain **"until all required information is known**" is not reasonable and does not reflect the real-world limitations that manufacturers of complex durable goods face in obtaining chemical data from a vast array of upstream suppliers.

One of our member suppliers, for example, has been proactively collecting PFAS data since 2016 with the goal of eliminating these substances from their supply chain. Under the federal definition of PFAS, they have made it a priority to eliminate any known PFAS. However, in preparing to comply with broader state-level mandates like Minnesota's, they expanded their outreach efforts to collect data aligned with the state's definition of PFAS. After several years of effort and repeated requests, they have received complete PFAS data from only 30–40% of their suppliers. The remaining suppliers either lack the information, are unable to share proprietary data, or are located in jurisdictions with no PFAS regulations.

This example demonstrates that even well-resourced, proactive companies face major challenges in accessing the data needed for compliance under the proposed Minnesota PFAS Reporting and Fees Rule.

RVIA recommends that MPCA adopt the Federal definition of "due diligence" as defined under the EPA TSCA 8(a)(7) PFAS reporting rule which say: "due diligence" reporting means companies must gather all information that is "known or reasonably ascertainable" regarding intentionally added PFAS in their products or those they import. Further, MPCA should clarify that "reasonably ascertainable" means information available through standard business documentation and supplier declarations—not information that requires testing, audits, or disclosure beyond what suppliers are willing or able to provide.

This would provide a more reasonable standard for collecting and reporting the required information from our supply chain and would create better consistency with Federal standards. Without such clarification, the rule will impose overly burdensome and unreasonable obligations on businesses across the RV industry. In fact, by using the current definition for due diligence being proposed, it may in fact be impossible for most manufacturers of complex durable goods to be fully compliant. This could put some manufacturers and suppliers in a very difficult position of deciding whether to operate in the state knowing that it is in noncompliance and would be particularly true for small businesses.

Questions and Clarifications for the Agency

We respectfully request clarification from the Minnesota Pollution Control Agency on the following questions regarding the proposed PFAS reporting rule:

- What is MPCA's plan for manufacturers that are unable to procure information from suppliers on the use of PFAS in products? (With tens of thousands of SKUs in RV manufacturer's products, it seems unlikely that some manufacturers would be able to obtain a complete inventory within the timeframe provided.)
- Will MPCA clarify what constitutes compliance when manufacturers have exercised due diligence but still lack complete supplier data?

- Will MPCA consider a phased-in compliance timeline for complex goods to accommodate necessary supplier outreach and data collection?
- Will replacement or aftermarket parts be exempt from the reporting requirement, particularly if sold individually outside of the original vehicle?
- Will MPCA consider issuing industry-specific guidance or templates for aggregate product-level reporting?
- Will the agency adopt a cooperative or collaborative approach to achieve compliance, especially where supply chain data gaps exist?

Thank you for this opportunity to provide comments on this important rulemaking. If you have questions or need additional information, please contact our Senior Manager of Regulatory Affairs, Bill Erny at: berny@rvia.org.

Respectfully submitted,

Jason Rano
Vice President, Government Affairs
RV Industry Association

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May 21, 2025

VIA ELECTRONIC SUBMISSION: https://minnesotaoah.granicusideas.com/

Minnesota Office of Administrative Hearings
Pollution Control Agency Notice of Hearing on PFAS in Products Reporting and Fee Rule

Re: OAH Docket No. 5-90003-40410

The Truck and Engine Manufacturers Association (EMA) hereby submits comments: In the Matter of Proposed New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS), Revisor's ID Number R-4828. (The proposed rules).

Introduction

EMA represents worldwide manufacturers of internal combustion engines and on-highway medium and heavy-duty vehicles (greater than 10,000 pounds gross vehicle weight rating). EMA member companies design and manufacture internal combustion engines that are used in a wide variety of applications, including: trucks and buses (including school buses); farm, construction, and industrial equipment; marine vessels; locomotives; lawn, garden and utility equipment, and electric generators and other stationary applications. PFAS is widely used in a variety of applications to provide products with strength, durability, stability, and resilience. It is also known to be used for its flame retardant properties.

Engines, vehicles and equipment support every aspect of life as we know it, including the functioning of hospitals, data centers, power plants, public transport, emergency and military equipment, food production, infrastructure development and transportation and delivery of goods (including food and medicine), just to name the most obvious. These products are "essential for health, safety, or the functioning of society" as described in the definition of "Currently unavoidable use" (Minnesota Statutes 116.943). PFAS is present at the component level, in extremely small quantities, (often de minimus levels), to ensure the functionality and safety of these products. Consequently, EMA's members are significantly and directly impacted by the proposed rules.

EMA also submitted comments on November 21, 2023, on the Minnesota Pollution Control Agency (MPCA) PFAS in Products Reporting Rule and on February 28, 2024, on the planned new rules for the MPCA determination of Currently Unavoidable Uses of PFAS in products.

7026.0030 REPORT; REQUIRED INFORMATION

Timeline is too Short and Scope is too large

Manufacturers are required to submit a report by January 1, 2026. Complex products, like heavy-duty engines, vehicles and equipment are composed of hundreds of components and thousands of parts. Additionally, there is a high level of customization with heavy-duty vehicles and equipment, with a variety of options and therefore differing components.

The proposed PFAS definition is extremely broad and could encompass millions of PFAS chemistries. The MPCA Statement of Need and Reasonableness (page 9) states, "Although the commonly used EPA Test Method 1633 can test for the presence of 40 PFAS, there are potentially millions of PFAS chemicals that meet the statutory definition of "PFAS" in Minn. Stat. § 116.943. It is very difficult to track such a broad-based chemical constituent with limited testing methods and resources. The proposed reporting program will address the inability to test for specific PFAS chemicals intentionally added to consumer products by requiring manufacturers to report the PFAS used in their products."

MPCA recognizes the difficulty in identifying substances according to this definition, but they fail to recognize that imposing the same task on individual manufacturers is unreasonable. They seem to rely on the assumption that manufacturers possess this information or that it can be obtained by manufacturers via persistence in making requests to suppliers. Both assumptions are false. MPCA is ignoring reality and applying a different standard of reasonableness on manufacturers than MPCA would impose on themselves.

While EPA has defined PFAS structurally to a more narrow subset of fluorinated chemical components (which must include one of three structures containing multiple saturated or F carbon atoms), Minnesota's definition, which only requires a component to contain a chemical with one (1) fluorinated carbon atom, is significantly broader and will likely expand the reporting requirements exponentially, to include compounds that are "lightly" fluorinated. EPA explicitly excluded these from reporting requirements. MPCA's definition goes well beyond the EPA definition without establishing a need or basis for such expansion, including their likely presence in the environment and their toxicity. In prior comments, EMA has requested that MPCA establish de minimus reporting thresholds and provide a defined list of CAS identified PFAS chemistries that are subject to the requirements. The proposed rule does not include such limits. Without reasonable limits on the scope of the requirements, manufacturers face an unworkable task of investigating thousands or more parts in a global supply chain consisting of hundreds or more suppliers. The MPCA definition requires manufacturers to identify and report on any component containing a chemical with one (1) fluorinated carbon atom, which likely includes thousands of chemicals that do not have toxic or persistent qualities of concern. As a starting point, MPCA should align their definition with the EPA definition being used for the purposes of reporting.

Extensive effort will be required to investigate and identify the presence of PFAS in the complex products produced by EMA's members. Hundreds of suppliers in global supply chains, some of whom are 8 to 10 layers deep in the supply chain, hold chemical composition information for parts and components. Chemical composition information is often considered proprietary, and

disclosure is not easily obtained. Manufacturers will need to investigate thousands of components, and that process is ongoing and incomplete. Although the compliance obligations in the proposed rule are directed at the manufacturers of products, PFAS use is fundamentally controlled at the supplier level. Material tracking systems are not fully developed on an industry-wide basis and disclosure of PFAS use is fundamentally controlled at the supplier level.

EMA members and their supply chain are actively engaged in gathering information on the uses of PFAS within their products, but not all have been identified. In part this is due to the challenges in their identification as many PFAS used in mixtures have not been classified as hazardous per the Globally Harmonised System for classification and labelling. In addition, many PFAS are not shown on material data sheets even though the substance is present. Moreover, when PFAS are used in articles or articles in complex objects, the parts suppliers are currently under no regulatory obligation to highlight the presence of PFAS.

Subpart 1. Report required. (lines 5.13-8.14)

While the draft rule allows grouping products, and components within products, together if they meet certain criteria (e.g. identical PFAS chemical composition, same concentration ranges, PFAS provides the same functional properties, and the products have the same basic form and function), that criteria is so narrow that it will require manufacturers to report each individual part separately. It is unclear if a manufacturer can submit a single report for multiple brands or if multiple vehicle models may be grouped for the purposes of reporting. The proposed criteria for grouping is so restrictive and detailed, that efforts to streamline reporting will be very limited. This will result in duplicative reporting burden for almost identical products and components with little resulting added benefit or meaningful information.

As proposed, the general reporting requirement will overburden manufacturers (and likely MPCA) with a virtually unlimited data collection task on millions of parts. Since many manufacturers do not conduct or possess chemical analyses on their products or product components, and an industry database containing this information does not exist, it would be reasonable to allow manufacturers to make determinations based on harmonized tariff codes or other reasonably available public information on whether certain products are likely to contain PFAS, and conduct due diligence and report only on those products reasonably likely to contain PFAS. Less restrictive criteria for grouped reporting should allow for reporting for general product categories where PFAS is intentionally added to provide the same basic property function (for example, flame retardant, durability, etc.), allowing manufacturers to identify products and the PFAS range, within that category.

It is unreasonable to require manufacturers to report the extremely detailed information required by the rule, including chemical composition information, for thousands of parts, when the information is held by suppliers under no regulatory obligation to provide such information, and to do so in less than 8 months. Furthermore, reporting of the total organic fluorine, determined using commercially available analytical methods, is required, if the amount of PFAS is not known within applicable due diligence standards. (7026.0030 Subpart 1, C.(2), lines 7.16-7.18). Testing is incredibly burdensome and costly for manufacturers of complex products. Not all manufacturers possess the ability to conduct testing in-house. External testing resources are finite, and it is

uncertain that they could meet the increased demand.

MPCA is grossly underestimating the complexity and vastness of the data collection and reporting process and imposing unreasonable timelines and expectations on entities who do not control the information sought by MPCA. Consequently, MPCA has also significantly underestimated the costs of compliance for manufacturers and those costs have implications for product availability in Minnesota. We do not support the proposed rule language.

Reporting System is Unknown and Untested

The timeline for reporting is even more unreasonable considering that the system is unknown, has yet to be fully developed, has not been beta-tested and it is uncertain when it will be available for testing by manufacturers. It is unreasonable to assume that the system will be released and beta-tested without need for further refinement and development and that process will take time. Moreover, we are unable to assess and provide comment on the reporting system because it does not currently exist. It is fundamentally unfair to deny manufacturers an opportunity to assess and comment on the reporting system that will be at the center of compliance responsibilities. System design and implementation issues could frustrate compliance. Manufacturers are also unable to proactively, fully prepare data for submission, in the absence of knowledge and user experience of the reporting system. Beta-testing by manufacturers, consideration of feedback, and refinement of the reporting system cannot reasonably be expected to be complete in less than six to eight months. There is no timeline provided for the development, completion, and testing of the system. However, the MPCA Statement of Need and Reasonableness on page 27 states "Detailed guidance on how reporting entities can submit on behalf of multiple manufacturers will be included in the reporting system instructions or in a supplemental guidance document. This information will be available once the reporting system's functional capabilities are fully established, ensuring that entities have clear, practical steps for submission on behalf of multiple manufacturers."

MPCA is expressing that the functional capabilities for the reporting system are not fully established. Additionally, the proposed rule fails to identify how reporting identities can report on behalf of other manufacturers. MPCA indicates that these critical details will be included in other documents i.e. system instructions or supplemental guidance. Guidance documents and reporting instructions are nonbinding. This failure of the MPCA to provide critical detail in the rule, that is necessary for manufacturers to determine how to comply with the reporting requirements, is unreasonable and denies manufacturers the opportunity to assess and comment on the reporting approach. Manufacturers are also unable to effectively plan and coordinate a reporting strategy with other manufacturers, without the detail to understand the practical implications and requirements of such an approach. Although this feature is touted as a tool to reduce the burden for manufacturers, it cannot be viewed as such in the absence of detail that supports its usefulness. In the absence of the detail, and given the timeline for reporting, coordination between multiple manufacturers is more likely to delay reporting, rather than facilitate compliance.

The absence of an operational data reporting system and the lack of real experience and knowledge of the operational characteristics of the system, means that data input efforts, which are anticipated to be very time-consuming, will be further slowed as users work to develop

proficiency in using the system when it becomes accessible. The failure of the MPCA to complete development and testing of the reporting system, reasonably in advance of compliance deadlines, and the failure to provide complete details related to a primary reporting approach, in the rule (rather than yet to be developed, nonbinding guidance and reporting instructions) further compounds the unreasonableness of the proposed rule.

A functionally complete and tested reporting system and a complete rule that includes critically important details including how entities can report on behalf of other entities must be available for review and comment by manufacturers. Moving forward without these crucial details and an opportunity for comment, is unreasonable.

7026.0080 DUE DILIGENCE

Subpart 2. Supply chain requests (lines 13.13-13.15)

The proposed rule requires manufacturers to request detailed disclosure of information from their supply chain until all required information is known. This sets up a requirement for never-ending inquiries to supply chains, even when it is evident that additional information will not be forthcoming. Information may be unattainable for many reasons including uncooperative suppliers, or simply a lack of available detail to disclose. If suppliers are unresponsive or do not have information to disclose, the manufacturer does not have the ability to compel a response. Similar reporting requirements have utilized a more reasonable standard of due diligence, described as "what is known or reasonably ascertainable." The standard of due diligence in the proposed rule is extreme, unnecessary, and completely unreasonable. It serves no purpose other than to impose additional burdens on manufacturers attempting to make good faith efforts to comply with reporting requirements. This is a completely unattainable standard of due diligence that essentially ensures non-compliance and may impact product availability in the state.

Subpart 3. Documentation and recordkeeping (lines 13.16-14.3)

The proposed rule requires documentation of all communication with suppliers to be kept for at least five years after products containing intentionally added PFAS are removed from the supply chain (paragraph C). The language is confusing and the requirements to maintain documentation are open-ended. If PFAS remains in use in a component as a "currently unavoidable use", does that mean that records related to that PFAS and/or part must be kept forever? Reasonable limits on the length of time that documentation must be kept, should be included in clear, understandable language. Retention of documentation should not be required beyond 5 years after submission of a report.

7026.0020 PARTIES RESPONSIBLE FOR REPORTING

(lines 4.4-4.23)

The proposed rule is not clear in identifying responsibility for reporting for complex products, service parts, and other components if there is not a reporting agreement in place. In the case of a complete motor vehicle, is the original equipment manufacturer responsible to report for

components in the vehicle? Is the component manufacturer, or both? Are service parts to be reported by the original equipment manufacturer if they are branded by the supplier?

(lines 4.21-4.23)

In the case of a reporting agreement, verification is not considered complete if all manufacturers do not submit the required fee. In the case of a manufacturer reporting on behalf of suppliers, and one of the suppliers does not pay the fee, the verification would not be considered complete and the manufacturer would be noncompliant. This effectively punishes the entity assuming the burden of reporting and compliance for the failure of a supplier over which the reporting entity has not control. This is not reasonable and will deter the use of reporting agreements, resulting in duplicative reporting, and increasing the burden of compliance on manufacturers. Duplicative reporting will result in less reliable, less representative, information about the presence of PFAS in the supply chain and in products.

7026.0040 REPORTING UPDATES

(lines 9.2-9.12)

The proposed rule requires annual updates or recertification if an update is not required. Updates should only be required if new information subject to reporting requirements related to PFAS content has been obtained, or if the manufacturer has new products falling within the scope of the rule, containing intentionally added PFAS. The language is vague and does not reasonably restrict the requirement for updates. The proposed rule also requires annual recertification in the absence of new information. This is onerous and provides no additional benefit while imposing significant reporting burden on manufacturers, along with an added fee to simply recertify previously reported information for which a fee has already been paid. The requirement for recertification is unreasonable.

7026.0060 EXTENSIONS

Subp.3. Extension request deadline; approval or denial. (lines 12.1-12.15)

The timelines in the extension request provisions do not provide sufficient time for manufacturers to report if an extension request is denied close to the deadline. Restricting extensions to 90 days is also unreasonable if manufacturers provide information that supports the need for a longer extension. Similarly, it is not clear that there is authority to grant multiple extensions.

Additionally, the extension language only references the 7026.0030 report criteria and the reporting due date detailed in 7026.0030. Extensions should also be available for “Reporting Updates” in 7026.0040 (updates and recertification) but there is no reference to extensions in those provisions (7026.0040) or under this section, 7026.0060 “Extensions”.

7026.0050 WAIVERS

Subp.4. Waiver request deadline (lines 11.1-11.9)

The timelines in the waiver request provisions do not provide sufficient time for manufacturers to report if a waiver request is denied close to the deadline.

7026.0070 TRADE SECRET DATA REQUEST

The information elements eligible for trade secret protection are far too narrow and could put commercially sensitive information in the public domain. Suppliers will be reluctant to fully disclose chemical information if they are concerned about a lack of robust CBI protection.

7026.0100 FEES Subparts 2 and 3 (lines 14.18-15.22)

In the case of a reporting agreement, submittal of the report is not considered complete if all manufacturers do not submit the required fee. In the case of a manufacturer reporting on behalf of suppliers, and one of the suppliers does not pay the fee, the report would not be considered complete and the manufacturer would be noncompliant. This effectively punishes the entity assuming the burden of reporting and compliance for the failure of a supplier over which the reporting entity has not control. This is not reasonable and will deter the use of reporting agreements, resulting in duplicative reporting, and increasing the burden of compliance on manufacturers.

Fees are also imposed for waiver requests, extension requests and are imposed annually for recertification. In addition, an automatic inflation adjustment is included. The fees are excessive, and duplicative where manufacturers are reporting as a group and fees are collected from individual manufactures in that group, despite there being a single report to process. The fees approach is unreasonable.

CURRENTLY UNAVOIDABLE USE DETERMINATION CRITERIA HAS NOT BEEN PROPOSED

The MPAC has chosen to treat the currently unavoidable use (CUU) determination as a separate rule but they have yet to release a rule proposal related to the criteria to be used and the process that will be implemented to make CUU determinations. They have sought initial input on the CUU determination process and EMA submitted comments on February 28, 2024.

The reporting rule and the CUU determination process cannot reasonably be considered in isolation from each other. EMA's members are manufacturers of complex products with a significant number of components that may contain PFAS. It is also likely that substitutes for the use of PFAS will not be readily available for many of the current uses in the products that EMA members produce. Manufacturers will need to seek CUU determinations to allow them to continue to sell products in Minnesota that contain PFAS. The initial information shared by MPCA in 2024 related to the approach to CUU determinations, outlined an approach that is extremely burdensome, time-consuming and challenging. That information was preliminary in nature and a

rule proposal has yet to be released. The failure of the MPAC to complete and make available for comment, a CUU rule proposal, concurrently with the reporting and fees rule proposal, severely undermines the ability of manufacturers to fully assess, comprehend and comment on the aspects of the PFAS approach that have been released for comment. The impacts of reporting and the process for seeking CUU determinations are cumulative in impact and will apply to the same entities.

Manufacturers will need to consider the reasonableness of the CUU determination process, and assess their ability to seek and secure CUU determinations where necessary, while also considering the burden of PFAS reporting. Manufacturers must also consider the feasibility of the reporting system that has yet to be identified and tested and whose functional capabilities are not fully established, according to MPCA.

Furthermore, contrary to the assertion of MPCA on page 46 of the Statement of Need and Reasonableness, manufacturers can support the essential need of PFAS in their products for the CUU rule, without the burden of the reporting rule. The reporting rule should not be viewed as a necessary precursor to the CUU determination.

The reporting rule and the CUU determination each have the potential to impact product availability in the state and manufacturers will consider the feasibility of the reporting rule and their ability to successfully secure CUU determinations as they assess the implications of the PFAS reporting rule and yet to be proposed CUU rule. In fact, it is unreasonable to separate the assessment of the reporting rule and the CUU rule. If the CUU proposed rule is infeasible, manufacturers will be unwilling to assume the burden of reporting, knowing that they will be unable to clear the hurdle of the CUU determination. Moreover, if the burden of reporting, or the burden of seeking a CUU determination, or the combined burden, is too excessive, manufacturers will act accordingly. The burden of each rule rests on the same entity and must be considered together to fairly assess the need and reasonableness of each part.

We appreciate the opportunity to provide these comments. Please do not hesitate to contact Dawn Friest at (519) 999-4480 (or at dfriest@emamail.org) if you have any questions.

Respectfully submitted,

TRUCK & ENGINE
MANUFACTURERS ASSOCIATION

139802.3

Flexible Packaging Association
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May 21, 2025

The Honorable James Mortenson, Administrative Law Judge
Minnesota Office of Administrative Hearings (OAH)
600 North Robert Street
PO Box 64620
St. Paul, Minnesota 55164-0620
Submitted electronically via Office of Administrative Hearings (OAH) Rulemaking eComments Website

Re: PFAS in Products: Reporting and Fees Rule

OAH Docket Number 5-9003-40410

Dear Judge Mortenson,

The Flexible Packaging Association (FPA) is pleased to offer these comments to the Minnesota Pollution Control Agency (MCPA) in response to the proposed PFAS in Products: Reporting and Fees Rule developed by the Agency.

FPA represents flexible packaging manufacturers and suppliers to the industry in the United States. Flexible packaging represents $42.9 billion in annual sales; is the second largest, and fastest-growing segment of the packaging industry; and employs approximately 85,000 workers in the United States. Flexible packaging is produced from paper, plastic, film, aluminum foil, or any combination of these materials, and includes bags, pouches, labels, liners, wraps, rollstock, and other flexible products. We are submitting these comments to help the State establish a reporting process for understanding when and where PFAS is added to products and when that addition is intentionally added versus currently unavoidable.

I. Definitional Clarity Around Packaging

In evaluating the proposed regulations, we are unsure how the definition of products with intentionally added PFAS might apply to our member's products—flexible packaging—as there are a few different explanations across the regulations. We suggest some additional clarity is merited as follows:

7026.0010

Subp.7. ("Component")

Per the regulation a component "*means a distinct and identifiable element or constituent of a product. Component includes packaging* ***only when the packaging is inseparable or integral to the final products containment, dispensing or preservation***.

Subp16 ("Packaging)

Refers to Minnesota Statute section 115A.03 which defines packaging as "*a container and any appurtenant material that provides a means of transporting, marketing, protecting or handling a product. "Packaging" includes pallets and packaging such as blocking, bracing, cushioning, weatherproofing, strapping, coating, closures, inks, dyes, pigments and labels*."

We are interpreting the regulation to require reporting on all packaging formats and components containing intentionally added PFAS , and that we should define them as either components **or** packaging under the description. Further clarity within the regulations to set the boundary of when packaging is considered a product requiring reporting or not would be helpful. If our interpretation is correct, we recommend adding a line to 7026.0020 Subpart1 "Scope" that states: "a manufacturer or group of manufacturers of a product **and its packaging sold…"**

Furthermore, while we believe it is implied in the statutory language that food service packaging would be exempt from this regulation due to the state's prohibition on intentionally added PFAS in food packaging products (Minnesota State 325F.05), some additional language within the regulations to clarify this would be beneficial.

II. Responsibility for Reporting

7026.0020 Item C

This section requires each manufacturer reporting via a group submission to: "*verify…that data submitted on their behalf is accurate and complete*." Requiring each individual manufacturer to verify

seems to contradict the intent of group reporting. We suggest the certification process could be better met by including a component within the group submission in which the reporting manufacturer certifies that it has contacted the other manufacturers included in the submission and that those manufacturers have assured the information provided in the report is accurate and complete. This would avoid the need for individual verification by each member of the group and would reduce the administrative workload of this requirement.

III. Group Submission Requirements

7026.0020 Item D

We propose an amendment to Item D so that failure to make payment by an individual manufacturer would not fail the entire group submission, but rather be tied to that specific individual manufacturer. We are concerned with multiple different manufacturers involved in a group submission, each with different payment processing requirements, unfairly penalizes those who are compliant. Furthermore, we do not believe competitors should bear the burden of making sure their fellow peers have made payments, nor be penalized for any oversights their peers may make. Peer companies do not have this type of influence over each other.

IV. Reporting Updates

7026.0040 Subpart 1 Updates Required.

As it currently reads, this section implies reporting is indefinite. We recommend this be amended to indicate that the last date to report is February 1, 2032, as stipulated in Minn Stat. § 116.943, subd 5(c), that all products that have not received a currently unavoidable use designation are prohibited for sale within Minnesota by January 1, 2032.

V. Conclusion and Next Steps

Thank you for the opportunity to comment, and your consideration of our recommendations on the MPCA's PFAS in Products: Reporting and Fees Rule. If we can provide further information or answer any questions, please do not hesitate to contact me at (602) 540-7544 or kfisher@flexpack.org.

Respectfully,

Kyla Fisher
Director of Regulatory Affairs and Sustainability
Flexible Packaging Association

RECEIVED
By: OAH on 5/21/2025
Andrew Bemus Attachment

SUSTAINABLE PFAS ACTION NETWORK

March 21, 2025

Administrative Law Judge Jim Mortenson
Minnesota Office of Administrative Hearings
600 North Robert Street
PO Box 64620
St. Paul, MN 55164-0620

Re: **In the Matter of Proposed New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS), Revisor's ID Number R-4828**

OAH Docket No. 5-9003-40410

Dear ALJ Mortenson:

SPAN is writing to provide these comments in response to the Minnesota Pollution Control Agency's ("MPCA" or "Agency") Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees (the "Proposed Rule"). SPAN appreciates MPCA's willingness to confer with SPAN previously and to consider these new comments on the Proposed Rule. As you know, SPAN is a coalition of PFAS users and producers committed to sustainable, risk-based PFAS management. Our members advocate for responsible policies grounded in science that provide assurance of long-term human health and environmental protection while recognizing the critical need for certain PFAS materials for U.S. economic growth and global competitiveness. SPAN was formed with the objectives of ensuring legislators and regulatory agencies are aware of the essentiality of products generated by our members while simultaneously supporting practical regulatory programs focused on protecting human health and the environment and maintaining America's global economic edge.

General Comments

Minnesota currently has the most expansive PFAS in products law in the country. For example, Minnesota currently is the only state that requires product-content reporting on all PFAS-containing products. As we approach the January 1, 2026, deadline for all manufacturers in the state to report their PFAS usage, SPAN strongly encourages MPCA to delay the impending reporting deadline so that reporting program is implemented effectively; providing sufficient time for all affected entities to fully understand and be able to fulfill their reporting obligations.

If the reporting program goes forward in its current state, entities having reporting obligations in Minnesota will face massive economic and regulatory burdens, and MCPA will experience administrative obstacles and suffer resource limitations that will be very difficult to fix after the fact. Many of the entities that will be required to report on January 1 of next year use thousands of products that proceed

along varied international supply chains. Manufacturers will need substantially more time to gather information and make a good faith effort to comply with the law. They need a final rule that clearly establishes the reporting requirements. They also will need guidance on the application of those regulations to their specific situations, and both MPCA and manufacturers will need additional time to become familiar with whatever reporting platform MPCA will use. Right now, even if a reporting platform can be developed and activated, MPCA is likely to receive varied and disjointed submissions in January of next year, which will make it difficult for the agency to process and to meaningfully use the data in any fashion. SPAN therefore believes MPCA must delay the reporting deadline to at least one year after the promulgation of the final rule and release of the reporting platform.

To further ease the burden, both on MPCA and manufacturers, SPAN suggests that MPCA consider phasing in the reporting requirements, looking at a finite number of PFAS and product categories to start. In this way, both MPCA and manufacturers will gain experience with reporting and the resources it entails, so that subsequent phases can incorporate lessons learned and make the process as efficient as possible.

Our comments on specific provisions in the Proposed Rule follow.

Definitions

The Proposed Rule requires the submission of a report by a manufacturer for each product or component that contains intentionally added PFAS. "Component" is defined as “a distinct and identifiable element or constituent of a product.” The Proposed Rule defines “Identifiable element" as “an element that can be recognized, distinguished, or discerned, even when not visually evident, as in the case of a mixture or formulation.” This definition results in a significant burden being placed on a product manufacturer in determining if PFAS is present in every single component. A component is literally any part of the product, no matter how small or insignificant. If MPCA truly wants useful information that can be efficiently obtained, this definition must be modified so that identifiable elements are truly distinct and separate components that appear as such to the consumer.

Reporting and Required Information

In an effort to ease compliance for manufacturers, MPCA has proposed allowing groups of manufacturers to jointly report, and for reports to cover groups of similar products. However, the criteria that must be met for a manufacturer to avail themselves of these tools are so specific that the likelihood is that they can never be used. What may appear to be identical products from different manufacturers, can often vary in material composition. In fact, variation in material composition can occur even in a single product from the same manufacturer, as components may be sourced from different suppliers during the course of a year for example. Thus, products thought to be “identical” may end up upon closer examination to not be exactly “identical” as there may be slight variations in the PFAS used or the quantity of a PFAS used.

SPAN suggests that MPCA should provide greater flexibility in the joint reporting process. MPCA could permit a report to contain multiple entries for “PFAS used” or multiple concentration ranges to cover all similar products within one product category. The report would still show that PFAS is present in the products covered in the report, which provides MPCA with the information being sought. At the same

time, the compliance burden for manufacturers – and the administrative burden for MPCA – is eased as there is no longer need for numerous individual reports.

SPAN further suggests that MPCA add flexibility in reporting some of the specific data points requested. Due to the complexities that exist in multi-layered global supply chains, it may be extremely difficult for manufacturers to get precise information on PFAS content from suppliers. SPAN believes that the need for obtaining information that underlies the reporting requirement can still be met by allowing, if necessary, manufacturers to report, for example, that PFAS are present as opposed to the particular PFAS used and specific concentration range. MPCA should acknowledge these complexities and balance the need for information against the resources needed to obtain it, assuming it can be obtained.

Annual Updates and Recertification

Under the Proposed Rule, by February 1 of each year, manufacturers must either update their reports to reflect changes to information previously submitted or recertify the previously submitted report.

SPAN understands that MPCA desires to obtain and to maintain information such that it remains accurate and up to date. SPAN recognizes the need for manufacturers to provide updated information when facts change. However, once the regulation imposes the basic requirement that a manufacturer has an affirmative obligation to report updated information, that is all that MPCA needs to do to ensure its information remains accurate. SPAN believes that the requirement in the Proposed Rule for an annual recertification is not needed and only serves to further burden manufacturers doing business in Minnesota – both with a compliance obligation and with a needless fee. Consequently, SPAN requests that the requirement for updates to be made when changes do occur be retained, while the annual recertification requirement and accompanying annual fee be removed.

Waivers

In the Proposed Rule, MPCA again evidences a willingness to ease compliance by allowing the commissioner to waive all or part of the information required if substantially equivalent information is publicly available. SPAN suggests that MPCA issue a general waiver for manufacturers that are also submitting data under the EPA's TSCA Section 8(a)(7) PFAS reporting rule. This would help avoid duplicative work and reduce compliance costs.

Protection of Confidential Business Information

The confidential business information of SPAN members – like that of most any business – can include vital intellectual property assets, and even sensitive national security information. Protecting the confidentiality of such information ensures that companies can innovate, compete fairly, and contribute to economic progress without the risk of losing their valuable know-how to competitors. Companies invest significant time, money, and resources into developing their proprietary knowledge.

The Proposed Rule recognizes that this information needs protection and establishes procedures to ensure that "trade secret data," is considered "not public." SPAN understands that the reporting platform MPCA intends to utilize is the Interstate Chemicals Clearinghouse (IC2) High Priority Chemicals Data System, an application that allows manufacturers to submit data on chemicals in products, and for participating states and the public to access that data. SPAN has serious concerns about how the trade

secret data submitted in reports will be protected from disclosure to others (and perhaps the general public) who can access the same systems. As this database is a system shared by multiple states, it appears that other jurisdictions will have access to this very information. SPAN requests that MPCA provide further details concerning how MCPA will indeed ensure that trade secret data will be protected and not made public.

The Standard for Due Diligence

The Proposed Rule currently states that manufacturers must keep asking suppliers for data "until all required information is known". This standard is unrealistic, especially for makers of complex products with thousands of component parts and independent suppliers located all over the world. Even if all the suppliers of components could be identified, there is no guarantee that they will timely respond to requests for information. Making requests for information ad infinitum of suppliers carries no guarantee that information will indeed be provided, and no guarantee that all required information will eventually be known – much less in a timely way.

The US EPA uses a more practical standard: companies must report what is "known to or reasonably ascertainable by" the reporter. This standard balances the need for data with the realities of global manufacturing. It is a standard with which industry is familiar and has been utilized successfully by EPA for many years. SPAN believes that if MPCA maintains the due diligence standard in the Proposed Rule, MPCA will be forcing the expenditure of valuable time and resources that will still ultimately result in non-compliance.

Fees

SPAN requests that MPCA clarify the fee structure. SPAN believes that any fee levied should be a one - time fee per manufacturer – not per report. If a fee was required for each report, the cost for manufacturers, especially those with many products, could be massive. SPAN requests that MPCA state in clear and unambiguous terms that the fee to report the first time is a one-time obligation of $1,000 for each manufacturer, regardless of how many reports that manufacturer submits.

As mentioned above, SPAN believes that annual recertification is unnecessary and should not require a fee when no changes have occurred. Accordingly, should MPCA maintain the annual recertification requirement, SPAN requests that the fee for the recertification be eliminated. A fee for a simple statement that nothing has changed is not warranted.

Exemptions

The Proposed Rule contains an exemption for reporting for a product for which federal law governs the presence of PFAS in the product in a manner that preempts state authority from the reporting requirements. SPAN requests that MPCA consider additional exemptions, such as for semiconductors, including semiconductors incorporated in electronic equipment, and materials used in the manufacture of semiconductors. Such an exemption has precedent, most recently in New Mexico's PFAS in products law[1]. Additionally, we recommend MPCA add fluoropolymers to the list of Reporting Exemptions in 7026.0090. Fluoropolymers are unique in that they are not water soluble and have a high molecular

[1] New Mexico HB 212 of 2025

weight. Fluoropolymers are critical for many applications and without viable alternatives, health, safety, and economic stability could be severely impacted. We recommend amending 7026.0090 to add:

> F. a product that contains fluoropolymers consisting of polymeric substances for which the backbone of the polymer is either a per- or polyfluorinated carbon-only backbone or a perfluorinated polyether backbone that is a solid at standard temperature and pressure.

Additionally, the exemption should apply to products that are required to meet standards or requirements of the Food & Drug Administration (FDA), Significant New Alternatives Policy (SNAP), United States Department of Transportation, Federal Aviation Administration, the National Aeronautics and Space Administration, the United States Department of Defense or the United States Department of Homeland Security. [2]

Conclusion

SPAN requests that MPCA carefully consider these comments and those submitted by other stakeholders. SPAN stresses that failure to implement some of the requested changes will adversely affect manufacturers that do business with or in Minnesota. As always, SPAN welcomes the opportunity to meet with MPCA staff to discuss and clarify our comments as MPCA continues with the rule promulgation process.

[2] See, for example, 38 Maine Revised Statutes 1614(4)

RECEIVED
By: OAH on 5/21/2025

Bruce Nustad Attachment

Minnesota RETAILERS
driving innovation, succeeding together

ELECTRONIC SUBMISSION ONLY

May 21, 2025

Honorable Judge Jim Mortenson
600 North Robert Street
St. Paul, MN 55101

Re: Minnesota Pollution Control Agency's Notice of Intent To Adopt New Rules Governing Reporting And Fees By Manufacturers Upon Submission of Required Information About Products Containing Per-And Polyfluoroalkyl Substances (PFAS), Revisor's ID Number R-4828, OAH Docket Number 5-9003-40410

Thank you for the opportunity to comment on the proposed rules related to PFAS in products. Minnesota Retailers represents 220 companies operating over 1,200 retail locations across the state, including local businesses, regional chains, and national brands. Our members support responsible environmental stewardship, and many have worked hard to respond to evolving chemical disclosure regulations. However, we have several concerns about the feasibility and clarity of the current proposed rules.

1. Retailer Access to PFAS Information

Retailers are typically not manufacturers of the products they sell and often have limited visibility into the specific chemicals used in those products, including own brand or national brand items manufactured by third-party vendors. PFAS can be used in complex supply chains and in microscopic quantities that are not apparent or disclosed to the retailer.

As proposed, the rule would require retailers to report intentionally added PFAS in products, but this is often information we do not have, cannot verify, and cannot legally compel from vendors. Without a clear mechanism for relying on supplier certifications or upstream declarations, this requirement will be extremely difficult, if not impossible, to meet accurately.

2. Inaccessible PFAS Use in Products

We request the MPCA consider an exemption or alternate pathway for products where PFAS is intentionally added but inaccessible to the consumer and serves a functional, technical purpose. For example, PFAS used as wire insulation inside a sealed home appliance does not present the same consumer exposure risk as other applications. Including such components in the same reporting framework adds significant burden without clear environmental or health benefit.

3. Due Diligence Standard is Too Broad

The proposed rule includes a due diligence obligation that appears to continue until all required information is known. This creates an indefinite and impractical standard for retailers, who may engage in extensive outreach and certification efforts without being able to guarantee full disclosure from upstream suppliers. We recommend aligning due diligence standards with other state-level product compliance frameworks that recognize good faith efforts and allow for certification reliance, rather than an unattainable threshold of absolute certainty.

4. Delegating Reporting Responsibilities

We ask the MPCA to clarify whether a retailer can formally notify vendors of Minnesota's reporting obligations and delegate the responsibility for compliance—especially for own brand, importer of record, or national brand products. If so, we also ask for clarification on whether the retailer remains legally liable if a vendor fails to report. Retailers need certainty on who holds the obligation in the supply chain in order to avoid duplicative or missed reporting.

5. Waiver and Extension Timelines

Retailers appreciate the ability to request a waiver or extension, however, the rules do not provide adequate timeframes or contingency allowances in the event a request is denied. If a waiver is rejected close to a compliance deadline, the retailer may not have enough time to gather the necessary information or complete a report. We urge the MPCA to build in a reasonable buffer period or an automatic temporary extension in these scenarios.

6. Trade Secret Protection is Too Narrow

We are concerned that the current list of data elements eligible for trade secret protection is too limited. Retailers and suppliers may be required to disclose proprietary product identifiers, functional descriptions, or vendor relationships that are commercially sensitive. We urge the MPCA to broaden the scope of allowable trade secret claims and offer clear guidance on how protected information will be handled to avoid unnecessary public disclosure of confidential business data.

7. Initial $1,000 Reporting Fee Clarity Needed

The rule currently lacks clarity around the initial $1,000 product reporting fee. Unlike the $500 annual recertification fee, the reporting fee is not clearly defined as a flat fee, and the rule is inconsistent about how it is applied. In some instances, the rule suggests it applies per manufacturer, in others by product group, and in other sections it references similar component parts. This ambiguity creates significant uncertainty about potential compliance costs. We urge MPCA to clarify how the fee is calculated and applied, and if multiple interpretations are possible, to adopt the least burdensome, lowest-cost structure.

8. Request for Multi-State Reporting Harmonization

We encourage MPCA to consider opportunities to harmonize its reporting system with those of other states implementing similar PFAS reporting requirements. Retailers and manufacturers that operate nationally or regionally face significant burdens in preparing unique reports for each state. A coordinated or interoperable system would reduce redundancy, lower compliance costs, and improve data consistency. We urge MPCA to engage with other state agencies and stakeholders to explore ways to align reporting formats, definitions, and submission processes wherever possible.

9. Guidance on Submissions on Behalf of Multiple Entities

In its Statement of Need and Reasonableness, MPCA indicated that it will provide guidance for how reporting entities can submit on behalf of multiple manufacturers. We agree that clear, practical steps for this submission approach are essential. Given the January 1, 2026 reporting deadline, it is critical that MPCA provide this guidance as early as possible to ensure reporting entities—particularly retailers—have sufficient time to adapt systems, coordinate with partners, and meet compliance requirements effectively.

We support efforts to phase out chemicals like PFAS when alternatives are feasible and effective. However, the proposed rule must account for the realities of complex retail supply chains, the limits of retailer control and knowledge, and the need for balanced, practical implementation timelines and responsibilities. We encourage MPCA to revise the rule to clarify roles, protect confidential business data, and ensure the regulation is workable for the retail sector.

We appreciate your consideration of our comments and welcome the opportunity to continue the conversation.

Sincerely,

Bruce Nustad
bruce@mnretail.org

CLEAN WATER ACTION
PEOPLE • ACTION • JUSTICE

May 10, 2025

The Honorable Jim Mortenson
Minnesota Office of Administrative Hearings
600 North Robert Street PO Box 64620
St. Paul, Minnesota 55164-0620

Dear Judge Mortenson,

Thank you for the opportunity to comment on the "Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees (PFAS), Revisor's ID Number R-4828".

Clean Water Action has worked in Minnesota since 1982, focusing on finding solutions to health, consumer, environmental and community problems, developing strong, community-based environmental leadership, and working for policies that improve lives and protect water. Our focus includes supporting environmental justice, protecting and restoring the Great Lakes for Minnesota, ensuring safer chemicals for use in our homes and daily lives, as well as source and toxics reduction in plastics and other forms of waste. All our work culminates in the overarching goal of protecting the water we drink for generations to come.

The use of PFAS in consumer products, from firefighting foam to clothing and cosmetics, has caused extensive contamination of drinking water, wildlife, food, and people. One of the primary reasons this contamination has occurred is that companies have not been required to disclose whether harmful chemicals are put into products. This new law in Minnesota and the resulting rules will help to rectify this problem. It will assist consumers in avoiding PFAS and allow the government agencies to know where PFAS are used in products and inform the PFAS ban. A strong rule is urgent and necessary to protect public health, drinking water, and the environment.

As the organization that led the work to pass Amara's Law in 2023, we are well versed in the arguments being made to extend deadlines, exempt certain products, and prolong the use of these chemicals that are linked to negative health impacts such as pre-eclampsia, low birth weight, learning disabilities, thyroid conditions, and cancer. We're also well versed in the progress being made around the world to phase out the use of these chemicals in consumer items and fire fighting foam.

1) Reporting – Waivers

Currently, the proposed rule allows for extensions and requires justification for the extension, but it does not offer guidance on how they will determine if a justification is valid/acceptable. This is an arbitrary process that should be clarified to prevent confusion.

Also, the proposed rule does not clarify that extension requests are only available once and cannot be renewed. The regulations should be clear that extensions shall not be renewed.

2) Trade Secrets

Currently the trade secrets provisions allow for the presence of PFAS to be considered a trade secret. The need to protect public health and give public information about the presence of PFAS

should override any trade secret concerns. We recommend that if the presence of PFAS is claimed as a trade secret, that the entity demonstrate to the agency the steps it takes internally to keep this information secret. Additionally, while the presence of a specific PFAS may be a trade secret, we recommend adding a provision that requires the disclosure of the use of PFAS generally in a product.

3) Internal Components

Many manufacturers are requesting that internal components be given an exemption or extension via the rule making process. This argument was presented to the legislature during the deliberations around Amara's Law and was rejected for several reasons. First, internal components that contain PFAS threaten the workers that manufacture and fix these components. Professions such as appliance repair technicians, furniture repair technicians, and vehicle mechanics are exposed to the chemicals that internal components contain. Second, the legislature was clear that the threat from PFAS was not merely from everyday use but also from manufacture and disposal of the products. 98 out of Minnesota's 101 landfills are leaching PFAS into the ground water. When items with PFAS are disposed of in landfills, those chemicals eventually make their way to our taps. No special exemption or extension should be given for internal or electronic components in the rule making process.

4) Information Disclosure & Supply Chain Exemptions

It is the responsibility of manufacturers to understand their supply chain to keep their customers informed and safe. Amara's Law requires information disclosure on "intentionally added PFAS" which means that PFAS was intentionally added to serve a function. It's added for a specific purpose related to the functioning of the product. It's our perspective that if a manufacturer is adding PFAS for a specific purpose, they should know about it.

Multiple states require information disclosure. If they can report in other states, they can comply in Minnesota.

Minnesota has been subject to national and international inquiry. Other states and countries are seeking to follow our lead related to turning off the tap of toxic PFAS. They understand exposure to these chemicals has long lasting consequences for human health, the environment, and taxpayers. It's important that Minnesota gets this right. We urge strong rules that honor the integrity of Amara's Law. Minnesota cannot afford the billions of dollars it will take to clean PFAS out of our environment. And our families cannot afford more loss and heartache when life is lost.

We must act now. We must act swiftly. We must act together.

Sincerely,

Avonna Starck
Clean Water Action
Minnesota State Director

WABASH™

Wabash 765-771-5443 onewabash.com

1000 Sagamore Parkway S.
Lafayette, IN 47905

May 21, 2025

VIA ELECTRONIC SUBMISSION: ***https://minnesotaoah.granicusideas.com/***

Honorable Judge Jim Mortenson
Administrative Law Judge
600 North Robert Street
St. Paul, MN 55011

RE: Minnesota Pollution Control Agency's Notice of Intent to Adopt New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per- and polyfluoroalkyl substances (PFAS), Revisor's ID Number R-4828, OAH docket number 5-9003-40410

Hon. Jim Mortenson:

Wabash National Corporation ("Wabash") hereby submits comments to the Minnesota Pollution Control Agency ("MPCA") regarding the subject proposed rule ("Proposed Rule"). Wabash is headquartered in Lafayette, Indiana with business locations across North America. Wabash is a world-class manufacturer of advanced engineered solutions and services for transportation, logistics and infrastructure markets and delivers innovative solutions for a wide range of customers to optimize their end-to-end supply chains across these markets. Wabash manufactures dry van and refrigerated semi-trailers, platform trailers, tank trailers, truck bodies, and other products for the transportation and shipping industries. Wabash appreciates the opportunity to comment on the following aspects of the Proposed Rule.

1) **Scope (Part 7026.0020, Subp.1): Clarification to the phrase "distribute for sale" and to reporting of "first" sales, offers for sale and distribution for sale**

Wabash recommends that Part 7026.0020, Subp. 1 (Scope) be revised to clarify which manufacturers and which products are subject to the Proposed Rule. As drafted the "Scope" provision states:

> **A manufacturer or group of manufacturers of a product sold, offered for sale, or distributed in the state must submit a report for each product or component that contains intentionally added PFAS.**

Wabash suggests two clarifications to the Scope. First, the Proposed Rule includes a definition of the phrase "Distribute for sale" in Part 7026.0010, Subp. 9, but this phrase is not consistently used in the remainder of the Proposed Rule including in the "Scope," which only mentions products…. "distributed in the state." Wabash believes the provision should use the defined term as follows: "distributed *for sale*…in the state."

Second, as drafted the Scope creates a potentially signficant ambiguity as to when a manufacturer must report intentionally added PFAS in a product. There are likely many situations in which a manufacturer sells the product to one entity in the chain of distribution (the "first buyer"), and the first buyer then sells the product to another buyer or to an end consumer (the "second buyer"). In many situations it would be impossible for the manufacturer to track a product after it is sold to the first buyer. If the manufacturer sold the product to the first buyer located in another state, and the first buyer sold it to the second buyer that is located in Minnesota without the manufacturer's knowledge, the manufacturer could not report on this sale as the Proposed Rule is drafted.

The Proposed Rule does not address this common situation, and Wabash believes this should be resolved by adding the word "first" as follows (and also including the "distribute for sale" change from above):

> ***A manufacturer or group of manufacturers of a product first sold, first offered for sale, or first distributed for sale in the state must submit a report for each product or component that contains intentionally added PFAS.***

Wabash notes that while the Proposed Rule does not address this directly, it does cover a similar concept in the definition of "manufacturer," which ends with the statement:

> ...In the case of a product that is imported into the United States when the person that created or produced the product or whose brand name is affixed to the product does not have a presence in the United States, manufacturer means either the importer or the **first** domestic distributor of the product, whichever is **first** to sell, offer for sale, or distribute for sale the product in the state. Emphasis added.

The same concept should apply to manufacturers within the United States as it does for importers.

2) **Deadline (Part 7026.0030, subp. 1): The January 1, 2026 initial report deadline is not reasonable or practically implementable given the current status of the rulemaking process and should be revised to 18 months following the effective date of the final rule.**

Wabash understands that Amara's law, passed in 2023, set the initial reporting deadline as January 1, 2026. However, with the Proposed Rule public comment period ending on May 21, 2025 and a final rule unlikely to be in effect until later in 2025, the timeframe for manufacturers to take all necessary actions to comply with the initial reporting deadline is not feasible.

Consider that in the Statement of Need and Reasonableness ("SONAR") for the Proposed Rule, MPCA acknowledges (regarding Part 7026.0020, Subp 2, Item A) that it does not have the reporting

system, instruction manual and/or guidance document ready at this time.[1] This is just one example of the type of critical information/guidance that is needed, but is not yet available, to manufacturers in order to meet the reporting goals and requirements. More broadly, MPCA recognizes that significant diligence may be required for manufacturers with complex supply chains to gather information that is required to be reported. Without a final rule (and possibly guidance and/or instructions), it will prove to be infeasible for most manufacturers to digest the final rule requirements and to-be issued instructions and/or guidance, perform all required diligence, vet the information obtained, discuss the information with relevant stakeholders, come to agreements with multiple manufacturers in the supply chain for combined reporting, and fill out the information in the reporting system.

Wabash recommends that MPCA work with the Minnesota legislature (as needed) to extend the initial reporting deadline until 18 months following the effective date of the final rule. Without extending the time period for the initial report, MPCA may (or is likely to) experience a great number of extension requests that MPCA will have to individually process. This would not be an efficient use of time and resources for MPCA or thousands of manufacturers.

3) **Due Diligence (Part 7026.0080, subp. 2): The due diligence requirement is overly burdensome and should be revised to provide a reasonable end point to the level of diligence a manufacturer must perform**

Unlike the "known or reasonably ascertainable" standard in the EPA TSCA PFAS Reporting Rule, the Proposed Rule requires manufactures to "request detailed disclosure of information required in Part 7026.0030 from their supply chain ***until all required information is known***.

Wabash appreciates MPCA's goals with the Proposed Rule, as stated in the SONAR to "gather comprehensive and accurate data on PFAS in products," and that "this thorough approach ensures that all relevant PFAS data is captured…" But the reality is that a manufacturer may never be able to meet this standard given the complexities of supply chains, the number of components that may be involved in products, and the potential for slow responses or no responses from suppliers.

Wabash understands that the Proposed Rule's extension process is in part intended to address this challenge, but the "until all information is known" standard may in practice be impossible to achieve. Wabash therefore supports a slightly more flexible standard, such as the "known or reasonably ascertainable" standard of the EPA TSCA Reporting Rule. If the Proposed Rule is not modified, MPCA is likely to receive a great number of extension requests, possibly repeatedly, which would not further MPCA's goals of gathering relevant data on intentionally added PFAS in products sold, offered for sale, or distributed for sale in the state.

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[1] The SONAR states: *Detailed guidance on how reporting entities can submit on behalf of multiple manufacturers will be included in the reporting system instructions or in a supplemental guidance document. This information will be available once the reporting system's functional capabilities are fully established, ensuring that entities have clear, practical steps for submission on behalf of multiple manufacturers.*

WABASH™ Wabash 765-771-5443 onewabash.com

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Lafayette, IN 47905

4) Grouping of Similar Products (Part 7026.0030, subp. 1.A.(1)(a)):

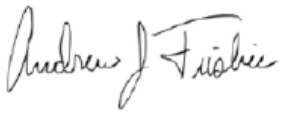
Wabash supports the concept of Part 7026.0030, subp. 1.A.(1)(a), allowing manufacturers to group together similar products. But Wabash believes these requirements as drafted are too narrow and could lead to excessive reporting obligations for Wabash and many other manufacturers.

As an example, one of the "products" Wabash manufacturers is semi-trailers, which are often highly customized based on customers' unique needs and orders. This results in significant variations in trailers even within a single trailer classification. To illustrate, the following is a non-exhaustive list of variables for Wabash trailers based on possible customer order preferences: chassis, overhead doors, lighting harnesses, refrigeration units, brakes, liftgates, door locking mechanisms, interior logistical tracks and cargo tie-down systems, tires, and aerodynamic devices such as trailer skirts. With a nearly limitless series of possible end product permutations with these and many other variables, there could be an excessive number of individual "products" if not logically grouped by product class:

As the Proposed Rule is currently drafted, it may be very difficult or impossible to meet the narrow and strict "homogenous materials" requirements. Instead, Wabash believes a more reasonable way of grouping similar products is to permit the manufacturer to group substantially similar products together (for example for Wabash this would be dry van semi-trailers, refrigerated van semi-trailers, tanks, platforms, dry truck bodies, and refrigerated truck bodies), and then allow the manufacturer to include a list of standard and optional components that may be included in variations of the primary product. This would allow MPCA to gather the information Amara's Law and the Proposed Rule seek to obtain without overly burdening manufacturers and MPCA.

Wabash appreciates the opportunity to submit these comments to MPCA. Please feel free to call me with any questions at 765-771-5443 or email at Andrew.frisbie@onewabash.com.

Sincerely,



Andrew Frisbie, Wabash National Corporation
Director, Environmental Health & Safety

RECEIVED
By: OAH on 5/21/2025

Gary Cross Attachment

May 21, 2025

VIA ELECTRONIC SUBMISSION:

https://minnesotaoah.granicusideas.com/

Honorable Judge Jim Mortenson
600 North Robert Street
St. Paul, MN 55101

Re: Minnesota Pollution Control Agency's Notice of Intent to Adopt New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per- and polyfluoroalkyl substances (PFAS), Revisor's ID Number R-4828, OAH docket number 5-9003-40410

INTRODUCTION

The Industrial Truck Association ("ITA"), which is the national trade association representing manufacturers of forklifts and other industrial trucks, respectfully submits these comments on the above-referenced Notice of Intent. As ITA commented in December of last year, MPCA's interpretation of Amara's law seemed to place an impossible burden on manufacturers of complex products, including the forklifts manufactured by ITA members, because "manufacturers of offroad vehicles do not have the visibility through their multi-tiered supply chains to enable them to determine whether a given component that resides at the beginning of the supply chain, such as a rubber seal or gasket, may have been formulated with one or more PFAS substances and, if so, the precise amount and formulation of the substance."

MPCA acknowledged this problem in response to questions posted on its website, stating that tracking and reporting PFAS information throughout the supply chain "can be complex, especially if there are multiple levels of suppliers involved" and noting that "[w]e are looking into a pathway for suppliers to report on behalf of another entity to meet the requirement as well." The proposed regulation now contains provisions for group reporting pursuant to agreement among the manufacturers in a supply chain. As ITA understands it from the

STATEMENT OF NEED AND REASONABLENESS ("SNR"), however, these provisions aim to reduce redundant reporting that could arise "because of the large overlap in common components used throughout the manufacturing of complex products," (SNR, p. 27) but they do not address the fundamental problem of determining where in the supply chain PFAS may have been added. These provisions also apparently assume that all U.S.-domestic members of the supply chain, including those who have nothing to do with marketing in Minnesota, must report under Amara's law. As explained hereafter, if this is MPCA's interpretation, ITA does not believe that it is reasonable or that the approach can work. While ITA strongly supports MPCA's inclusion of due diligence standards as a way to address an otherwise impossible burden placed upon manufacturers of complex products, we offer some proposed modifications to those standards that we believe are more consistent with a proper reading of the statute and place more realistic obligations on manufacturers of complex products.

SUPPLY CHAIN REPORTING RESPONSIBILITIES

As ITA reads the proposed regulation and the explanation in the SNR, MPCA interprets Amara's law as imposing an overlapping obligation on each manufacturer of finished products, assemblies, components, subcomponents, and raw materials to report any PFAS that may have been introduced at an earlier stage of the supply chain.[1] If PFAS was introduced at the initial stage, such as by the manufacturer of an underlying polymer, then all manufacturers in the supply chain would have the same reporting obligation for that PFAS. The proposed regulation

[1] As stated in the SNR (p. 27), "It is reasonable to notify all members of the supply chain that they must be aware of PFAS in the products that are being sold and to report the product containing PFAS accordingly." Nowhere does the SNR exclude from the reporting obligation those supply-chain members who have nothing to do with whether the PFAS-containing part enters the state.

then addresses this redundancy by permitting the members of the supply chain to enter into an agreement whereby one member—perhaps the member who introduced the PFAS and has the detailed information required to be reported—will report on behalf of all the others.

For example, if a rubber gasket in an engine contains PFAS, then the manufacturer of the underlying polymer, the manufacturer of the rubber compound, the manufacturer of the gasket, the manufacturer of whatever subcomponent or component contains the gasket, the manufacturer of whatever assembly contains the component, the manufacturer of the completed engine, and the manufacturer of the equipment that uses the engine each have an independent regulatory obligation to report on the same PFAS content in the gasket. Any manufacturer in the supply chain can agree to report on behalf of one or more others in the supply chain, but those supply-chain manufacturers who do not themselves report must be able to provide a copy of an agreement showing that another supply-chain manufacturer has fulfilled their reporting responsibility for the PFAS in that gasket. And all members in the supply chain who manufactured a part containing the gasket must pay the prescribed fee.[2]

ITA questions whether, under a fair reading of Amara's law, all supply-chain members (or importers of parts manufactured by a supply-chain member), as opposed to the finished-product manufacturer, have a legal obligation to report under the statute. Without such a legal obligation, MPCA's approach to address overlapping reporting, as discussed in the SNR (p.27-28) under "7026.0020 PARTIES RESPONSIBLE FOR REPORTING," lacks a foundation. Indeed, there is no reporting redundancy for a given product if the only manufacturer having a

[2] In ITA's understanding, if Company A sells a PFAS-containing finished product in Minnesota and Company E is the supply-chain participant that introduced the PFAS, each of Companies A,B,C,D and E must either report the same PFAS or have a reporting agreement to cover it. Regardless of how the reporting occurs, Companies A-E must also each pay the fee.

reporting obligation is the manufacturer of the finished product who markets it in Minnesota.[3] ITA believes this is the better reading of the statute.

ITA acknowledges that Amara's law can be read to impose a reporting obligation on supply-chain members other than the finished-product manufacturer, so long as those other supply-chain members sell, offer for sale, or distribute their products in the state. But this does not seem to be MPCA's interpretation, given the SNR's sweeping statement (p. 27), "It is reasonable to notify *all members of the supply chain* that they must be aware of PFAS in the products that are being sold and to report the product containing PFAS accordingly." (Emphasis added.) And group reporting only works if all supply-chain members have a reporting duty. Therefore, pending further clarification, ITA assumes that MPCA believes "all members of the supply chain," even those who did not sell, offer for sale, or distribute their products in the state, must report.[4]

If this is MPCA's interpretation, ITA cannot agree. While some sections of Amara's law use passive phrasing, such as "a manufacturer of a **product sold, offered for sale, or distributed** in the state that contains intentionally added PFAS" (subdivision 2.a), without specifying *who* has sold, offered for sale or distributed the product, subdivision 2.d makes it clear that the law reaches only those who target the state: "**A person may not sell, offer for sale, or distribute for sale in the state** a product containing intentionally added PFAS if the

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[3] There may be many instances where a part manufacturer sells its part, such as a rubber gasket, for use in the finished product of more than one manufacturer. Even under MPCA's approach, this would yield substantial redundant reporting.

[4] One statement in a different section of the SNR (p. 42) seems to recognize that reporting is limited to those who target the state: "There is a possibility that a manufacturer will choose not to sell a PFAS containing product in the state of Minnesota if they determine that the burden and cost of reporting is too much." ITA is unable to reconcile this statement with the remainder of the SNR.

manufacturer has failed to provide the information required under this subdivision and the person has received notification under subdivision 4." (Emphasis added.) Thus, a person who merely manufactures a subcomponent that ends up in a product sold in Minnesota, but who has not sold, offered for sale, or distributed the subcomponent in the state, would have no reporting obligation.

The statute's definition of "product" supports this conclusion. The statute places the reporting obligation on manufacturers of "products," which are items sold "to consumers . . . for personal, residential, commercial, or industrial use, including for use in making other products." This definition describes completed end products that are put to their intended use, not components that merely form constituents of end products.[5] While there is a separate definition of "product component," the reporting obligation is only for "products." As ITA reads it, this means that the finished product manufacturer, not every participant in the supply chain, has the reporting obligation.[6] This makes sense because it is the finished-product manufacturer who decides where to sell the product-- upstream supply-chain members typically do not know, much less control, the final destination of the parts they manufacture.

Without an overlapping reporting obligation throughout the U.S. domestic supply chain,[7] the allowance for group reporting pursuant to an agreement among the supply-chain participants lacks a statutory basis, is unnecessary, and cannot be a solution to the problem faced by manufacturers of complex products. ITA appreciates MPCA's recognition of the problem facing manufacturers of complex products. As discussed in the next section, however, a solution that

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[5] The phrase "including for use in making other products" is not necessarily a reference to components. Components are constituents of finished products, rather than products "for use in making" finished products.

[6] Likewise, only manufacturers who have a reporting obligation should be required to pay a fee.

[7] The statute does not purport to reach members of the supply chain that do not have a presence in the U.S.; in those cases, the manufacturer is the importer or first domestic distributor of the product.

calls for unachievable coordination among often unknown members of the supply chain seems more likely to compound the problem.

LACK OF SUPPLY-CHAIN VISIBILITY AND CONTROL STILL REMAINS

Even if Amara's law does impose a reporting obligation on all U.S. manufacturers throughout the supply chain for a single PFAS-containing part, the coordination problems associated with reporting as a group would be as severe as the information-gathering problems that face a finished-product manufacturer trying to fulfill the sole reporting responsibility. Under 7026.0020 of the proposed regulation, an ITA member whose forklift has a PFAS-containing part and who intends to rely on the manufacturer at the beginning of the supply chain to supply the reportable information must have documentation of a "reporting responsibility agreement" and must verify that all the reported information is accurate. But this requires knowing whether PFAS was introduced at the first level in a multi-level supply chain, often by a manufacturer that has no U.S. presence. ITA members and other manufacturers of complex products have commercial relationships with their first-tier suppliers and typically receive, and can request, product-related information from them. This is not true of the preceding levels. Moreover, a supplier at the beginning of a supply chain is not likely to accept the idea that it has an independent reporting obligation to Minnesota, despite having no other contacts with the state, merely because the finished product ended up in Minnesota.

It is the unrealistic assumption that manufacturers of complex products can determine or verify the chemical composition of generic parts by reaching back to the beginning of the supply chain that makes compliance impossible, whether the program contemplates redundant reporting by individual manufacturers or single reporting on behalf of a group. Either way, determining

who may have the relevant information and inducing those parties to provide it remains the problem for complex products.[8]

ITA'S RECOMMENDATION

ITA recommends that due diligence for supply-chain inquiries by manufacturers of finished products who have sold, offered for sale, or distributed those products in Minnesota be limited to their first-tier suppliers and to other known participants in the supply chain where there is a reason to believe that they can provide reportable information. A reason to believe that other supply-chain participants may have reportable information might come from the inquiry to the first-tier supplier and appropriate follow-up from that inquiry, from information in the manufacturer's possession (e.g., Safety Data Sheets), or from other sources. But manufacturers should not face the impossible task of seeking "detailed disclosure of information . . . until all required information is known," as proposed in 7026.0080.

ITA bases this recommendation on its understanding of Amara's law. To summarize, under subdivision 1.g, the definition of "product" is limited to finished goods sold to consumers and does not appear to include components. Thus, since the reporting obligation falls on the "manufacturer" pursuant to subdivision 2.a, only the manufacturer of the finished goods has the reporting obligation, even though that obligation includes reporting as to the product's components, subcomponents, etc. But even if "product" includes components, so that manufacturers of components are also considered to be manufacturers of products who have a reporting obligation, it is clear from subdivision 2.d, that the reporting requirements are limited

[8] Indeed, requiring each manufacturer in the supply chain for a single part to reach a written agreement with the first link in the chain and independently verify the detailed PFAS information may be more of a complication than a simplification. It seems unlikely that manufacturers would see group reporting as any easier.

to manufacturers who have directed their products (whether finished goods or components) to distribution in the state. Since there will be few if any instances where all manufacturers in the supply chain for a complex product have directly offered their products in the state, there will seldom be a basis on which all members of the supply chain can reach an agreement to report as a group.

It is reasonable that due diligence for end-product manufacturers would include seeking information from first-tier suppliers because those suppliers are known and there is a direct commercial relationship with them. But manufacturers should not face the impossible task of seeking "detailed disclosure of information . . . until all required information is known," as proposed in 7026.0080. Determining the precise chemical composition, function, concentration, and quantity of every PFAS used in every product in the state is not feasible and should not be the measure of when manufacturers have discharged their reporting obligation.

CONCLUSION

ITA appreciates MPCA's effort to implement Amara's law faithfully while addressing the vexing problem of locating PFAS-related information at the beginning of a long supply chain for a complex manufactured product. In our view, however, MPCA's proposed regulation rests on an unsound interpretation of the statute and, even then, leaves manufacturers without clear guidance or realistic expectations of what is required. Imposing on end-goods manufacturers the impossible task of identifying chemical elements within subparts of components rather than focusing on the manufacturer who knowingly introduced those chemicals into their product, while also compounding fees that will increase product prices, is in ITA's opinion not a workable approach. These comments offer an alternative that may strike a better balance among

adherence to the law's text, a workable set of reporting requirements for manufacturers, and the continued availability of valuable products in Minnesota.

Respectfully submitted,

Gary E. Cross (202-415-0540, gcross27103@earthlink.net)
Dunaway & Cross
General Counsel to the Industrial Truck Association

RECEIVED
By: OAH on 5/21/2025

TERUMO BLOOD AND CELL TECHNOLOGIES

Unlocking Potential

May 21, 2025

Submitted via Electronic Delivery

Minnesota Pollution Control Agency
Resource Management and Assistance Division
520 Lafayette Road N
St. Paul, MN 55155-4194

Re: Response to Request for Comments to the Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees (c-pfas-rule1-06) and Statement of Need and Reasonableness for PFAS in products reporting and fees rulemaking (c-pfas-rule1-07)

To whom it may concern,

Terumo Blood and Cell Technologies (BCT) appreciates the opportunity to submit the following response to inform the Minnesota Pollution Control Agency's (MPCA) request for comments on proposed permanent rules relating to PFAS in products; Reporting and Fees (c-pfas-rule1-06) and Statement of Need and Reasonableness for PFAS in products reporting and fees rulemaking (c-pfas-rule1-07) as directed by Minn. Stat. § 116.943. We are dedicated to operational and manufacturing excellence through healthy associates, a safe workplace, and a commitment to protecting the environment. Since 1964, Terumo BCT has been a global medical device leader committed to setting a standard that enables an innovative product pipeline supporting expanded treatment options for conditions like sickle cell disease, blood cancers, and rare diseases—improving lives in Minnesota and around the world.

With this in mind, we have outlined thoughtful recommendations below for your consideration in future rulemaking.

Reporting Exemption for Medical Devices

Terumo BCT Recommendation:

- Explicitly exempt federally regulated products such as "human blood collection and storage bags, apheresis and cell therapy blood kits and bags, including integral tubing, or to any product that is a medical device or drug or that is otherwise used in a medical setting or in medical applications regulated by the United States Food and Drug Administration (FDA)" from reporting requirements in future rulemaking.

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TERUMOBCT.COM

We appreciate that MPCA has recognized the unique nature of PFAS in medical devices and exempting these products from the ban. However, we respectfully reiterate our request that "human blood collection and storage bags, apheresis and cell therapy blood kits and bags, including integral tubing, or to any product that is a medical device or drug or that is otherwise used in a medical setting or in medical applications regulated by the FDA" be exempted from not only subdivision 4 and 5 but reporting as well. Medical devices like ours and drugs are thoroughly assessed and regulated by the FDA and are subject to federal requirements. Last year, Terumo BCT devices enabled over 8,000 lifesaving whole blood transfusions across the state of Minnesota in service of patients experiencing medical traumas or labor and delivery complications, and over 3,000 blood component transfusions for patients living with chronic conditions such as sickle cell disease. Rulemaking that does not exempt the aforementioned blood collection and storage materials would severely interfere with Minnesota patients' ability to access lifesaving medical services statewide. Moreover, New Mexico and Maine's amended law have exempted medical devices in their PFAS laws recognizing that medical devices and drugs are distinct from many of the other products that are subject to this rule. In fact, New Mexico exempted fluoropolymers from their recently passed law recognizing not all PFAS is the same. A reporting exemption for medical devices and drugs would also allow MPCA to focus on PFAS-containing products that are not subject to the same rigorous regulatory scrutiny as medical technologies.

We believe that the current language under proposed exemptions (MINN. R. 7026.0090-A) is confusing and leaves room for interpretation. It is for that reason that we respectfully request a full exemption for medical devices and drugs which are critical for lifesaving care for patients.

The Role of PFAS in Medical Devices

Per- and polyfluoroalkyl substances, known as PFAS, are a broad class of over 12,000 substances that are found in a variety of consumer, commercial and industrial products, including medical devices and their packaging. PFAS can essentially be divided into two separate classes: water-soluble PFAS and water insoluble PFAS. PFAS used in medical devices is overwhelmingly water insoluble. Water insoluble PFAS (e.g., fluoropolymers) are a larger, higher molecular weight PFAS molecule that are inherently stable, insoluble in water, and less bioavailable. Due to their unique properties of thermal stability, chemical resistance, and low friction devices like blood collection and storage bags, apheresis and cell therapy blood kits and bags, including integral tubing rely on PFAS, as well as packaging for surgical tools, implantables, and pre-filled syringes that require sterilization. These unique properties make fluoropolymers essential in medical devices and medical products regulated by the FDA.

The FDA considers human health and safety risks, optimal product quality, and assessment of who will be utilizing the device (practitioner or patient) in their approval processes for medical devices and medical products. The health risks of these medical devices are thoroughly assessed by the FDA before they make it on the market and must undergo multiple tests to prove biocompatibility in compliance with the international biocompatibility standard, ISO 10993.

As part of FDA's regulatory process for medical devices coming to market, materials of the product as well as the packaging may be considered a component of the device itself, or it could be a part of the final design specifications of the device as it is meant to be sold and distributed. FDA must validate these products as safe, non-toxic, and resilient enough to withstand sterilization, transport, storage, and normal use so that it can function as intended without any damage or harm to the patient.

The Adoption of a One-Year Reporting Delay at Minimum

Terumo BCT Recommendation:

- Adopt at minimum of one-year reporting delay rather than the options for 90-day delays at the discretion of the Commissioner.

While the MPCA has been working towards the January 1, 2026, goal, we believe that there are many areas of this rule that still need to be refined. Terumo BCT urges the MPCA to adopt at minimum a one-year reporting delay rather than the options for 90-day delays at the discretion of the Commissioner. By adopting a fixed length delay, it will help focus all stakeholders on a new date rather than moving in 90-day increments. Manufacturers need to have sufficient time to understand and implement these requirements. We are concerned that the report framework is still not clarified to a level so that manufacturers can understand the process.

A one-year extension would further allow MPCA to develop and receive comments on the proposed reporting platform, beta testing of that platform, and the proposed guidance to ensure certainty for medical device innovators. Without this information for stakeholders to review, stakeholders will be providing incomplete feedback and will be inadequately prepared to comply with this rule. Further, guidance and FAQs will be needed for those reporting to understand how to use the portal when it is time for submissions.

In the case of medical devices, they can be complex products, potentially with supply chains that are sometimes eight to ten layers deep that will need to be reviewed and notified. It is unreasonable for those subject to reporting to be in a position to meet the January 1, 2026, implementation if the rule is not finalized yet.

Broad Reporting and Compliance Challenges

Terumo BCT is concerned that the reporting mechanisms are not clarified to the level that the full process can be understood and feasible. In a supply chain that is highly complex and eight to ten or more layers deep, often, a component material supplier views their component design as their intellectual property (IP), including the specific material used. In those instances, the FDA has a regulatory approach for those suppliers to divulge information to the FDA but not to the manufacturer. As a result, medical device manufacturers will struggle to achieve full disclosure to MPCA in a timely manner. While this information is provided to the FDA and the materials in the products are highly regulated, the information provided to manufacturers is not always consistent or standardized regarding the materials in the product.

Like many within the medical device industry, we are well over a year into our PFAS supply chain identification and it may take several more years to even identify where in the supply chain regulated PFAS

substances occur before we all can attempt to mitigate and change their processes. There is no "commercially available" technique that can assess all 12,000+ PFAS chemicals at one time which makes this process time consuming and labor intensive.

In fact, European Chemical Agencies PFAS restriction proposal, Annex XV Report of the Registry of Restriction Intention states that chemical standards for only 40 PFAS exist for quantitative analysis. Additionally, analytical techniques can only assess what can be extracted out of a device, it becomes near impossible to identify what is present rather than what can leach out. Furthermore, the very nature of fluorine means it is naturally monoisotopic and, therefore, extremely difficult to identify de novo in extracts as part of an unknown. Commercially available software algorithms have an inherent bias to deduce a chemical formula containing fluorine through the use of high-resolution mass spectrometry. This inherent bias leads to a high number of false positives.

While there are upwards of 12,000 PFAS currently known, this is an evolving and growing number. Less than 1% of these PFAS have a commercially available analytical reference standard (CAARS) and since a CAARS is needed to perform a quantitative analysis of a given material to determine the amount of all PFAS potentially in the sample, this simply is not practically achievable, unless and until, an analytical reference standard is available commercially for each of the 10,000+ PFAS. Even then, the burden of trying to test a given sample for 12,000+ different PFAS to potentially certify that no PFAS are present, will be a massive burden on obligated parties as well as the test labs performing the work, given that potentially thousands of manufacturers will simultaneously need this testing.

Definitions

Terumo BCT Recommendations:

We request the following additions and clarifications to the Definitions (MINN. R. 7026.0010) in the proposed rule:

> Intentionally Added PFAS: MPCA should include a definition in the final rule for "intentionally added PFAS" to reiterate the definition found in Minn. Stat. § 116.943.
>
> Additionally, we request clarification as to what intentionally added captures. For example, if a PFAS used as a polymer processing aid was deliberately added to the polymerization pot to perform a specific function (emulsification), but has no function once the fluoropolymer (a different PFAS) has been made and is not desired in the finished fluoropolymer, and the finished fluoropolymer is used to make an article (such as a medical device), it is our understanding that the fluoropolymer would be intentionally added to the medical device, but any trace residual of the polymer processing aid potentially incorporated into the medical device because it remained in the finished fluoropolymer would not be an intentionally added PFAS. We would ask the MPCA to please confirm our understanding.

Chemical identifying number: It is also possible that one chemical identifying name may correspond to different names for the same chemical, so we would ask this definition to be updated to include: "A particular chemical may have more than one chemical identifying number, *and one chemical identifying name may correspond to different names for the same chemical."*

Distribute for sale: MPCA should clarify that "distribute for sale" refers to distribute for sale in Minnesota. As the definition currently reads, if a product was shipped to Minnesota but then transferred out of the state for sale without being sold in Minnesota, it would be subject to this rule. We believe products that are shipped through the state but not sold there should not be subject to this rule.

Manufacturer: Additional clarity is needed around the term manufacturer. There are circumstances in which two different entities meet the current definition for the same product. One manufacturer may manufacture the product, and another may legally affix their name to that product. In this circumstance it is unclear who the "manufacturer" is, and which entity is responsible for reporting.

Additionally, this proposed rule does not adequately account for manufacturers whose products are sold by distributors and may be unaware that their products are being offered for sale in Minnesota. In this situation, they may be unable to report under this rule and we would recommend that there be an ability for the distributor to report instead of the manufacturer in situations like this. There could also be a similar situation in which a manufacturer licenses their logo-branded product but does not sell the product. In this situation, there should also be a provision for the reporting requirement to be managed by the licensee not the licensor. A similar situation would arise in which the original manufacturer is not the entity completing the sale through an online platform and may not be able to track that transaction or have control over it.

Numeric Product Code: MINN. R. 7026.0010, Subp. 15. (lines 3.3-3.7) references HTS codes. There are three different levels of HTS codes (6 digit, 8 digit, and 10 digit), with the higher digit codes having more specificity. We would request that the use of the 6 digit HTS code is acceptable. Further, we ask that the HTS option be available for any product where it is relevant and not just for imported products.

Packaging: Terumo BCT appreciates the MPCA addressing packaging in a previous FAQ and would ask that interpretation and clarification from MPCA is included in the final rule to help provide additional guidance.

Parties Responsible for Reporting

Terumo BCT appreciates that the MPCA created an opportunity for manufacturers to report as a group, however we believe that this will not enable streamlined reporting as intended. There are no provisions related to reasonably ascertainable information, and because of that the due diligence requirement would be impossible to meet in many circumstances. For medical devices and other products with deep, global supply chains, this could be particularly challenging. As we shared earlier in this comment letter, it is not unusual for a component material supplier to view their component design as their intellectual property, including the specific material

used. In those instances, the FDA has a regulatory approach for those suppliers to divulge information to the FDA but not to the manufacturer. As a result, medical device manufacturers will never be able to achieve 100% disclosure to MPCA.

In MINN. R. 7026.0020, Subpart 1, Terumo BCT asks for clarification on the requirement of "each product or component", is it the finished product, each component part, or both?

Terumo BCT Recommendation(s):

- Clarify that the reporting on behalf of other manufacturers (Subpart 2) only relates to products that are components of the final product and not for every component that a manufacturer may produce.
- Provide guidance on how to report if a supplier has gone out of business during a reporting period and the manufacturer cannot access information to complete reporting.

Required Reporting Information

Terumo BCT is concerned with the lack of clarity around the reporting requirements (MINN. R. 7026.0030). Medical devices are complex products, and we are concerned about the feasibility of the reporting.

> New products: In Subp. 1., we are concerned that a new product with intentionally added PFAS must submit a report before the product can be sold, offered for sale, or distributed in the state. We do not believe that this is a reasonable amount of time to complete the full reporting and would ask that new products be reported within 12 months of being sold, offered for sale, or distributed into the state. This could directly impact federal procurement for medical devices, such as medical imaging equipment for Veterans Administration (VA) facilities. It is not unusual for a VA contract to stipulate that the manufacturer must provide the latest model when it comes time for delivery and installation. It could also impact patient access to novel or specialized medical devices and drugs when timely access is critical.
>
> Concentration Disclosure Requirements: In MINN. R. 7026.0030, Subp. 1.C.1.a. (line 7.7) we are concerned that the concentration range is too detailed. We would propose the first range be 100 ppm to <1,000 ppm (0.1 percent) as levels below that could potentially be inadvertent. Additionally, some companies do not capture PFAS less than 1,000 ppm. We would also appreciate an alignment with the existing TSCA 8a7 ranges as it will ease the reporting burden on many industries in the United States that already report to the United States Environmental Protection Agency (EPA).
>
> Terumo BCT is also opposed to the inclusion of MINN. R. 7026.0030, Subp. 1.C.2. (lines 7.16-7.18) of the option to report total organic fluorine (TOF) and would instead propose the option to report as "(i) present but the amount or concentration range is unknown" (line 7.15) and include a due diligence standard so that manufacturers can update the concentration information once they have obtained the information. For example, when Maine was updating their PFAS law, their initial bill included TOF testing, but it was removed after much opposition to it being too broad of a testing method. Instead,

Maine requires reporting of the total product weight. TOF captures more than just PFAS and could potentially include inorganic fluorine. TOF is also a very lengthy and expensive process for many complex products, and it would further hinder compliance with this rule.

Manufacturer information: Terumo BCT asks for clarification on MINN. R. 7026.030, Subp. 1.E. through 7026.030, Subp. 1.G (line 8.10). Does the manufacturer referenced here refer to the PFAS manufacturer or the manufacturer of the product overall?

Product grouping: Terumo BCT requests broader flexibility on the grouping of products to account for products that have commonalities but not necessarily the same concentrations. We propose the striking of Subpart 1.A.1.a.ii (lines 5.16-5.17) and Subpart 1.A.1.b.ii (lines 6.4-6.5) and adding *"v. if the PFAS chemicals in the products fall into different concentration ranges, the highest concentration range must be reported so it is understood that all products in this reporting group contain that concentration range or less."* This flexibility would help streamline reporting for manufacturers that have tens of thousands of products or components subject to reporting.

Additionally, the proposed language in MINN. R. 7026.0030, Subp. 3 is inconsistent with the existing statutory language on remedy through notice and testing only.

Reporting Updates

Terumo BCT Recommendation:

- Include a voluntary update.

In MINN. R. 7026.0040, Subp. 2., we are concerned that the annual recertification, if an update is not required, is an administrative burden with no added value. Without access to even a beta portal to review, there is no way of knowing if the information submitted is carried over year-to-year or if it would have to be re-entered every year. If it is the latter, that would be a large annual undertaking for companies that are reporting tens of thousands of products or components subject to reporting. We believe that the relevant information would be captured in the updates required in Subp.1.

Waivers

Terumo BCT would appreciate clarity regarding publicly available information that is used as substantially equivalent information. It is possible that verified, publicly available information may be dated and could be used to support this request. Would that be allowed?

Terumo BCT Recommendation:

- Include language that allows MPCA to grant or a manufacturer to request a waiver for all reporting requirements or deadlines for certain groups (either products or manufacturers) subject to reporting.

Extension Requests

Terumo BCT Recommendation:

- Adopt at minimum a 180-day extension request rather than the 90-days proposal to consider the complexity of the products.

In MINN. R. 7026.0060, Subp. 3. Extension request deadline; approval or denial., (starting line 12.1) there is no timeframe in which the commissioner must decide whether to approve an extension request for the petitioning manufacturer or group of manufacturers. Additionally, it does not specify whether the manufacturer will be out of compliance if the reporting due date passes while waiting for the extension to be approved or denied. This is an unreasonable amount of leeway to grant MPCA.

We are also concerned that a 90-day extension is insufficient given the complexity of some products and multi-layered supply chains. Medical devices can be exceptionally complex, and there could be tens of thousands, if not more, component pieces. Ninety days is unlikely to be enough time to continue to work through a supply chain that is eight or ten layers deep.

Due Diligence

Terumo BCT Recommendation:

- MPCA should align the due diligence requirements in this proposed rule with other jurisdictions and reporting bodies. The requirements set forth in this section make it unreasonable and impossible for those subject to the rule to reach compliance.

In considering due diligence requirements, the TSCA reporting rule requires for reporters to provide information that "Such information would be reported for each year since 2011 in which a covered PFAS was manufactured, to the extent such information were known to or reasonably ascertainable by the reporter."

In the case of supply chain requests (MINN. R. 7026.0080, Subp. 2) we are concerned that suppliers will not provide their trade secret information to a customer inquiry unless they have confidence that it will continue to be protected as a trade secret. There are also circumstances that the supplier's trade secret may not be their customer's (an upstream manufacturer) trade secret. Therefore, we request that "until all required information is known" (line 13.15) is updated to "and take reasonable steps to obtain responses."

We are also concerned that the documentation and recordkeeping language in 7026.0080, Subp. 3. A-C (lines 13.16-14.3) is overly broad and unreasonable. We propose that "A manufacturer or group of manufacturers must maintain documentation of its relevant reporting responsibility agreements with and/or notifications from other manufacturers as provided in part 7026.0020, Subp. 2." Additionally, Subp.3.C. (lines 14.1-14.3) would create a permanent retention policy for products that are not subject to the ban or obtain a critical use exemption and are not reformulated. We would ask that MPCA revise the language to specify a length of time (ex: 3 years) or while the reporting responsibility agreement remains in effect.

Trade Secret Data Request

Terumo BCT Recommendation:

- In addition to the data outlined in MINN. R. 7026.0070, Subp. 1.A-C. (lines 12.21-12.23), MPCA should add the PFAS concentration range and the function of the PFAS to the data that can be requested that the Commissioner maintain as trade secret data. Both possess economic value, which are not generally known, and manufacturers, as well as their suppliers, have taken reasonable steps to protect this information.

Additional Comments

Terumo BCT urges MCPA to consider expeditiously issuing a request for comments on "current unavoidable use" of PFAS, under subdivision 5. While FDA regulated medical technology is exempt from subdivision 5, our suppliers are not. The industry is extremely concerned about the resiliency of our supply chain if additional suppliers exit the market without substitutes that meet the unique properties necessary to maintain FDA standards for medical devices and packaging.

Advancing the rulemaking process for subdivision 5(c) and issuing a list of products not subject to the ban well in advance of 2032 would provide clarity to manufacturers about the potential supply chain risks and prevent disruptions to critical infrastructure, including health care.

We are also encouraging MPCA to pursue some form of information collection request (ICR) to better inform the regulator of the current state on PFAS by industry type before finalizing a rule. This could be done confidentially without the need for disclosing proprietary information and would allow for a more considered approach to addressing this issue. This has been done in the past and did give the regulator a better footing for a risk reduction-based approach in a final rule.

In closing, our recommendations are intended to position the MPCA as a valuable public sector leader. We appreciate the opportunity to respond to MPCA's Request for Comments and we look forward to working with MPCA and being a technical resource on this complex and precedent setting rulemaking.

Sincerely,

Latoya S. Thomas
Head of Public Policy & Government Affairs – U.S.
Terumo Blood and Cell Technologies

Complex Products Manufacturers Coalition

May 21, 2025

The Honorable Jim Mortenson
Minnesota Office of Administrative Hearings
600 North Robert Street
PO Box 64620
St. Paul, Minnesota 55164-0620

Via eComment at https://minnesotaoah.granicusideas.com/

Re: Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees; Revisor's ID Number R-4828, OAH docket number 5-9003-40410

Your Honor:

The Complex Products Manufacturers Coalition (CPMCoalition) hereby provides comments on the "Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees" (Proposed Rules) as published by the Minnesota Pollution Control Agency (MPCA or Agency) on April 21, 2025.[1] We appreciate this opportunity to submit these comments for your consideration.

The CPMCoalition looks forward to continuing the dialogue on the important work to implement Minn. Stat. § 116.943 and to develop a comprehensive framework for evaluating and regulating per- and polyfluoroalkyl substances (PFAS) in Minnesota. We ask that our previously submitted written comments to MPCA are incorporated herein.[2]

The CPMCoalition is a multi-stakeholder group comprised of companies who manufacture, assemble, and distribute complex durable goods.[3] CPMCoalition members assemble up to thousands of parts, components, and raw materials to manufacture and distribute products that are frequently referred to as "complex products" or "complex durable goods." These include industrial, commercial, and consumer products such as appliances, batteries, communication devices, electrical and power transmission and distribution equipment, electronics, HVACR-WH systems, lighting, outdoor power equipment, vehicles, vessels, and others, as well as their components and replacement parts. Complex products are used to support nearly every major sector in the nation, providing critical and often life-saving services upon which our modern society depends.

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[1] Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees; Revisor's ID Number R-4828, OAH docket number 5-9003-40410.
[2] CPMCoalition comments to MPCA on "Planned New Rules Governing Currently Unavoidable Use Determinations About Products Containing Per- and Polyfluoroalkyl Substances, Revisor's ID No. R-4837" submitted on March 1, 2024; please see Appendix III.
[3] For more information about the CPMCoalition and our policy priorities, please visit www.CPMCPMCoalition.com.

1. Introduction.

The CPMCoalition understands MPCA's necessary work to implement Minn. Stat. § 116.943, and we appreciate the Agency's efforts to promulgate appropriate rules. As stated in its "Statement of Need and Reasonableness in the Matter of Proposed Minnesota Rules New Chapter 7026; Revisor ID No. RD-4828" (SONAR) the purpose of the Proposed Rule is "to clarify whether the statute applies to the manufacturer, clarify which product reporting requirements may apply, and specify how and what to report to the MPCA."[4]

In this response, the CPMCoalition respectfully urges MPCA to consider the following comments to inform its final rules relating to reporting requirements and fees for PFAS in products.

2. Summary of Comments.

a. Definitions. The CPMCoalition recommends adoption of a definition for "complex products." Additionally, the CPMCoalition strongly recommends narrowing the PFAS definition and providing CAS Numbers to increase the workability of the final regulation for both MPCA and the regulated community.

b. Reporting Exemptions. The CPMCoalition recommends that MPCA use its authority under the law to promulgate additional exemptions for complex products, including but not limited to industrial, commercial, and consumer products such as appliances, batteries, communication devices, electrical and power transmission and distribution equipment, electronics, HVACR-WH systems, lighting, outdoor power equipment, vehicles, vessels, and others, as well as their components and replacement parts. Exemptions should also be applied to complex products' essential chemical components such as low-risk refrigerants, fluoropolymers, and insulating gases, and their replacement parts, as well as any *de minimis* amounts, in its final regulations. MPCA should also include all exemptions stated in Minn. Stat. § 116.943. MPCA should prioritize chemicals management using a risk-based approach that considers both hazard and exposure.

c. Waivers. The CPMCoalition asserts that by Minn. Stat. § 116.943, the MPCA has the authority under the law to grant additional waivers, including an information requirement waiver. We further assert that MPCA should use this authority to *proactively* grant information requirement waivers for complex products, including but not limited to industrial, commercial, and consumer products such as appliances, batteries, communication devices, electrical and power transmission and distribution equipment, electronics, HVACR-WH systems, lighting, outdoor power equipment, vehicles, vessels, and others, as well as their components and replacement parts. Exemptions should also be applied to complex products' essential chemical components such as low-risk refrigerants, fluoropolymers, and insulating gases, and their replacement parts, as well as any *de minimis* amounts, in its final regulations.

[4] MPCA "Statement of Need and Reasonableness in the Matter of Proposed Minnesota Rules New Chapter 7026; Revisor ID No. RD-4828" (SONAR) published April, 2025.

d. Reporting Deadline. The CPMCoalition recommends that MPCA use its existing authority under the law to extend its reporting deadline. The CPMCoalition suggests that to avoid issuing multiple postponements, MPCA should extend the deadline to by at least two years, especially for complex products, their essential chemical components such as low-risk refrigerants, fluoropolymers, and insulating gases, and their replacement parts, as well as any *de minimis* amounts.

e. Reporting Updates. The CPMCoalition recommends removing the "annual recertification" section. A requirement for recertification every five years would be a more manageable cadence for both the agency and the regulated community, especially for complex products, their essential chemical components such as low-risk refrigerants, fluoropolymers, and insulating gases, and their replacement parts, as well as any *de minimis* amounts.

f. Extensions. The CPMCoalition requests that MPCA use its authority under the law to provide manufacturers with much-needed additional time and recommends granting an additional six months especially for complex products, their essential chemical components such as low-risk refrigerants, fluoropolymers, and insulating gases, and their replacement parts, as well as any *de minimis* amounts.

g. Parties Responsible for Reporting**.** The CPMCoalition recommends modifying and clarifying the concept of "group reporting." MCPA should address antitrust and proprietary information considerations, such as by requiring reporting in ranges and ensuring confidential business information (CBI) protection. MPCA should also confirm that downstream companies can reference or rely on reports submitted by their direct suppliers where appropriate.

h. Due Diligence. The CPMCoalition believes the requirement for manufacturers to enquiry the supply chain "until all required information is known" is unrealistic and not achievable. CPMCoalition recommends using the EPA standard found in the TSCA 8(a)(7) PFAS Reporting Rule, "known or reasonably ascertainable," for complex products.

i. Reporting Fees. The CPMCoalition recommends that MPCA revise the fee structure and schedule to correspond with our recommendations to eliminate annual recertification requirements and related requests.

3. 7026.0010 DEFINITIONS; Recommendations to Improve Clarity and Workability.

The CPMCoalition appreciates the MPCA providing definitions to help clarify and implement the Proposed Rule, however, we would like to make the following recommendations that we believe would benefit both the Agency and the regulated community in the final regulation.

a. Complex Products:

The CPMCoalition recommends that in the Proposed Rule, MPCA include a definition for "complex products," similar to that which is codified at the federal level.[5] The CPMCoalition suggests MPCA adopt the following language:

> "complex products" means 1) manufactured goods; 2) composed multiple manufactured components; 3) with an intended useful life of three or more years; and 4) where the product is typically not consumed, destroyed, or discarded after a single use.[6]

Examples of complex products include industrial, commercial, and consumer products such as appliances, batteries, communication devices, electrical and power transmission and distribution equipment, electronics, HVACR-WH systems, lighting, outdoor power equipment, vehicles, vessels, and others, as well as their components and replacement parts.

Adding this definition to cover complex products such as those identified above will provide clarity and certainty to the regulated community and will provide a vehicle for MPCA to provide necessary exemptions and waivers, as detailed later in these comments.

b. PFAS Definition:

The CPMCoalition recommends that MPCA narrow the scope of PFAS in its final regulations. Minn. Stat. § 116.943 provides a definition for PFAS: "'Perfluoroalkyl and polyfluoroalkyl substances' or 'PFAS' means a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom."[7] While the statue provides the minimum characterization of PFAS, the law does not prevent MPCA from narrowing the definition or from providing further clarification for this family of chemicals.

Under the Biden Administration, the federal government recognized that the class of over 12,000 chemicals in the PFAS family is too large to target in a single, initial regulation. And in fact, MPCA's own SONAR states that, "… there are potentially millions of PFAS chemicals that meet the statutory definition of "PFAS" in Minn. Stat. § 116.943..."[8]

Narrowing the scope of chemicals included in the PFAS definition will also recognize the broad diversity in the PFAS family. In a class of over 12,000 substances, there is a great range in

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[5] For example, see 15 U.S. Code § 2605 - Prioritization, risk evaluation, and regulation of chemical substances and mixtures: "(I)the term 'complex consumer goods' means electronic or mechanical devices composed of multiple manufactured components, with an intended useful life of 3 or more years, where the product is typically not consumed, destroyed, or discarded after a single use, and the components of which would be impracticable to redesign or replace; and (II)the term 'complex durable goods' means manufactured goods composed of 100 or more manufactured components, with an intended useful life of 5 or more years, where the product is typically not consumed, destroyed, or discarded after a single use." 15 U.S. Code § 2605(c)(2)(D)(ii).

[6] Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees; Revisor's ID Number R-4828, OAH docket number 5-9003-40410.

[7] Minn. Stat. § 116.943, Subdivision 1(p); https://www.revisor.mn.gov/laws/2023/0/Session+Law/Chapter/60/#laws.3.21.2.

[8] MPCA "Statement of Need and Reasonableness in the Matter of Proposed Minnesota Rules New Chapter 7026; Revisor ID No. RD-4828" (SONAR) published April, 2025.

potential hazards with many chemicals demonstrating minimal threat to human health and the environment, particularly because potential releases to the environment are appropriately managed and controlled. In complex products, exposure is generally minimal from a product use standpoint all the way through to its end-of-life.

It is broadly recognized by international experts, as clarified by the Organisation for Economic Co-operation and Development (OECD) in its 2021 revised guidance, "Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance." This directive states that, "[t]he term 'PFASs' does not inform whether a compound is harmful or not, but only communicates that the compounds under this term share the same trait for having a fully fluorinated methyl or methylene carbon moiety..."[9]

Additionally, MPCA could add clarity and certainty to its final regulations by providing a list of specific Chemical Abstracts Services Registration Numbers (CAS Numbers) as is found in federal law under the Toxic Substances Control Act (TSCA).[10] MPCA should evaluate if it is possible to make an administrative finding that this list is sufficiently representative of the majority of PFAS likely to be in commerce today and limit reporting to the active PFAS that are listed on the TSCA Inventory.

Narrowing the list of reportable substances as representative of the PFAS in commerce today and providing CAS Numbers in its final regulation is MPCA's chance to make this law practical not only for the regulated community but also for a state agency with limited resources. Making these two changes will greatly increase the workability of the final regulation and will keep resources focused on reducing potential exposure to harmful chemicals.

4. 7026.0090 REPORTING EXEMPTIONS; MPCA Should Use Its Authority to Provide Additional Exemptions.

The CPMCoalition urges MPCA to use its authority to provide additional exemptions for complex products as described above, their essential chemical components such as low-risk refrigerants, fluoropolymers, and insulating gases, and their replacement parts, as well as any *de minimis* amounts.

Minn. Stat. § 116.943 provides the following language regarding exemptions:

> (a) This section does not apply to:
> (1) a product for which federal law governs the presence of PFAS in the product in a manner that preempts state authority;
> (2) a product regulated under section 325F.072 or 325F.075; or
> (3) the sale or resale of a used product.
> (b) Subdivisions 4 and 5 do not apply to a prosthetic or orthotic device or to any product that is a medical device or drug or that is otherwise used in a

[9] "Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance"; https://one.oecd.org/document/ENV/CBC/MONO(2021)25/En/pdf.
[10] US Toxic Substances Control Act (TSCA) Sec. 8(a)(7).

> medical setting or in medical applications regulated by the United States Food and Drug Administration.[11]

The Proposed Rule provides the following language regarding exemptions:

> The following are exempt from the reporting requirements under parts 7026.0020 to 14.6 7026.0080:
>
> A. a product for which federal law governs the presence of PFAS in the product in a manner that preempts state authority;
>
> B. a product regulated under Minnesota Statutes, section 325F.072 or 325F.075;
>
> C. the sale or resale of a used product;
>
> D. a product reported to the Department of Agriculture as meeting the reporting waiver requirements under Minnesota Statutes, section 116.943, subdivision 3, paragraph (b); and
>
> E. information regarding PFAS-containing products or components that is provided to any federal government agency and that is classified information as defined in United States Code, title 18, section 798.[12]

The CPMCoalition does not understand why the exemptions provided for under the statute are not included in the Proposed Rule. Furthermore, by developing exemptions beyond those specified in the statute, MPCA illustrates its authority to expand upon the statutory language. In fact, the statute does not prevent the Agency from promulgating additional exemptions, and in fact states that "[t]he commissioner may adopt rules necessary to implement this section."[13]

Providing these exemptions would allow the Agency to prioritize its efforts. To protect human health and the environment, a risk-based approach focuses limited Agency and business resources on the highest priorities based on actual environmental, health, and safety risk from particular chemistries, not just the mere presence of a substance.

The more than 12,000 chemicals in the PFAS family have a wide variety of properties, structures, uses, and many, such as fluoropolymers, refrigerants, and insulating gases, have been widely recognized as presenting low risk to human health and the environment. For this reason, each chemical should be analyzed for its specific characteristics and policymakers should avoid class-wide targets which unnecessarily include high-value, low-risk substances.

MPCA should instead prioritize chemicals for its management policies based on risk. When assessing risk, both hazard and exposure must be considered. The potential hazard of a chemical is only one part of the equation; exposure must also be considered, a concept which is well-established in controlling federal law, other jurisdictions, *and in Minnesota.* The risk prioritization concept is exemplified in Minn. Stat. § 116.943 because the law identifies 11 initial priority

[11] Minn. Stat. § 116.943, Subdivision 8; https://www.revisor.mn.gov/laws/2023/0/Session+Law/Chapter/60/#laws.3.21.2.

[12] Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees; Revisor's ID Number R-4828, OAH docket number 5-9003-40410.

[13] Minn. Stat. § 116.943, Subdivision 9; https://www.revisor.mn.gov/laws/2023/0/Session+Law/Chapter/60/#laws.3.21.2.

categories of products that are considered high-priority for prohibition.[14] The MPCA's final regulation should follow a similar timeline and focus on these 11 product categories only initially.

In most cases, complex products incorporate PFAS in internal components that are essential to the product's ability to function properly and are often part of an internal part. Being encased in the product interior means that any components that may include PFAS in their design are not accessible to consumers and therefore have little to no risk of exposure. Furthermore, products are bound by stringent safety and environmental protocols. Lastly, complex goods have well-established recycling frameworks, thus reducing the risk of exposure at end-of-life.

For these reasons, the CPMCoalition urges MPCA to provide for additional exemptions including those in the statute, as well as provide exemptions for complex products, including but not limited to industrial, commercial, and consumer products such as appliances, batteries, communication devices, electrical and power transmission and distribution equipment, electronics, HVACR-WH systems, lighting, outdoor power equipment, vehicles, vessels, and others, as well as their components and replacement parts. Exemptions should also be applied to complex products' essential chemical components such as low-risk refrigerants, fluoropolymers, and insulating gases, and their replacement parts, as well as any *de minimis* amounts, in its final regulations.

5. 7026.0050 WAIVERS; Need to Provide Waivers, Supporting Criteria, and Extended Time for Complex Products.

a. Waiver Eligibility; Need for Proactively Provided Waivers for Certain Information When Reporting for Complex Products.

In this section of the Proposed Rule, MPCA outlines the criteria for waiver eligibility, and states,

> [u]pon request of a manufacturer or group of manufacturers, the commissioner must waive all or part of the information required under part 7026.0030 if the commissioner determines that substantially equivalent information is publicly available. Gaining access to the information must not impose an undue burden in terms of resources required for collection. When determining whether access imposes an undue burden, the commissioner must consider fees, the number of locations to be accessed, and other relevant factors.[15]

While the acknowledgement of the difficulties associated with gaining access to certain reportable information is very much appreciated, the proposal is an unnecessarily narrow implementation of the Minn. Stat. § 116.943, which states that "[t]he commissioner may waive all or part of the information requirement under subdivision 2 if the commissioner determines that substantially equivalent information is already publicly available. *The commissioner may*

[14] Minn. Stat. § 116.943, Subdivision 5(a); https://www.revisor.mn.gov/laws/2023/0/Session+Law/Chapter/60/#laws.3.21.2.

[15] Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees; Revisor's ID Number R-4828, OAH docket number 5-9003-40410.

grant a waiver under this paragraph to a manufacturer or a group of manufacturers for multiple products or a product category" (emphasis added).[16]

As explained by MPCA during our recent meeting,[17] this paragraph in the statute contains two important, but *separate*, concepts. The first sentence addresses waiver eligibility for any already "publicly available" information, which MPCA includes in its Proposed Rule.[18]

The second sentence provides MPCA with authority to grant additional waivers. Although this sentence is in the same paragraph with language addressing waivers for "publicly available" information, MPCA's view is that the two sentences are meant to be separate from each other.[19] *The language that a "commissioner may grant a waiver" is standalone language meant to be interpreted independently and not in conjunction with any other language in that paragraph.*[20] Therefore, MPCA has the authority under the current law to grant additional waivers, including an information requirement waiver.

When Minnesota legislators included this provision, they recognized that certain sectors would need special consideration and accordingly, included this important language. Therefore, the CPMCoalition does not understand why MPCA chose to ignore this important segment of the statute which would enable the Agency to provide much-needed relief for its own taxed resources and for the regulated community.

The CPMCoalition asserts that under Minn. Stat. § 116.943,[21] MPCA has authority to grant relief to the regulated community through the waiver process. We therefore recommend that MPCA uses its authority under the law to *proactively* grant information requirement waivers for complex products, including but not limited to industrial, commercial, and consumer products such as appliances, batteries, communication devices, electrical and power transmission and distribution equipment, electronics, HVACR-WH systems, lighting, outdoor power equipment, vehicles, vessels, and others, as well as their components and replacement parts. Exemptions should also be applied to complex products' essential chemical components such as low-risk refrigerants, fluoropolymers, and insulating gases, and their replacement parts, as well as any *de minimis* amounts, in its final regulations.

[16] Minn. Stat. § 116.943, Subdivision 3(a); https://www.revisor.mn.gov/laws/2023/0/Session+Law/Chapter/60/#laws.3.21.2.
[17] Statements made by MPCA during April 29, 2025, in-person meeting with the Complex Products Manufacturers Coalition.
[18] It should be noted that there is not much "publicly available" reported PFAS data at this time since the US EPA has postponed its reporting program twice (as of May 12, 2025) and Maine has provided numerous extensions and exemptions.
[19] Statements made by MPCA during April 29, 2025, in-person meeting with the Complex Products Manufacturers Coalition.
[20] Statements made by MPCA during April 29, 2025, in-person meeting with the Complex Products Manufacturers Coalition.
[21] Minn. Stat. § 116.943, Subdivision 8; https://www.revisor.mn.gov/laws/2023/0/Session+Law/Chapter/60/#laws.3.21.2.

b. Difficulty in Tracking Chemicals; Need for Proactively Provided Waivers for Downstream Chemical Users Such as Complex Products Manufacturers.

As established above, MPCA has the authority to grant information requirement waivers. In this section, the CPMCoalition provides further evidence as to why the Agency must grant waivers for downstream chemical users such as complex products manufacturers.

In its SONAR, MPCA states,

> [a]lthough the commonly used EPA Test Method 1633 can test for the presence of 40 PFAS, there are potentially millions of PFAS chemicals that meet the statutory definition of "PFAS" in Minn. Stat. § 116.943. It is very difficult to track such a broad-based chemical constituent with limited testing methods and resources. The proposed reporting program will address the inability to test for specific PFAS chemicals intentionally added to consumer products by requiring manufacturers to report the PFAS used in their products.[22]

Here the MPCA states clearly the problem faced by downstream users of PFAS chemicals. Complex products manufacturers' supply chains are complex, multi-tiered global networks that make tracking even a single chemical extremely difficult, especially in the absence of CAS Numbers which are the global standard for identifying chemicals. Manufacturers must rely on reports from its supply chain with little assurance of response or accuracy.

For this reason, MPCA should focus its reporting requirements on those entities that actually have this information, the chemical producers. Manufacturers, assemblers and distributors of complex products should be exempt from reporting information that they do not have and that is unreasonably burdensome to obtain. Focusing on the source is the more efficient and accurate means to obtain the information about PFAS use it is seeking.

Therefore, the CPMCoalition recommends that MPCA uses its authority under the law to *proactively* grant information requirement waivers for complex products, including but not limited to industrial, commercial, and consumer products such as appliances, batteries, communication devices, electrical and power transmission and distribution equipment, electronics, HVACR-WH systems, lighting, outdoor power equipment, vehicles, vessels, and others, as well as their components and replacement parts. Exemptions should also be applied to complex products' essential chemical components such as low-risk refrigerants, fluoropolymers, and insulating gases, and their replacement parts, as well as any *de minimis* amounts, in its final regulations.

c. Waiver Requests; Need to Develop Criteria, Extend Time, and Provide Clarification.

As explained above, through its authority under the law, MPCA should expand the scope of waiver eligibility. Correspondingly, there will need to be an expansion of the criteria for waivers. Since Minn. Stat. § 116.943 states "[t]he commissioner may grant a waiver under this paragraph

[22] MPCA "Statement of Need and Reasonableness in the Matter of Proposed Minnesota Rules New Chapter 7026; Revisor ID No. RD-4828" (SONAR) published April, 2025.

to a manufacturer or a group of manufacturers for multiple products or a product category"[23] it is clear that the legislators did not intend to limit the waiver eligibility. Therefore, in promulgating criteria for this section, MPCA should maintain the broad applicability and not develop too narrow or specific conditions.

The Proposed Rule also states that a "manufacturer or group of manufacturers must submit the waiver request to the commissioner at least 30 days before the applicable reporting due date."[24] We appreciate that MPCA is including this mechanism, however, the CPMCoalition urges MPCA to proactively provide information requirement waivers to complex products manufacturers under its authority as detailed and established above.

The Proposed Rule further states that, "If the commissioner denies a waiver request, the manufacturer or group of manufacturers must submit their report according to part 7026.0030 or 7026.0040 within 30 days of the notice of denial or by the established reporting due date, whichever is later."[25] The CPMCoalition again urges the MPCA to proactively provide waivers because the timeline of this process is not workable. 30 days is an insufficient amount of time; there is no guarantee that MPCA could evaluate, process, and inform stakeholders as to the status of their request in time for them to then comply in the case of denials.

An additional concern about timing relates to the need for annual submissions for waiver requests. Any issue that warrants the receipt of an initial waiver is likely due to legitimate problems with finding and implementing alternatives, a problem that usually takes many years to resolve, if at all. It should be noted that often manufacturers are unable to find suitable alternatives and simply discontinue the product line or move their business to a different jurisdiction.

The reason this process is so difficult is that to make a substitution for just a single chemical can easily require several years. Manufacturers must complete three lengthy, resource-intensive stages: 1) determine the presence of PFAS throughout its supply chain and manufacturing processes; 2) find a suitable alternative (if one is available); and 3) testing to implement the alternative.

These efforts may affect hundreds or thousands of products, both directly and indirectly through the parts and components in which they are used.[26] For the vast majority of essential complex products and services, and even with considerable investment of resources, feasible PFAS alternatives with demonstrated suitability (and any requisite regulatory approvals) are not reasonably available (or may even be restricted from use by other laws). (Please see Appendix I for more information.)

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[23] Minn. Stat. § 116.943, Subdivision 3(a); https://www.revisor.mn.gov/laws/2023/0/Session+Law/Chapter/60/#laws.3.21.2.

[24] Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees; Revisor's ID Number R-4828, OAH docket number 5-9003-40410.

[25] Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees; Revisor's ID Number R-4828, OAH docket number 5-9003-40410.

[26] See for example an extensive study prepared under an agreement with and funded by the U.S. Department of Energy, discussing the availability of alternatives for fluoropolymers and the feasibility of replacement: Stephanie Jacobs, David S. Kosson, *Assessment of Fluoropolymer Production and Use with Analysis of Alternative Replacement Materials* (January 2024), https://www.osti.gov/biblio/2370520. See also Appendix II.

Furthermore, clarification is needed to understand what is meant by an eligible "group of manufacturers." Please see our comments below in Section 9; the CPMCoalition has concerns about "group reporting" and recommends eliminating this concept in final regulations.

6. 7026.0030 REPORT; REQUIRED INFORMATION; Recommendation for Extension of Program Deadline.

The CPMCoalition has concerns about the reporting deadline and requests waivers for complex products manufacturers. The CPMCoalition recognized that the current law requires that "[o]n or before January 1, 2026, a manufacturer of a product sold, offered for sale, or distributed in the state that contains intentionally added PFAS must submit to the commissioner information…"[27]

However, the CPMCoalition believes that with the necessary rulemaking procedures, development and implementation of reporting platforms, and other necessary elements of developing and implementing an unprecedented and large-scale endeavor is such that neither the MPCA nor the regulated community will be ready to meet this aggressive timeline.

Although the current law provides for the January 1, 2026, reporting deadline, it also further states that "[t]he commissioner may extend the deadline for submission by a manufacturer of the information required under subdivision 2 if the commissioner determines that more time is needed by the manufacturer to comply with the submission requirement."[28] The CPMCoalition asserts that this extension authority can be applied broadly for all manufacturers thus giving MPCA the ability to provide the extra time needed for the Agency and for the regulated community.

The CPMCoalition recommends that like other leading jurisdictions (e.g., TSCA and the State of Maine), MPCA uses its authority under the law to extend its reporting deadline. The CPMCoalition suggests that to avoid issuing multiple postponements,[29] MPCA provide the additional time needed by complex products manufacturers to work through the three complex stages of the chemical substitution process and extend the deadline by at least two years.

7. 7026.0040 REPORTING UPDATES; Recommendation to Remove Annual Recertification Section.

The CPMCoalition understands the requirement found in Proposed Rule, Subpart 1, to submit an update to the report when a new product is offered for sale, or for similar situations, however we do not support the requirement to provide annual recertification. The Proposed Rule states that "[i]f an update is not required under subpart 1, a manufacturer or group of manufacturers must recertify the report submitted under part by February 1 each year."

[27] Minn. Stat. § 116.943, Subdivision 2(a); https://www.revisor.mn.gov/laws/2023/0/Session+Law/Chapter/60/#laws.3.21.2.
[28] Minn. Stat. § 116.943, Subdivision 3(d); https://www.revisor.mn.gov/laws/2023/0/Session+Law/Chapter/60/#laws.3.21.2.
[29] As of May 12, 2025, EPA has issued its second postponement; other jurisdictions have had similar delays.

This is unreasonably burdensome for both the MPCA and the regulated community. The SONAR and the Proposed Rule do not provide sufficient rationale for this provision. We recognize MPCA's need to fund its program, but we assert that the way to do that would be to narrow the scope of regulated PFAS, the scope of the regulation, and the scope of the targeted parties. In this way, fewer Agency resources would be required. It seems that the recertification funds would be needed simply to process the recertification information! A requirement for recertification every five years would be a more manageable cadence for both the agency and the regulated community.

8. 7026.0060 EXTENSIONS; Need for Additional Time.

The CPMCoalition appreciates the MPCA providing the regulated community with an opportunity to obtain an extension to the reporting requirement deadline but asserts that 90 days is an insufficient amount of time. The CPMCoalition recommends that any extensions that are granted provide at least 180 days.

Furthermore, like the waiver process, 30 days is insufficient amount of time for the regulated community to be informed if their request is denied. There is no guarantee that MPCA could evaluate, process, and inform stakeholders as to the status of their request in time for them to then comply with regulatory deadlines in the case of denials.

For these reasons, the CPMCoalition reasserts its recommendation that MPCA proactively provide waivers because the timeline of this process is not workable.

9. 7026.0020 PARTIES RESPONSIBLE FOR REPORTING; Recommendation to Modify and Clarify "Group Reporting."

The CPMCoalition has concerns about "group reporting" and recommends changing this section. We appreciate that MPCA is working to streamline the reporting process by allowing both manufacturers or a "group of manufacturers" to report. Providing that "[a] manufacturer may submit the information required for reporting on behalf of another manufacturer" is intended to minimize the regulation's burdensome effect on both the regulated community and the Agency. Although the CPMCoalition supports "grouping" industry sectors for the purposes of exclusions and exemptions, for example, we support exemptions for complex products manufacturers,[30] we have questions and concerns about how this "grouping" concept would be applied for reporting purposes.

First, there is confusion within the regulated community as to whether "group reporting" is meant to group manufacturers from like industry sectors together or if it is meant to place responsibility on the final goods manufacturers for the manufacturers in its supply chain. To this point, the CPMCoalition recommends clarifying the language, "[a]ll manufacturers must assume

[30] Please see CPMCoalition comments to MPCA on "Planned New Rules Governing Currently Unavoidable Use Determinations About Products Containing Per- and Polyfluoroalkyl Substances, Revisor's ID No. R-4837" submitted on March 1, 2024.

responsibility to report unless manufacturers in the same supply chain enter into an agreement to establish their respective reporting responsibilities."

Furthermore, the Proposed Rule's "Due Diligence" section states, "[a] manufacturer must assume responsibility for reporting products containing intentionally added PFAS unless notification from another manufacturer is received according to part 7026.0020, subpart 2, confirming that the reporting requirements under part 7026.0030 have been fulfilled" could create legal jeopardy for manufacturers as one manufacturer would have to rely on another for compliance and companies generally don't perform coordinated compliance activities.

In addition to the specific liability concerns identified above, in general, most companies do not or cannot perform compliance activities together, due to the need to avoid antitrust issues and to protect confidential business information (CBI). MCPA should address antitrust and proprietary information considerations, such as by requiring reporting in ranges and ensuring confidential business information protection. MPCA should also confirm that downstream companies can reference or rely on reports submitted by their direct suppliers where appropriate. Potentially, reporting could be performed by an outside party such as a coalition, law firm, or trade association, but this would be unusual and would require stakeholder engagement to develop an acceptable framework.

Due to the questions and concerns we have outlined herein, the CPMCoalition recommends that the MPCA work with stakeholders to modify and clarify this section.

10. 7026.0080 DUE DILIGENCE; Concerns about Reporting Due Diligence and Supply Chain Requests.

a. <u>Reporting Due Diligence.</u>

As introduced in the "Group Reporting" section above, the CPMCoalition has concerns about the Proposed Rule's "Due Diligence" section which states, "[a] manufacturer must assume responsibility for reporting products containing intentionally added PFAS unless notification from another manufacturer is received according to part 7026.0020, subpart 2, confirming that the reporting requirements under part 7026.0030 have been fulfilled."[31] This responsibility could create legal risk for manufacturers in that they would have to rely on one another for compliance. Companies generally don't perform coordinated compliance activities at the level of detail called for by the proposed rule, due to the need to avoid antitrust issues and to protect confidential business information (CBI), and other issues. Adjustments should be made to address these legal considerations.

b. <u>Supply Chain Requests.</u>

The Proposed Rule states that "[a] manufacturer or group of manufacturers must request detailed disclosure of information required in part 7026.0030 from their supply chain until all required

[31] Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees; Revisor's ID Number R-4828, OAH docket number 5-9003-40410.

information is known."[32] While it is reasonable to expect companies to reach out to their supply chain in certain situations, the mandate to continue to do so "until all required information is known" is literally impossible.

Complex products manufacturers' supply chains are complex, multi-tiered global networks that rely on voluntary cooperation with little assurance of response or the accuracy of the responses that are received. Typical response rates from suppliers are between 30-40%. This requirement seems unclear, unduly burdensome for manufacturers and in many cases will be impossible to comply with, especially before the January 1, 2026, deadline.

Instead of mandating this impossible standard, we recommend that MPCA adopt language similar to that which seen under TSCA's Section 8(a)(7) PFAS reporting requirements which provides for due diligence to that "which is known or reasonably ascertainable."[33] Furthermore, in the EPA's final implementing rule, it provides that for manufacturers who cannot attain requested data elements from its suppliers, they can report that this information is ''Not Known or Reasonably Ascertainable (NKRA)."[34] These area more reasonable, and more importantly, *achievable* standard.

11. 7026.0100 FEES; Recommendation to Revise Fee Structure and Schedule.

The CPMCoalition recommends the following changes to the fee structure and schedule. As detailed in our earlier comments, the CPMCoalition does not support the "group reporting" concept as it is currently written and recommends altering the fee language that pertains to this concept accordingly.

As we stated in our comments above, we find the annual reporting to be unreasonable, and therefore we also recommend adjusting the fee schedule to lessen the burden of processing on both the Agency and the regulated community to a more manageable cadence of requiring recertification every five years

Lastly, we find the "inflation" allowance to be vague and unreasonable. We recommend removing this section and instead provide certainty to how these fees might change in the future.

* * *

[32] Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees; Revisor's ID Number R-4828, OAH docket number 5-9003-40410.
[33] US Toxic Substances Control Act (TSCA) Sec. 8(a)(7).
[34] Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, 88 Fed. Reg. 70516, (October 11, 2023). Please also see, EPA's "Instructions for Reporting PFAS Under TSCA Section 8(a)(7)" reporting guidance, chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.epa.gov/system/files/documents/2024-05/tsca-8a7-reporting-instructions_may2024.pdf

Thank you for your consideration of these comments. For additional information, please contact Stacy Tatman, Executive Director, Complex Products Manufacturers Coalition, Wiley Rein LLP, 2050 M Street, N.W. Washington, D.C. 20036, 202-875-4352, statman@wiley.law.

Best regards,

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Appendix I: Chemical Substitution Process

Finding suitable chemical alternatives for complex products usually takes many years. Manufacturers must complete three lengthy, resource-intensive stages: 1) determine the presence of PFAS throughout its supply chain and manufacturing processes; 2) find a suitable alternative (if one is available); and 3) testing to implement the alternative.

These efforts may affect hundreds or thousands of products, both directly and indirectly through the parts and components in which they are used.[35] For the vast majority of essential complex products and services, and even with considerable investment of resources, feasible PFAS alternatives with demonstrated suitability (and any requisite regulatory approvals) are not reasonably available (or may even be restricted from use by other laws).

a) Determining the Presence of PFAS in the Supply Chain

Today's complex, global, multi-tiered supply chains are vast and complicated, particularly for complex products which may depend on subassemblies, materials, or processing aids. To initiate a chemical substitution, manufacturers must delve into their supplier network, requesting detailed information from manufacturers and distributors who then cascade the request through the many layers of the supply chain. The scale of outreach and data management required by, not only the complex product manufacturer, but suppliers along the supply chain is substantial and time-consuming.

It is made more challenging when regulators target the entire class of PFAS which is comprised of over 12,000 unique chemicals, and do not provide the industry standard for identifying chemicals, which is to use Chemical Abstracts Service Registration Numbers (CAS Number or CASRN). Without these unique identifiers, it is extremely difficult for suppliers to identify chemicals and manufacturers must rely on responses from their suppliers who, as downstream users, often do not have the proper knowledge that a chemical producer would have to supply the necessary information.

In the absence of *de minimis* exemption, this process must be conducted for even trace amounts of a chemical, even for those that are not added intentionally. It can easily take months to get even initial responses from businesses many layers down in the supply chain.

To determine the presence of a single chemical with a CAS Number takes many months. To identify over 12,000 chemicals with no CAS Numbers may not realistically be possible. A conservative estimate for this step is that, even with the investment of considerable resources, it would take complex products manufacturers approximately two to three years to achieve and would always be subject to the accuracy and completeness of the third-party providing the information.

b) *Finding* a Technically and Economically Feasible Safer Alternative

[35] See for example an extensive study prepared under an agreement with and funded by the U.S. Department of Energy, discussing the availability of alternatives for fluoropolymers and the feasibility of replacement: Stephanie Jacobs, David S. Kosson, *Assessment of Fluoropolymer Production and Use with Analysis of Alternative Replacement Materials* (January 2024), https://www.osti.gov/biblio/2370520. See also Appendix II.
[35] Minn. Stat. § 116.943, Subdivision 2(a);

For complex products that are made of hundreds or thousands of parts, the process of finding starts with years of research and development, until a feasible alternative is identified. For the vast majority of complex products, such an alternative is not yet available. Because currently there are no reasonably available, known-to-be-suitable, PFAS alternatives for the majority of complex products, these manufacturers would need to identify an immediate substitution of alternate formulations for companies to maintain production. This means that, without appropriate regulatory flexibility, many products on which the health and well-being of society depends would no longer be available.

But finding a suitable chemical substitute requires significant time and resources, with no guarantee of success. Even an initial screen for potential PFAS alternatives can take months to years, depending on the complexity of the product. According to the California Department of Toxic Substances Control's 302-page guide, proper alternative analyses require collecting information on safety, performance, availability, and economic feasibility and could take many years.[36] It is realistic to expect that this step would require several years for manufacturers to collect the information necessary to allow a manufacturer to safely commit to moving forward with a particular alternative.

Many complex products manufacturers are already conducting research on alternatives, however, even in the rare cases in which a feasible alternative is available, 15 years or more are necessary to implement substitutions across the supply chain.

c) *Implementing* a Technically and Economically Feasible Safer Alternative

Once an alternative formulation has been identified, additional time is needed for implementation due to the need for the redesigning and testing of any new components that contain PFAS alternatives. Some manufacturers may require additional time to obtain requisite regulatory approvals or other product-specific requirements before any alternative can proceed to market. This step must ensure the attainment of applicable safety and other standards, compliance with already-existing laws and regulations, and the ability to meet consumer demands and expectations.

This testing includes completion—and passage—of not only component-level approval processes and testing of the part itself, but also testing of the product, and in some applications also requires the final product to be tested by the original equipment manufacturers.

Additionally, it takes multiple years to retrofit facilities to accommodate any such future alternative and to obtain the approvals required to confirm the technical, economic, and commercial feasibility of the non-PFAS alternatives. Any proposed alternative must complete the multi-layer testing processes to confirm technical and economic feasibility.

A conservative estimate of the time needed to implement a *single* alternative to PFAS is three to five years. When products contain multiple PFAS, this timeline increases (especially if the substitution of many PFAS are happening concurrently), as different PFAS perform different

[36] For more information about the complexities of a chemical alternatives analysis, please see the California Department of Toxic Substances Control (DTSC) 302-page guide: https://dtsc.ca.gov/wpcontent/uploads/sites/31/2016/01/AA-Guide-Version-1-0_June-2017.pdf.

functions in products. If alternatives are identified, this time estimate compounded across the hundreds of thousands of applications means that industries will need between 7-20 years, depending on the product type.

* * *

Appendix II

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Assessment of Fluoropolymer Production and Use With Analysis of Alternative Replacement Materials

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January 2024

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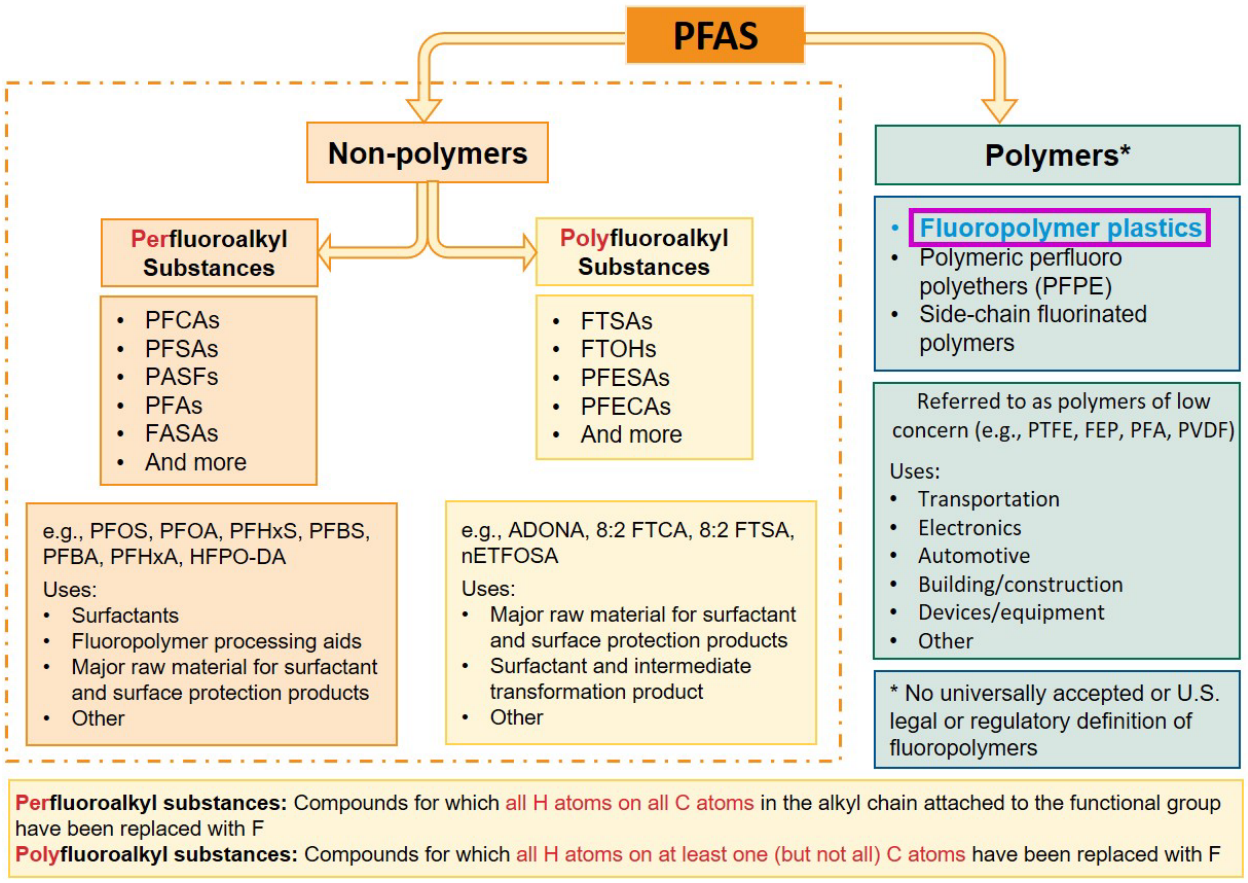
EXECUTIVE SUMMARY

This report focuses on fluoropolymers, which are a subgroup of the much larger class of fluorinated chemicals known as per- and polyfluoroalkyl substances (PFAS). Clearly distinguishing fluoropolymers is important to understanding their distinctive chemical properties, associated risks and benefits, and roles in commerce. In this report, the factors that are considered in a lifecycle assessment (LCA) of fluoropolymers will be discussed. These include the manufacturing of fluoropolymers, their use in industry, and available replacement technologies. Emphasis is placed on fluoropolymer plastics because of their extensive use in the commerce sectors considered here, specifically aerospace, automotive, battery, building construction, chemical processing, electronics, infrastructure, semiconductor, solar panel, and wind energy industries.

The thousands of individual PFAS that have been developed divide into two classes: non-polymeric PFAS, consisting of a single unit (monomer), and polymeric PFAS, consisting of a chain of smaller repeating units (Figure ES-1). Non-polymeric PFAS (single molecule PFAS) are further divided into perfluoroalkyl and polyfluoroalkyl substances. These non-polymeric PFAS have a relatively small molecular weight and particle size. Extensive use of non-polymeric PFAS, such as the aqueous film-forming foam (AFFF) used for firefighting, has resulted in environmental contamination. Non-polymeric PFAS also are often used in the production of polymeric PFAS, including fluoropolymers. Non-polymeric PFAS are persistent and mobile in a variety of media, including water, air, soils, and sediments. This mobility increases the dispersion of non-polymeric PFAS in the environment and can lead to concerns about biological uptake and accumulation in plants and animals, with potential human health impacts.

Recent scientific and public concern has focused on the commercial use and fate of non-polymeric PFAS (e.g., perfluorooctane sulfonic acid [PFOS] and perfluorooctanoic acid [PFOA]) and the potential release of low molecular weight non-polymeric PFAS during the life cycle of polymeric PFAS.



Source: ITRC, 2022, "PFAS — Per- and Polyfluoroalkyl Substances," Report No. PFAS-1, Interstate Technology and Regulatory Council, Washington, D.C.

Figure ES-1. Per- and Polyfluoroalkyl Substances Family Tree and Classification

PFAS, including fluoropolymers, are a research priority of federal health and environmental agencies, including the Agency for Toxic Substances and Disease Registry,[1] Centers for Disease Control and Prevention,[2] U.S. Environmental Protection Agency,[3] National Institute of Environmental Health Sciences,[4] and National Institute for Occupational Safety and Health.[5] However, the environmental fate and impacts of non-polymeric and polymeric PFAS (not identified as fluoropolymers) are beyond the scope of this study.

[1] ATSDR, 2023, "Per- and Polyfluoroalkyl Substances (PFAS) and Your Health: Pease Study," Agency for Toxic Substances and Disease Registry, Atlanta, Georgia.
[2] CDC, 2022, "Per- and Polyfluorinated Substances (PFAS) Factsheet," Centers for Disease Control and Prevention, Atlanta, Georgia.
[3] EPA, 2023a, "Increasing Our Understanding of the Health Risks from PFAS and How to Address Them," U.S. Environmental Protection Agency, Washington, D.C.
[4] NIEHS, 2023, "PFAS Research," National Institute of Environmental Health Sciences, Durham, North Carolina.
[5] NIOSH, 2022, "Per- and polyfluoroalkyl substances (PFAS)," National Institute for Occupational Safety and Health, Washington, D.C.; https://www.cdc.gov/niosh/topics/pfas.

Fluoropolymers include three subgroups of polymerized PFAS that are high molecular weight polymers and copolymers[6] that consist of a carbon backbone with fluorine atoms directly bonded to the carbon atoms. Fluoropolymers are generally not soluble in water. The other two subgroups of polymerized PFAS include oligomeric[7] perfluoropolyether (PFPE) compounds (used largely as chemically resistant lubricant oils and greases) and side-chain fluorinated polymers (used for surface protection and coatings mainly in fabrics, textiles, and apparel articles, and for food contact paper and paperboard). There is no globally accepted definition of either PFAS or the fluoropolymer subgroup, which challenges clarity in attribution of potential benefits, impacts, and controls; however, in this report, the discussion is focused on fluoropolymer plastics (as defined in Section 3.0[8]), which are considered distinct from fluorinated side-chain polymers and oligomeric PFPEs because of differing structural properties and uses. Oligomeric PFPEs contain a carbon and oxygen polymer backbone, with fluorine atoms directly attached to the carbon atoms. Side-chain fluorinated polymers branch off of a non-fluorinated polymer backbone. Due to their molecular structure, fluoropolymer plastics have unique physical and chemical properties that have led to wide-spread integration into many sectors of modern commerce, including aerospace, automotive, chemical processes and storage, infrastructure, solar and wind energies, electronics, and many others. Fluoropolymer plastics are emphasized in this report because of the overlap among the sectors of interest for this report and typical fluoropolymer uses.

Fluoropolymers can be chemically modified to optimize properties for specific applications, and many of these formulas are proprietary. Several fluoropolymers widely used in commerce include polytetrafluoroethylene (PTFE, also known as Teflon[9]), polychlorotrifluoroethylene (PCTFE), fluorinated ethylene propylene (FEP), polyvinyl fluoride (PVF), perfluoroalkoxy (PFA), ethylene tetrafluoroethylene (ETFE), ethylene chlorotrifluoroethylene (ECTFE), Nafion,[10] and polyvinylidene fluoride (PVDF).

Table ES-1 and Table ES-2 summarize fluoropolymer properties and uses. Fluoropolymers are thermally and chemically stable, electrically non-conductive, flame retardant, and water-repellent, making them useful in a wide range of applications. Fluoropolymers can also be used in multiple forms, including as lubricants, coatings, sheeting, and additives. As an example of their versatility, fluoropolymers can be found in the coating on electrical wiring, seals and gaskets, fuel lines, and anti-vandal paint. Fluoropolymers are also used in tank and piping liners, valves, pumps, and personal protective equipment; their non-stick and weather resistance properties are also desirable in these applications. The unique properties of fluoropolymers make them long-lasting, stable, and resistant to chemical or biological breakdown, while still being light-weight and adaptable. Fluoropolymers enhance the durability, safety, and longevity of a wide range of products. Some applications use multiple fluoropolymers or fluoropolymers blended with other fluorinated or non-fluorinated polymers.

[6] In this report, terpolymers (i.e., those copolymers obtained from three monomers) are grouped in the copolymer class.
[7] Oligomers comprise the same monomers as polymers, but their chain is much shorter.
[8] In the context of this report, fluoropolymer plastics include both thermoplastic (rigid materials formed by heating or machining) and elastomeric (flexible material) forms and refer to water-insoluble, solid-state materials (either hard or soft), composed of fluoropolymers and useful for fabrication of physical articles.
[9] Teflon is a registered trademark of The Chemours Company FC, LLC (formally DuPont), Wilmington, Delaware.
[10] Nafion is trademark of The Chemours Company FC, LLC (formerly DuPont), Wilmington, Delaware.

Table ES-1. Typical Applications of Fluoropolymers for Different Industry Sectors

Industries	Functions	Forms
Automotive	Mechanical property, thermal property, chemical property, and friction property	O-rings, gaskets, valve stem seals, shaft seals, linings for fuel hoses, power steering, and transmission
Chemical	Chemical resistance, mechanical property, thermal property, and weather stability	Coatings for heat exchangers, pumps, diaphragms, impellers, tanks, reaction vessels, autoclaves, containers, flue duct expansion joints, and heavy-wall solid pipe and fittings
Electrical/electronic	Dielectric constant, flame resistance, and thermal stability	Electrical insulation, flexible printed circuits, ultra-pure components for semiconductor manufacture
Architectural and domestic	Weatherability, flame retardancy, friction property, thermal stability	Water-repellent fabric, architectural fabric, non-stick coatings for cookware, and fiberglass composite for construction
Engineering	Mechanical property, thermal stability, chemical stability, weatherability, and surface energy	Seats and plugs, bearings, non-stick surfaces, coatings for pipes, fittings, valve and pump parts, and gears
Medical	Surface energy, biological stability, mechanical property, chemical resistance	Cardiovascular grafts, ligament replacement, and heart patches

Source: Teng, H., 2012, "Overview of the Development of the Fluoropolymer Industry," *Applied Sciences*, 2(2), pp 496–512.

Alternative materials and technologies have been identified for some specific uses of fluoropolymers. However, because of the combination of beneficial properties of fluoropolymers, no alternatives have been identified that could replace fluoropolymers in many, or over a broad range, of applications in the sectors considered in this report. As industry research and development and commercial pilot projects progress, substitutes for fluoropolymers in additional applications may be developed.[11]

[11] Toloken, S., 2023, "An 'enormous' push to find PFAS replacements in manufacturing," *Plastics News*, Detroit, Michigan.

Table ES-2. Selected Fluoropolymers and Example Uses for Sectors of Interest

Industries end uses	Transportation		Chemical		Telecommunications		Infrastructure construction and architecture	Renewable energy		
	Auto-motive	Aero-space	Oil and gas	Chemical process industry (CPI)	Electronics and semiconductors	Internet and wireless communi-cations		Energy production	Hydrogen production	Energy storage
Fluoropolymer Thermoplastics										
PTFE	●	●	●	●	●	●	●	●	●	●
ETFE	●	●	●	●	●	●	●	●		●
FEP	●	●	●	●	●			●		
PFA	●	●	●	●	●			●		
PVDF homopolymer	●	●	●	●	●	●	●	●	●	●
PVDF copolymer	●	●		●	●	●	●		●	●
ECTFE copolymer		●	●	●	●	●	●			
ECTFE terpolymer			●	●						
PCTFE		●			●					
FEVE	●	●			●		●			
EFEP	●			●	●					
CPT	●				●					
THV	●	●		●	●		●	●		●
Fluoropolymer Elastomers										
FEPM	●	●	●	●	●		●	●		
FKM	●	●	●	●	●		●	●	●	●
FFKM		●	●	●	●					
Specialty Fluoropolymers										
Amorphous		●		●	●	●			●	●
Ionomer	●			●	●			●	●	●

Source: Based on Henry et al., 2018, "A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers," and Korzeniowski et al., 2023, "A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers," *Integrated Environmental Assessment and Management*.

CPT = chlorotrifluoroethylene-perfluoroalkoxy-tetrafluoroethylene.
ECTFE = ethylene chlorotrifluoroethylene.
EFEP = ethylene-tetrafluoroethylene-hexafluoropropylene.
ETFE = ethylene tetrafluoroethylene.
FEP = fluorinated ethylene propylene.
FEPM = trifluoroethylene-propylene copolymer.
FEVE = fluoroethylene-vinyl ether.
FFKM = TFE-PMVE perfluoroelastomer.
FKM = fluorine Kautschuk material.
PCTFE = polychlorotrifluoroethylene.
PFA = perfluoroalkoxy polymer.
PTFE = polytetrafluoroethylene.
PVDF = polyvinylidene fluoride.
THV = TFE-HFP-VF2.

A life cycle assessment of every fluoropolymer is not practical because of the variety of fluoropolymers and the large number of applications for each type of fluoropolymer. While a quantitative comparative life cycle assessment of a limited number of important fluoropolymers and their alternatives would be useful, it is instructive to consider, as done in this report, specific phases of the life cycle of fluoropolymers and identify the most important potential routes for environmental releases, exposures, and adverse impacts.

The most important life cycle phases of fluoropolymers are production, use, recycling, and disposal:

- **Production** – Non-polymeric PFAS polymerization aids are nonreactive additives that are used in fluoropolymer synthesis. In some fluoropolymers, the non-polymeric PFAS act as raw materials. During fluoropolymer synthesis, most of the polymerization aid is recycled or recovered, with the remaining fraction of non-polymeric PFAS being emitted or disposed of with the effluent wastewater or waste. Typical polymerization aids used in industry are PFOA, perfluorononanoic acid (PFNA), and hexafluoropropylene oxide dimer acid (HFPO-DA).

A very low concentration of the processing aid is likely to remain incorporated with the fluoropolymer and may be emitted during downstream processing (parts forming or coatings) or use. Use of fluorinated processing aids has resulted in environmental releases and contamination proximate to production sites. Current and evolving fluoropolymer production has focused on reducing or eliminating the use of PFAS as processing aids and placing stringent controls on remaining non-polymeric PFAS as part of fluoropolymer production. Monitoring and discharge limits at wastewater treatment plants have also resulted in reductions in the quantities of PFAS released to the environment from production processes.

- **Use** – Residual, non-polymeric PFAS present in fluoropolymers from incomplete separation of processing aids during production may be leached from fluoropolymers in contact with water or other liquids; however, water or liquid contact does not occur during many fluoropolymer uses. Reduction or elimination of the use of fluorinated polymerization aids and increased focus on minimizing residual non-polymeric PFAS present in fluoropolymers should reduce or eliminate release of non-polymeric PFAS during use. The formation and environmental transport of fluoropolymer microplastics during fluoropolymer use in outdoor applications with potentially abrasive conditions (e.g., external building or solar panel coatings) and the presence of microplastic fluoropolymers in environmental systems (e.g., surface waters or biota) have not been studied.
- **Recycling** – Recycling of fluoropolymers in most circumstances is impractical because the fluoropolymer is embedded in a product and not readily separated as an initial recycling processing step. In cases where fluoropolymer recycling is practical (e.g., with scrap from forming products), non-polymeric PFAS formed during material softening by irradiation subsequently may be volatilized during processing or released through water contact.
- **Disposal** – Because recycling of fluoropolymers is often impractical, landfilling is frequently used. Studies examining the release of non-polymeric PFAS from landfills are confounded by the range of products and waste disposed of, which contain an unknown quantity and range of non-polymeric and polymeric PFAS in addition to fluoropolymers; thus, source attribution has not been possible. Studies examining the fate of fluoropolymers during incineration have been limited to analysis of a European rotary kiln pilot-scale incinerator, which indicated absence of PFAS in the exhaust gas. However, the primary combustion chamber was not representative of municipal solid waste incinerators in the U.S., which typically have less efficient moving grate combustion chambers, and therefore, the potential for PFAS residuals in the bottom ash from incomplete combustion is unknown.

The life cycle and cost-benefit understanding of fluoropolymers is at an early stage and still rapidly evolving. Industrial research and development into possible replacements of fluoropolymers is relatively recent, as is public health and environmental research into the impacts of fluoropolymers. Robust findings take many years to develop, even when prioritized by the government and private sector.

Carrying out an exhaustive cost-benefit analysis of removing fluoropolymers from the U.S. supply chain and replacing them with alternative materials presents several practical limitations. Fluoropolymers are used in thousands of end-use applications, and potential trade-offs would need to be considered for a significant number of those applications. In many instances, necessary data are not publicly available. However, much insight could be gained from well-done life cycle assessment and cost-benefit analysis case studies on a limited number of important fluoropolymers and alternatives. The barriers to overcome are the lack of detailed quantitative information on fluoropolymer production, use, and benefits in specific applications, and the associated environmental and public health impacts in the different stages of the life cycle. Similarly, getting access to analogous comprehensive information on substitute materials if used in the same applications is challenging. In addition, such case studies would likely require access to proprietary data about fluoropolymers, alternatives, and applications to be evaluated.

Removing fluoropolymers generally or from specific uses could lead to increased costs, not only in terms of raw material and manufacturing but also from equipment modifications and maintenance and compliance with or revision of industry standards. A transition to fluoropolymer alternatives may necessitate expensive retrofitting of existing infrastructure and machinery. In addition, restrictions in use of fluoropolymers may result in the loss of technological advances and innovation (e.g., in semi-conductor and microelectronics production, and miniaturization and durability of products). With fluoropolymers playing an increasingly important role in the clean energy transition, efforts to replace fluoropolymers need to be studied carefully for effectiveness and affordability.

Overall, the key challenges and knowledge gaps in evaluating the comparative life cycle and cost-benefits of fluoropolymers versus alternative materials include the following:

- Limited number of alternative materials and technologies that provide acceptable performance as substitutes for fluoropolymers
- Lack of publicly available data on the life cycle of fluoropolymers and consequences of using alternative materials and processes
- Very limited amount of information on the environmental releases of fluoropolymer microplastics and non-polymeric PFAS during fluoropolymer production, product use, disposal, and recycling
- Lack of sufficient knowledge of the exposure pathways, fate and transport in the environment, and subsequent public health and environmental impacts of different fluoropolymers
- Lack of publicly available economic information regarding the supply chains, production, and use of fluoropolymers and alternatives
- Lack of transparency on fluoropolymer production processes used in other countries and the resulting impurities in materials that subsequently enter the U.S. supply chain (e.g., when non-polymeric PFOA is being used as the polymerization aid and may be released during subsequent end-product forming, use and disposal).

Importantly, the absence of clarity and agreement on the definition of the category of fluoropolymers confounds discourse and resolution of concerns associated with the materials.

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3D	three-dimensional
$Å^3$	cubic angstrom
ACA	American Coatings Association
ACM	acrylic rubber
ADONA	trade name for 4,8-dioxa-3H-perfluorononanoate
AEM	ethylene acrylic elastomer
AF	amorphous fluoropolymer
AFFF	aqueous film-forming foam
AGC	AGC Inc. (formerly Asahi Glass Co., Ltd.)
AiT	AI Technology Inc.
APFN	ammonium perfluorononanoate
APFO	ammonium perfluorooctanoate
ATSDR	Agency for Toxic Substances and Disease Registry
BA	Bachelor of Arts
BAE	Biosystems and Agricultural Engineering
BCEEM	Board-Certified Environmental Engineering Member
BE	Bachelor of Engineering
BS	Bachelor of Science
C	carbon
C_2F_4	tetrafluoroethylene
CAGR	compound annual growth rate
CAS	Chemical Abstracts Service
CBA	cost-benefit analysis
CDC	Centers for Disease Control and Prevention
CED	cumulative energy demand
CEH	Chemical Economics Handbook
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CF	characterization factor
CH_4	methane
Chemours	The Chemours Company FC, LLC
CITS	Center for International Trade and Security
CMAQ	Community Multiscale Air Quality
CMC	carboxymethyl cellulose
CO_2	carbon dioxide
CPI	chemical process industry
CPT	chlorotrifluoroethylene-perfluoroalkoxy-tetrafluoroethylene
CPVC	chlorinated polyvinyl chloride
CRESP	Consortium for Risk Evaluation with Stakeholder Participation
CST	crystalline silicotitanate

CTFE	chlorotrifluoroethylene
Da	dalton
DEQ	Department of Environmental Quality
DOD	U.S. Department of Defense
DOE	U.S. Department of Energy
DOE-EHSS	U.S. Department of Energy, Office of Environment, Health, Safety and Security
DOE-EM	U.S. Department of Energy, Office of Environmental Management
DOECAP-AP	Department of Energy Consolidated Audit Program – Accreditation Program
ECHA	European Chemicals Agency
ECTFE	ethylene chlorotrifluoroethylene
EFEP	ethylene-tetrafluoroethylene-hexafluoropropylene
EHSS	U.S. Department of Energy, Office of Environment, Health, Safety and Security
EHSS-21	U.S. Department of Energy, Office of Sustainable Environmental Stewardship
EM	U.S. Department of Energy, Office of Environmental Management
EMAB	Environmental Management Advisory Board
EPA	U.S. Environmental Protection Agency
EPDM	ethylene propylene diene monomer
EPR	ethylene propylene rubber
ES&H	Environment, Safety and Health
ETFE	ethylene tetrafluoroethylene
EVOH	ethylene vinyl alcohol resin
EXAFS	extended X-ray absorption fine structure
F	fluorine
FASA	fluoroalkyl sulfonamide
FEP	fluorinated ethylene propylene
FEPM	trifluoroethylene-propylene copolymer
FEVE	fluoroethylene-vinyl ether
FFKM	TFE-PMVE perfluoroelastomer
FFRDC	Federally Funded Research and Development Center
FKM	fluorine Kautschuk material
FLCAC	Federal Life Cycle Assessment Commons
FP	fluoropolymer
FPA	fluoropolymer processing aid
FR	Federal Register
FRP	fiber-reinforced plastic
FTCA	fluorotelomer carboxylic acid
FTOH	fluorotelomer alcohol
FTSA	fluorotelomer sulfonic acid
FVMQ	fluorosilicone
GREET	Greenhouse Gases, Regulated Emissions, and Energy Use in Technologies
GWP	global warming potential
H	hydrogen

HCl	hydrochloric acid
HDPE	high-density polyethylene
HFFR	halogen-free flame retardant
HFP	hexafluoropropylene
HFPO-DA	hexafluoropropylene oxide dimer acid
HNBR	hydrogenated nitrile butadiene rubber
IIASA	International Institute for Applied Systems Analysis
INSITE	Induced Spectral Interrogation Technology for the Environment
IPCC	Intergovernmental Panel on Climate Change
ISO	International Organization for Standardization
ITRC	Interstate Technology and Regulatory Council
LCA	life cycle assessment
LCC	life cycle costing
LCI	life cycle inventory
LCIA	life cycle impact assessment
LEAF	Leaching Environmental Assessment Framework
LLDPE	linear low-density polyethylene
MeHg	methylmercury
MFA	methyl fluoroacetate
MJ	megajoule
MJe	megajoule equivalents
MLIS	Master's in Library and Information Science
MS	Master of Science
MW	molecular weight
NAICS	North American Industry Classification System
NBR	nitrile butadiene rubber
NC	North Carolina
NC DEQ	North Carolina Department of Environmental Quality
nEtFOSA	N-ethyl perfluorooctane sulfonamide
NETL	National Energy Technology Laboratory
NIEHS	National Institute of Environmental Health Sciences
NIOSH	National Institute for Occupational Safety and Health
NMP	n-methyl-2-pyrrolidone
NNLEMS	Network of National Laboratories for Environmental Management and Stewardship
NNSA	National Nuclear Security Administration
NO_x	nitrogen oxides
NPDES	National Pollutant Discharge Elimination System
NRC	U.S. Nuclear Regulatory Commission
NREL	National Renewable Energy Laboratory
OECD	Organisation for Economic Co-operation and Development
P	propylene
PA	polyamide

PAA	polyacrylic acid
PAI	polyamideimide
PAN	polyacrylonitrile
PASF	perfluoroalkane sulfonyl fluoride
Pb	lead
PBI	polybenzimidazole
PBVE	perfluoro-3-butenylvinylether
PC	polycarbonate
PCR	product category rule
PCTFE	polychlorotrifluoroethylene
PDD	perfluoro-2,2-dimethyl-1,3-dioxole
PE	polyethylene
PEEK	polyetheretherketone
PEG	polyethylene glycol
PEI	polyetherimide
PEM	polymer electrolyte membrane
PEO	polyethylene oxide
PES	polyethersulfone
PET	polyethylene terephthalate
PEVE	perfluoroethylvinylether
PFA	perfluoroalkoxy
PFAA	perfluoroalkyl acid
PFAS	per- and polyfluoroalkyl substances
PFBA	perfluorobutanoic acid
PFBE	perfluorobutylethylene
PFBS	perfluorobutanesulfonic acid
PFCA	perfluoroalkylcarboxylic acid
PFECA	perfluoroether carboxylic acid
PFESA	perfluoroether sulfonic acid
PFH	perfluorohexane sulfonic acid
PFH_xA	perfluorohexanoic acid
PFH_xS	perfluorohexanesulfonic acid
PFIB	perfluoroisobutylene
PFNA	perfluorononanoic acid
PFOA	perfluorooctanoic acid
PFOS	perfluorooctane sulfonic acid
PFPE	perfluoropolyether
PFSA	perfluoroalkane sulfonic acid
PhD	Doctor of Philosophy
PMIA	poly m-phenylene isophthalamide
PMMA	polymethyl methacrylate
PMVE	perfluoromethylvinylether

PNNL	Pacific Northwest National Laboratory
POM	polyoxymethylene
PP	polypropylene
PPSU	polyphenylsulfone
PPVE	perfluoropropylvinylether
PSF	polysulfone
PTFE	polytetrafluoroethylene
PU	polyurethane
PVA	polyvinyl alcohol
PVAC	polyvinyl acetate
PVC	polyvinyl chloride
PVDF	polyvinylidene fluoride
PVDF-CTFE	poly(vinylidene fluoride-chlorotrifluoroethylene)
PVDF-HFP	poly(vinylidene fluoride-hexafluoropropylene)
PVDF-TrFE	poly(vinylidene fluoride-trifluoroethylene)
PVF	polyvinyl fluoride
R22	difluorochloromethane
RCRA	Resource Conservation and Recovery Act
RMOA	Regulatory Management Option Analysis
SBR	styrene butadiene rubber
SBS	polystyrene-b-butadiene-b-styrene
SETAC	Society of Environmental Toxicology and Chemistry
SF_6	sulfur hexafluoride
SIP	spectral-induced polarization
SLCA	social life cycle assessment
SNUR	significant new use rule
SRNL	Savannah River National Laboratory
SRS	Savannah River Site
TCE	trichloroethylene
TFE	tetrafluoroethylene
THV	tetrafluoroethylene-hexafluoropropylene-vinylidene fluoride (TFE-HFP-VF2)
TPE	thermoplastic elastomer
TRACI	Tool for Reduction and Assessment of Chemicals and Other Environmental Impacts
TrFE	trifluoroethylene
TSCA	Toxic Substances Control Act
TTD	2,2,4-trifluoro-5-trifluoromethoxy-1,3-dioxole
UF_6	uranium hexafluoride
UHMWPE	ultra-high molecular weight polyethylene
UNEP	United Nations Environment Program
U.S.	United States
USD	United States Dollar
USLCI	U.S. Life Cycle Inventory Database

UV	ultraviolet
VDF	vinylidene fluoride
VDF-HFP	vinylidene fluoride-hexafluoropropylene
VF	vinyl fluoride
VF-HFP	vinyl fluoride-hexafluoropropylene
VF2	vinylidene fluoride
VF2-HFP	vinylidene fluoride-hexafluoropropylene
XANES	X-ray absorption near-edge structure
XAS	X-ray absorption spectroscopy
XLPE	cross-linked polyethylene

LIST OF TRADEMARKS/BRAND NAMES

TRADEMARK DISCLAIMER. Reference herein to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise, does not necessarily constitute or imply its endorsement, recommendation, or favoring by the United States Government or any agency thereof or its contractors or subcontractors.

Aclar: Registered trademark of Honeywell International Inc., Charlotte, North Carolina.

Aflon: Registered trademark of AGC Inc. (formerly Asahi Glass Co., Ltd.), Tokyo, Japan.

Alfas: Registered trademark of Asahi Glass Company, Tokyo, Japan.

Armylor: Registered trademark of Mersen, Courbevoie, France.

Chemraz: Registered trademark of Greene Tweed, Selma, Texas.

Cytop: Trademark of AGC Inc., Tokyo, Japan.

Dai-el: Registered trademark of Daikin Industries, Osaka, Japan.

Dyneon: Registered trademark of 3M Company, St. Paul, Minnesota.

Fluon: Registered trademark of AGC Chemicals, Exton, Pennsylvania.

Fluorel: Trademark of 3M Company, St. Paul, Minnesota.

Halar: Registered trademark of Solvay S.A., Brussels, Belgium.

Halon: Registered trademark of Allied Corporation, Morristown, New Jersey.

Hostaflon: Registered trademark of Hoechst Celanese, Irving, Texas.

Hyflon: Registered trademark of Solvay S.A., Brussels, Belgium.

Kalrez: Registered trademark of DuPont Performance Elastomers, Wilmington, Delaware.

Kel-F: Registered trademark of 3M Company, St. Paul, Minnesota (discontinued production in1995).

Kynar: Registered trademark of Arkema S.A., Colombes, France.

Licity: Registered trademark of BASF, Ludwigshafen, Germany.

Lycra: Registered trademark of The LYCRA Company, Wilmington, Delaware.

Mylar: Registered trademark of the DuPont Teijin Corporation, Chester, Virginia.

Nafion: Trademark of The Chemours Company FC, LLC (formerly DuPont), Wilmington, Delaware.

Neoflon: Registered trademark of Daikin Industries, Ltd., Osaka, Japan.

Plaskon: Registered trademark of Panasonic Electric Works Electronic Materials Singapore Pte Ltd, Singapore.

Polyflon: Registered trademark of Daikin Industries, Ltd., Osaka, Japan.

SOLAR-THRU: Trademark of AI Technology Inc., Princeton Junction, New Jersey.

Solef: Registered trademark of Solvay S.A., Brussels, Belgium.

Tecnoflon: Registered trademark of Solvay S.A., Brussels, Belgium.

Tedlar: Registered trademark of DuPont, Wilmington, Delaware.

Teflon: Registered trademark of The Chemours Company FC, LLC (formally DuPont), Wilmington, Delaware.

Tefzel: Trademark of The Chemours Company FC, LLC, Wilmington, Delaware, for its brand of ETFE fluoropolymer resins.

Texlon: Registered trademark of Vector Foiltec GmbH, Siegsdorf, Germany.

Viton/Viton Extreme: Registered trademarks of The Chemours Company FC, LLC (formally DuPont), Wilmington, Delaware.

Voltalef: Registered trademark of Arkema S.A., Colombes, France.

Xirallic: Registered trademark of Merck KGaA, Darmstadt, Germany.

1.0 INTRODUCTION

Fluoropolymers were first synthesized by DuPont in 1938 and in the decades since their initial creation have become tightly woven into the fabric of modern life. Fluoropolymers are used in a wide range of sectors such as infrastructure, aerospace, microelectronics, and green-energy solutions.

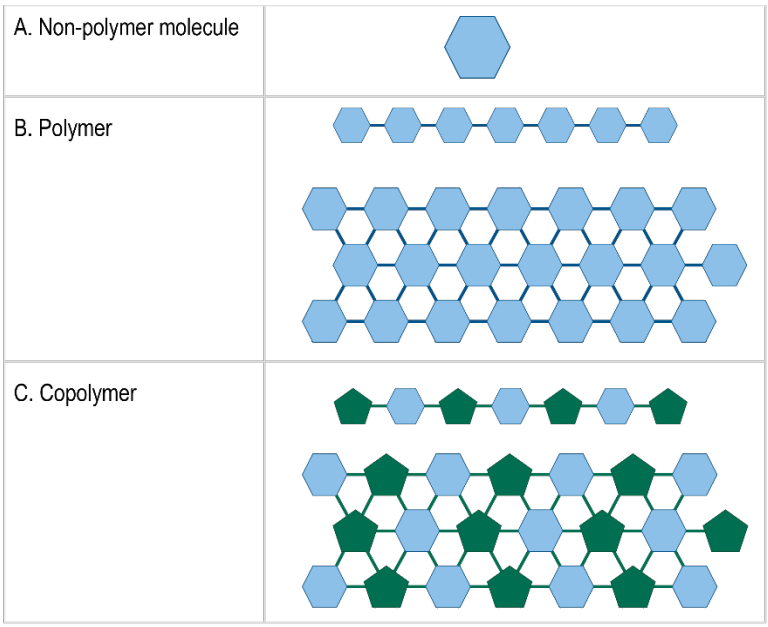


Figure 1-1. Non-polymer, Polymer, and Copolymer Molecules

Concerns over the environmental and health impacts of the family of per- and polyfluoroalkyl substances (PFAS), which includes fluoropolymers, have grown significantly in recent decades. These substances tend to be highly persistent when released into the environment, prompting states and nations to consider further restrictions on the production and general use of PFAS. This report contains a qualitative life cycle assessment (Section 5.1) and cost-benefit analysis of common fluoropolymers currently in use (Section 5.2) and potential replacements of fluoropolymers in commerce. Due to limited availability of data on fluoropolymers, *de novo* quantitative life cycle assessments and cost-benefit analyses are not included in this report. In some cases, insufficient knowledge exists; while in other cases, the data are not publicly available to undertake the quantitative analyses.

1.1 What is a Fluoropolymer?

Fluoropolymers are a distinct subclass of PFAS, which are a large class of synthetic (or man-made) chemicals. The thousands of individual PFAS that have been developed divide into two classes: non-polymeric PFAS, consisting of a single unit (monomer), and polymeric PFAS, consisting of a chain of smaller repeating units. Non-polymeric PFAS consist of a single molecule of varying size (Figure 1-1A). Additional details on select, specific non-polymeric PFAS are provided in Sections 2.0 and 3.0. Non-polymeric PFAS (single molecule PFAS) are further divided into perfluoroalkyl and polyfluoroalkyl substances. These non-polymeric PFAS have a relatively small molecular weight and particle size. Non-polymeric PFAS are persistent and mobile in a variety of media, including water, air, soils, and sediments. This mobility increases the dispersion of non-polymeric PFAS in the environment and can lead to concerns about biological uptake and accumulation in plants and animals. Non-polymeric PFAS are often used in the production of polymeric PFAS, including fluoropolymers. The production of fluoropolymer plastics, defined herein and the focus of this report, is discussed in detail in Section 3.0.

There is no universally agreed on definition of the subcategories of polymeric PFAS, leading to confusion in the discussion and distinctions of different types of PFAS. For the purposes of this report, different subcategories of polymeric PFAS are distinguished as follows. The polymeric PFAS class comprises polymers and copolymers. Polymers are large molecules of smaller repeating units (called monomers) linked together in a chain-like or sheet-like form (Figure 1-1B). Copolymers consist of two or more different repeating monomers (Figure 1-1C).

PFAS, both polymers and copolymers, can also be divided into three main types: fluoropolymer plastics, oligomeric perfluoropolyether (PFPE) compounds, and side-chain fluorinated polymers. Polymeric

PFAS are generally not soluble in water. Fluoropolymer plastics fall into this class. Fluoropolymer plastics are high molecular weight polymers and copolymers that consist of a carbon backbone with fluorine atoms directly bonded to the carbon atoms. Fluoropolymer plastics include both thermoplastic and elastomeric solid-state materials composed of fluoropolymers and are useful for fabrication of physical articles (which are distinct from fluorinated side-chain polymers mainly used for surface protection and coatings or oligomeric PFPEs used largely as chemically resistant lubricant oils and greases). Due to their molecular structure, fluoropolymer plastics have unique physical and chemical properties that have led to wide-spread integration into many sectors of modern commerce, including aerospace, automotive, chemical processes and storage, infrastructure, solar and wind energies, electronics, and many others. Selected applications are described in Section 4.0. Fluoropolymers can be chemically modified to optimize properties for specific applications, and many of these formulas are proprietary.

1.2 What Properties Make Fluoropolymers Desirable?

Fluoropolymers are thermally and chemically stable, lipophobic (i.e., reject oil/grease), and water-repellent, making them useful in a wide range of applications. Fluoropolymers can also be used in multiple forms, including surfactants, coatings, sheetings, and additives. As an example of their versatility, fluoropolymers can be found in the coating on electrical wiring, water and stain resistant fabrics, seals and gaskets, non-stick cookware, fuel lines, and anti-vandal paint. These unique forms make fluoropolymers long-lasting, stable, and resistant to chemical or biological breakdown, while still being light-weight and adaptable. Fluoropolymers enhance the durability, safety, and longevity of a wide range of products. Some applications rely on multiple fluoropolymer properties, with the most desired property being the primary determinant of the specific fluoropolymer used.

Fluoropolymers are used in thermally variable applications, including aerospace, automotive, and electronics, and are often used in electrical insulation, circuitry, and semiconductors for their thermal stability. Fluoropolymers add stability and safety to these applications due to their high melting points and insulation abilities; their flexibility is also a key property, allowing wiring to be run in corners and circuits to be printed. Their chemical-resistant properties add to their inclusion in applications where other materials breakdown quickly, including corrosive and acidic environments.

Fluoropolymers are used as tank and piping liners, seals and plugs, pumps and gaskets, fuel lines, and personal protective equipment; their non-stick nature and resistance to weathering are also desirable properties in these applications. The ability of fluoropolymers to repel water makes them ideal for applications such as outdoor and architectural fabric, cookware, and fiberglass coatings for construction and automotive applications. Additionally, their flame resistance, biostability, and durability increase their usefulness in these applications. These examples identify just a few of the industries and sectors where fluoropolymers have become integral components of various consumer products. A more detailed discussion is provided in Section 4.0.

1.3 Regulatory and Mitigation Efforts for Fluoropolymers

PFAS have been dubbed “forever chemicals” due to their stability and longevity in the environment. Researchers have noted many pathways through which PFAS enter the environment, including the use of aqueous film-forming foam (AFFF) for firefighting, runoff from fertilizer application, and discharges from the production of certain types of fluoropolymers. The polymer and copolymer fluoropolymers are typically not water-soluble and are resistant to breakdown by weathering. Fluoropolymers have not been identified as an environmental or human health hazard; however, their production may involve the use and release of PFAS of concern.

Importantly, fluoropolymers have not been singled out for significant regulatory efforts in the U.S. However, a number of compounds in the broader PFAS family have been the focus of both regulatory and industry mitigation efforts. In the U.S., states have taken the initiative to regulate PFAS. States are employing multiple approaches to mitigating the environmental effects of PFAS, including limiting PFAS as a source material, establishing guidelines or notification levels for PFAS in water, and eliminating the use of AFFF in training exercises.

Federal regulatory action has been directed primarily by the U.S. Environmental Protection Agency (EPA). Since 2000, these actions have followed two tracks. First, EPA began extensive data collection and information gathering efforts regarding PFAS under the *Toxic Substances Control Act of 1976* (TSCA) due to concerns about potential harmful effects to humans and the environment. This information gathering effort led to EPA's intended designation of two specific compounds – perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) – as hazardous substances under Section 102 of the *Comprehensive Environmental Response, Compensation, and Liability Act of 1980* (CERCLA). In 2023, EPA proposed a significant new use rule (SNUR) under TSCA preventing the resumption of manufacturing or processing of phased-out PFAS without EPA review (EPA, 2023b). EPA has also made determinations for drinking water regulations for six PFAS (PFOS, PFOA, perfluorohexanesulfonic acid [PFH_xS], hexafluoropropylene oxide dimer acid [HFPO-DA], perfluorononanoic acid [PFNA], and perfluorobutanesulfonic acid [PFBS]).

Second, EPA worked with producers to implement voluntary phaseouts of the non-polymeric PFAS of concern. These efforts have resulted in the effective removal of non-polymeric PFAS from production and use in the U.S. 3M was the sole producer of PFOA and reported to EPA in 2000 that they had determined PFOA posed a significant risk to humans and the environment. 3M subsequently pledged to end all PFOA production, which they achieved by 2002. In 2006, PFOS was targeted for a similar voluntary program. In December 2022, 3M announced that manufacturing of all 3M fluoropolymers, fluorinated fluids, and PFAS-based additive products will be discontinued by the end of 2025.

EPA worked with eight of the major producers to implement the PFOS Stewardship Program. These companies achieved complete phaseouts of PFOS by 2017. Industry data submitted to EPA show over 90% reductions in PFOA emissions from 2000 to 2015 as part of an EPA-monitored voluntary control program (EPA, 2023b). The Centers for Disease Control and Prevention (CDC) confirm that the PFOA levels in the blood of the U.S. general population have declined 60% from 2000 to 2014. Even larger reductions – 80% – were reported for PFOS. However, CDC cautioned that as PFOS and PFOA are phased out and replaced, people may be exposed to other PFAS (ATSDR, 2017).

1.4 Discovery Methodology

To produce this report, a team of subject matter experts was convened from national laboratories and universities. The team gathered information through multiple sources, as described below, however, due to the lack of publicly available data, *de novo* data calculations could not be produced. Further, because this document is a public document, proprietary information, research, and data were not used in the completion of this report. Additional research and discovery efforts may be underway but not included in this document if the developer considers the efforts proprietary. The subject matter experts used the methods of discovery described below.

1.4.1 Existing Data and Literature

Existing literature was used in the development of the report. These sources included:

- Surveys and studies conducted by universities, government agencies, industries, and industry working groups

- Product documentation provided by manufacturers and industry working groups
- Market reports
- Industry, government, and non-government organization websites
- Peer-reviewed published literature and patents
- Documents generated by other government agencies.

1.4.2 Fluoropolymer Industry Survey

The subject matter expert team generated a survey (Appendix A), administered by Vanderbilt University (hereafter referred to as the Vanderbilt survey), directed toward fluoropolymer manufacturers, formulators, and end users. The survey was anonymous, and responses were only used in an aggregated manner to protect the companies' and product identities. Completion of the survey was entirely voluntary. The survey was used to gather additional available information directly from fluoropolymer manufacturers, formulators, and end users and to verify data and information gathered through existing data and literature sources.

Outreach Data

26 Industry and trade organizations
22 Individual industries
32 Direct surveys sent
16 Surveys returned
10 Engagements with environmental advocacy organizations

Coordination with federal agencies

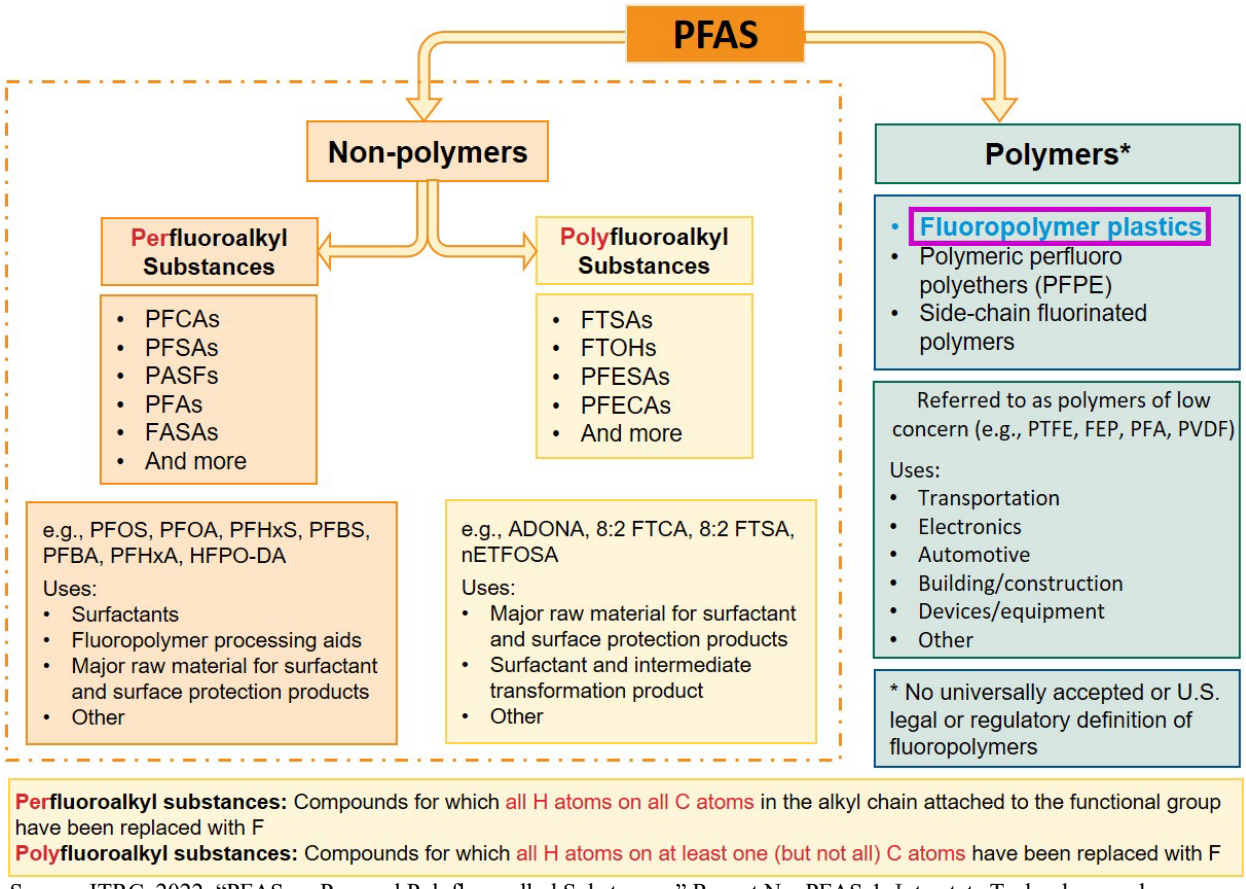
1.4.3 Interviews and Engagements

The team hosted and participated in engagements with industry partners, government agencies, and non-government organizations; several willingly participated in interviews with the subject matter expert team, providing valuable direct information and industry perspectives. Government interagency working groups, non-government organizations, and other government agencies were able to provide direct feedback to the team on methods employed and information gathered by the team.

2.0 FORMS, PROPERTIES, AND USES OF COMMON FLUOROPOLYMERS

Fluoropolymers are high molecular weight polymers consisting of a carbon (C) backbone and fluorine (F) atoms that are directly attached to the carbon atoms. These compounds are a distinct class of PFAS with a unique combination of attributes, such as chemical, biological, and thermal stability; low dielectric constant; and negligible solubility in water. These attributes, along with their high stability, help explain the extensive use of fluoropolymers in commerce and industry. Although stable, fluoropolymers may present environmental and human health challenges at certain points in their life cycle, including through low molecular weight PFAS by-products from manufacturing, degradation under certain conditions of use or disposal resulting in the generation of microplastics, and incomplete breakdown during thermal destruction.

PFAS constitute a large family of fluorinated chemicals, exceeding several thousand different chemicals, including high molecular weight fluoropolymers used in commercial (Section 4.0) and critical defense applications (Section 4.1.4), and low molecular weight non-polymeric PFAS and microplastics that have been emitted to the environment from production, misuse, or degradation of fluoropolymers. There is no universally accepted definition of PFAS nor the commercially important subcategory of fluoropolymers that is the subject of this report, which can result in confusion in identifying and attributing environmental impacts to specific groups of PFAS, including fluoropolymers (Buck et al., 2021). PFAS have been characterized as having carbon atoms linked to each other (i.e., a carbon "backbone") and bonded to fluorine atoms at most or all of the available carbon bonding sites by which fluorination imparts properties to the molecule. As shown in Figure 2-1, fluoropolymers are an important subgroup of PFAS.



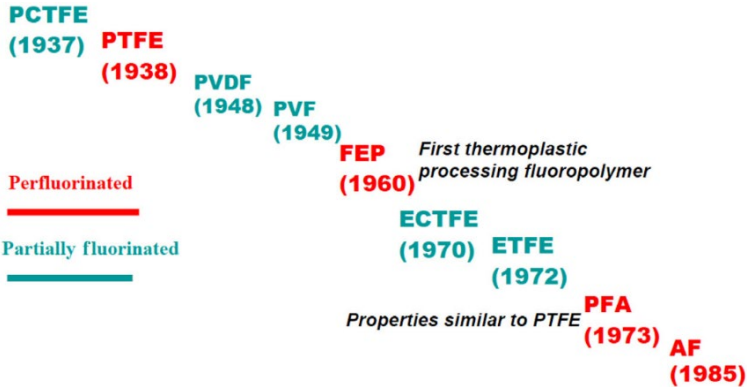
Source: ITRC, 2022, "PFAS — Per- and Polyfluoroalkyl Substances," Report No. PFAS-1, Interstate Technology and Regulatory Council, Washington, D.C.

Figure 2-1. Per- and Polyfluoroalkyl Substances Family Tree and Classification

In addition, the term fluoropolymer may refer to any chemical substance formed by reaction of fluorinated monomeric precursors to form a macromolecular repeating structure. In the context of this report, the discussion is focused on fluoropolymer plastics (as defined herein), which are considered distinct from fluorinated side-chain polymers (used for surface protection and coatings) and oligomeric PFPE (used largely as chemically resistant lubricant oils and greases) because of differing structural properties and uses (Section 3.0). PFPEs contain a carbon and oxygen polymer backbone with fluorine atoms directly attached to the carbon atoms. Side-chain fluorinated polymers branch off of a non-fluorinated polymer backbone.

2.1 Development of the Fluoropolymer Industry

The fluoropolymer development industry began with the accidental discovery of polytetrafluoroethylene (PTFE) in 1938 by Dr. Roy J. Plunkett and his team at DuPont while conducting commercial experiments with chlorofluorocarbon refrigerants (Plunkett, 1986). However, the material did not initially gain much market attention because of its high cost. Later, during World War II, a scale-up in production was supported due to the need for handling extremely corrosive chemicals. The U.S. Army Corps of Engineers, and then the U.S. Atomic Energy Commission, controlled some production methods of the chemicals until the late 1940s (Okazoe, 2009). Since then, the fluoropolymer industry has expanded over the years to a wide range of products with applications in many industries, including aerospace, automotive, aviation, chemical processing, construction, electronics, medical, semiconductor manufacturing, and consumer products. An accidental discovery opened the door to the fluoropolymer industry, which many consider the most important in the field of applied chemistry, and has influenced the world for the last nine decades. Many new fluoropolymers were developed between the 1940s and 1970s; the timeline of the development of fluoropolymers and commercial application is presented in Figure 2-2.



Source: Ebnesajjad, S., 2021, "3 - Fluoropolymers—Discovery, History, Evolution, and Consumption," *Introduction to Fluoropolymers*: *Materials, Technology, and Applications*, Second Edition, pp 19-31.

Figure 2-2. Innovation Waves and Evolution of Fluoropolymers During its History

2.2 Per- and Polyfluoroalkyl Substances

PFAS are a large, complex group of synthetic fluorinated substances that have a wide variety of chemical and physical properties, as dictated by the chain length and degree of fluorination. PFAS are defined as a specific class of fluorinated organic substances that include solids, liquids, dispersions, and gases; polymers like fluoropolymers and non-polymers (e.g., low molecular weight PFAS); soluble and insoluble substances; reactive and inert substances; and volatile and non-volatile substances (Buck et al., 2011). An important distinction exists within the PFAS class (e.g., solids, liquids, and gases), as the state of matter affects the mobility of the PFAS. For example, the liquid-state PFAS-containing firefighting foams (e.g., AFFF, which is not a fluoropolymer) has greatly contributed to soil and water contamination (ITRC, 2022). Similarly, the gaseous-state PFAS (e.g., created from incineration at insufficiently low temperatures) contributes to air contamination. With their diverse properties, PFAS are organized in a family tree (taxonomy) of two primary classes, polymers (including fluoropolymer plastics) and non-polymers, where each class contains subclasses, groups, and subgroups. As shown in the classification of the PFAS family in Figure 2-1, fluoropolymer plastics, the subject of this study, are under the class of fluoropolymers with high molecular weights.

Significant differences exist between polymeric and non-polymeric PFAS.

- **Polymeric PFAS** (high molecular weight) consist of thousands of repeating molecular units with a carbon-only polymer backbone, with fluorine atoms directly attached to carbon atoms, thus making the polymers more stable and non-water soluble. The polymeric PFAS can be further divided into fluoropolymer plastics, oligomeric PFPE, and side-chain fluorinated polymers, as indicated in Figure 2-1.
- **Non-polymeric PFAS** (low molecular weight) consist of a single molecule (i.e., carbon atoms linked to each other and bonded to fluorine atoms at most or all of the available carbon bonding sites) with a relatively low molecular size/weight, which is more mobile and water-soluble, and therefore easy to spread in the environment (water/air/soil).

Per- and Polyfluoroalkyl Substances Classification

Fluoropolymers are a distinct class of synthetic polymeric PFAS with high molecular weights, with fluorine attached to the carbon atoms, forming their carbon-only backbone. The higher the content of fluorine atoms in the polymer chain, the stronger the specific properties of the molecule due to unique intermolecular and intramolecular interactions between the fluorinated polymer segments. This degree of fluorination imparts essential and important mechanical and physicochemical characteristics to the polymers that allow these materials to be used in demanding applications.

Selected Fluoropolymers and Trade or Brand Name(s)
Polytetrafluoroethylene (PTFE) – Teflon®
Ethylene copolymer of tetrafluoroethylene (ETFE) – Tefzel™, Fluon®, Neoflon®, Texlon®
Fluorinated ethylene propylene (FEP) – Teflon® FEP, Neoflon®, Dyneon® FEP
Perfluoroalkoxy (PFA) – Teflon® PFA
Polyvinyldifluoride (PVDF) – Kynar®, Solef®, Dyneon® PVDF
Ethylene copolymer of chlorotrifluoroethylene (ECTFE) – Halar®
Polychlorotrifluoroethylene (PCTFE) – Voltalef®, Kel-F®, Neoflon®, Aclar®, Halon®, Fluon®, Hostaflon®, Plaskon®
Fluorine Kautschuk material (FKM) – Viton®, Dyneon®, Tecnoflon®

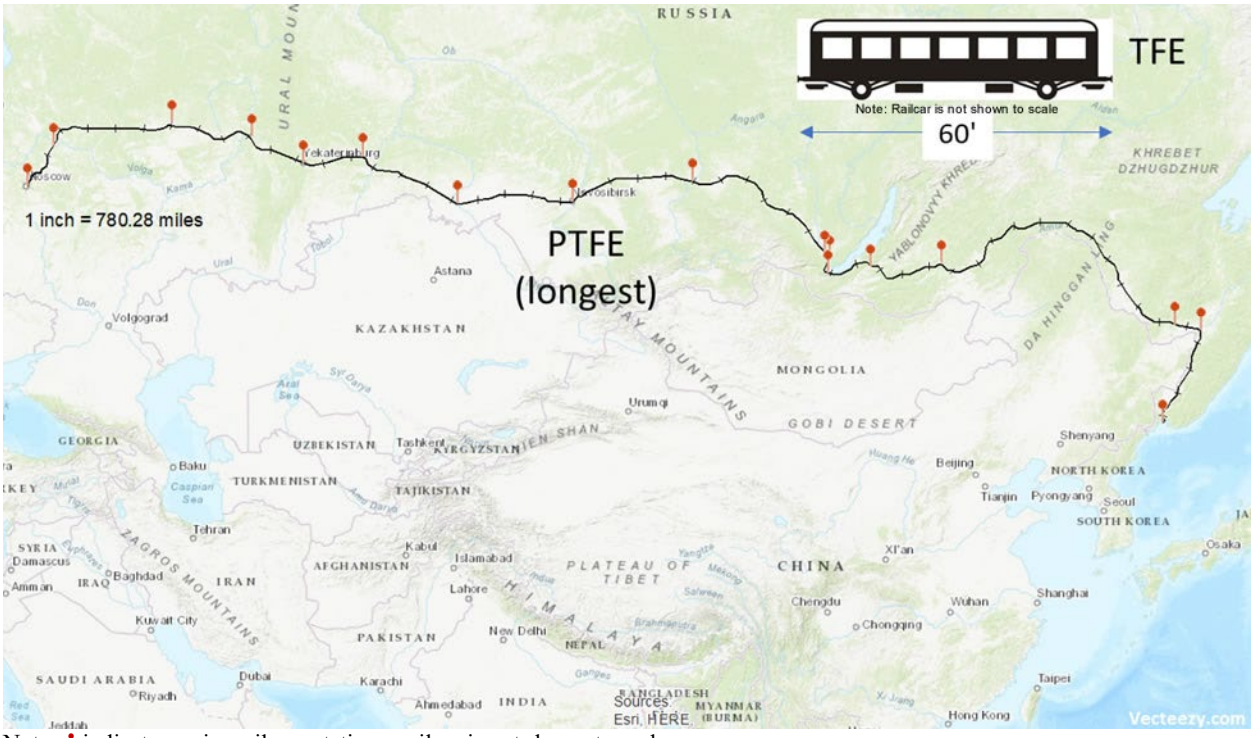
Fluoropolymers can be classified into two types: homopolymers – repeatedly joined monomers, and copolymers – alternating monomers of different species (including terpolymers for this study). Fluoropolymers are a group of polymers within the class of PFAS, whereby monomers and oligomers (i.e., not polymers) can be emitted during the production, processing, use, or treatment of fluoropolymers. Because of their special chemical and physical characteristics, fluoropolymers are widely applied in the architectural, aerospace, automotive, chemical, construction, electrical, and electronic industries that are the focus of this report (defined in Section 1.0). Several commercially important fluoropolymers include PTFE (also known as Teflon[12]), polychlorotrifluoroethylene (PCTFE), fluorinated ethylene propylene (FEP), polyvinyl fluoride (PVF), perfluoroalkoxy (PFA), ethylene tetrafluoroethylene (ETFE), ethylene chlorotrifluoroethylene (ECTFE), Nafion,[13] polyvinylidene fluoride (PVDF), and more.

Non-polymeric PFAS are often divided into two sub-classes: perfluoroalkyl and polyfluoroalkyl substances, as shown previously in Figure 2-1. Perfluoroalkyl substances are alkyl chains with all hydrogen (H) atoms on all C atoms replaced with F atoms. Polyfluoroalkyl substances are alkyl chains where all H atoms on at least one C atom (but not all) have been replaced with F atoms.

A simple way to think of differences in scale between non-polymeric PFAS monomers like tetrafluoroethylene (TFE, with a molecular weight of 100.02 dalton [Da]) and PTFE (made from TFE with a molecular weight between 389,000 and 45,000,000 Da [Henry et al., 2018]) is the way that railcars are used to form a train. Assuming the length of a standard U.S. railcar (60 ft) represents the molecular weight of the TFE monomer, between 3,890 and almost 450,000 coupled railcars would represent the molecular weight range of the PTFE fluoropolymer.

[12] Teflon is a registered trademark of The Chemours Company FC, LLC (formally DuPont), Wilmington, Delaware.
[13] Nafion is trademark of The Chemours Company FC, LLC (formerly DuPont), Wilmington, Delaware.

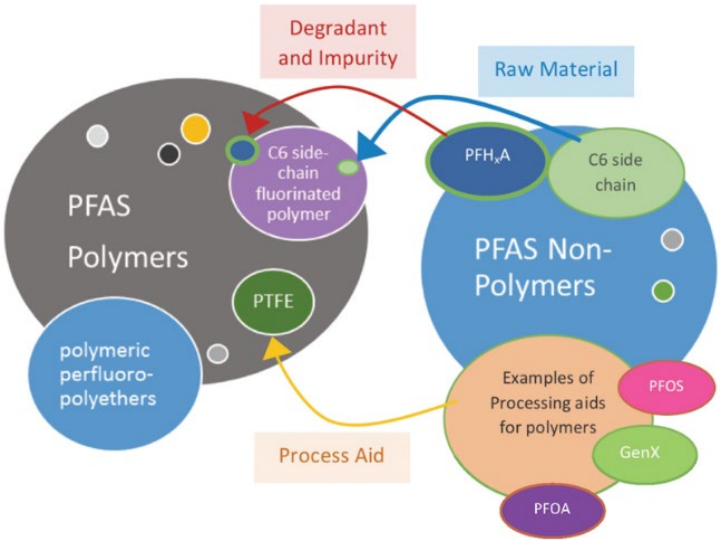
Another way to think of this is that the train comprising 3,890 railcars would stretch continuously for 45 miles (i.e., the lowest molecular weight for PTFE would be represented by a train 45 miles long), whereas the train with 450,000 railcars would stretch almost the length of the Trans-Siberian Railway (over 5,000 miles), the longest railway in the world (Figure 2-3 provides a graphical representation).



Note: 📍 indicates major railway stations; railcar is not shown to scale.

Figure 2-3. Graphical Illustration of the Difference in Molecular Weights Between a Monomer (TFE) and a Fluoropolymer (PTFE)

A complex interdependence exists among some polymeric PFAS (including high molecular weight fluoropolymers) and non-polymeric PFAS. The low molecular weight non-polymeric PFAS can play a vital role as processing aids and raw materials for polymeric PFAS production. As a result, low molecular weight non-polymeric PFAS can be emitted during manufacturing or as unintentional by-products or impurities from polymeric PFAS. Non-polymeric PFAS may also be generated as combustion by-products during incineration, depending on conditions such as temperature, residence time, and physical state.



Source: Sullivan, H., 2021, "Dyeing, Printing & Finishing: PFAS – A Textile Perspective," *Textile World.*

Figure 2-4. The Interdependency of Per- and Polyfluoroalkyl Substances (Polymer and Non-polymer)

The interdependency and complexity of polymeric PFAS and non-polymeric PFAS are represented in Figure 2-4, where typical examples of low molecular weight PFAS materials like PFOA and HFPO-DA can be used as processing aids, and the C6 side-chain can be used as a raw material for polymeric PFAS production.

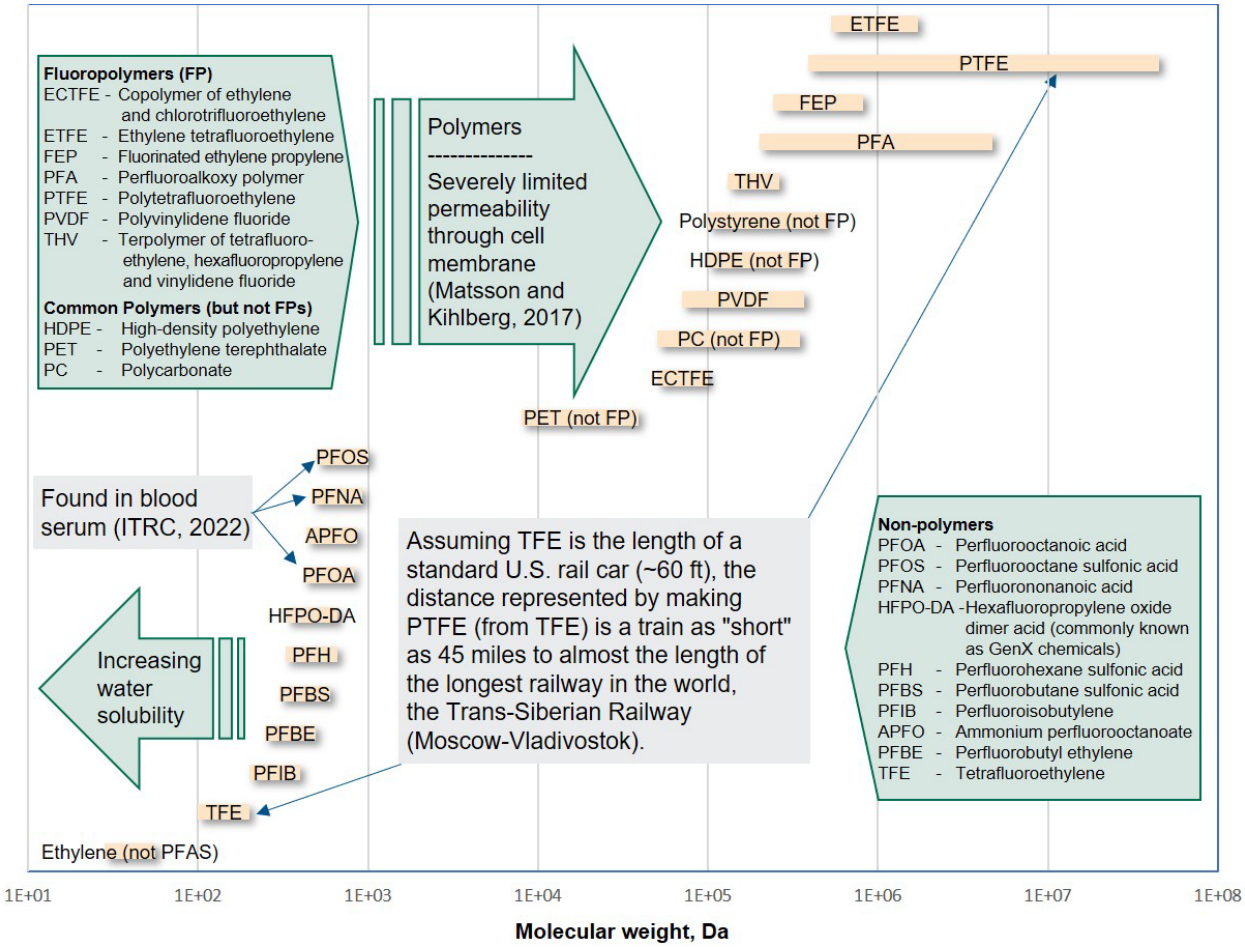


Figure 2-5. Properties of Polymeric and Non-Polymeric Per- and Polyfluoroalkyl Substances (PFAS) as a Function of Molecular Weight

Suggesting that all polymeric PFAS can be considered polymers of low concern is not straightforward because of their stability and water insolubility when compared to low molecular weight non-polymeric PFAS (Lohmann et al., 2020). The relatively small size and low molecular weight of non-polymeric PFAS make them highly mobile and easy to spread in water and air, as illustrated in Figure 2-5. Henry et al. (2018) suggest that polymers, including fluoropolymers, are too large to penetrate the cell membrane; however, Lohmann et al. (2020) disputes this assertion based on evidence for polymers other than fluoropolymers. With multiple pathways through a cell membrane, a more precise description is given by Matsson and Kihlberg (2017) for polymers in general, where the authors state that molecular sizes "severely limit[ed] permeability above 1000 $Å^3$ [cubic angstrom], i.e., at a MW [molecular weight] of approximately 1000 Da." Thus, when considering these compounds in general, fluoropolymers themselves may not present substantial risk – instead, the low molecular weight PFAS used to manufacture fluoropolymers, or degradation products from the fluoropolymers (including potentially from treatment), may dominate risks to human health and the environment associated with fluoropolymers.

The definition of PFAS has evolved to reflect the continued study of these compounds and may take different forms depending on the operational criteria used and the intended scope and application of the included list of chemicals (Buck et al., 2021). For example, the definition of PFAS used in a study by the Organisation for Economic Co-operation and Development (OECD) and the United Nations Environment Program (UNEP) expanded the Buck et al. (2011) definition to include chemicals that contain the C_nF_{2n} – moiety in addition to the C_nF_{2n+1} – moiety. This definition encompasses chemicals with both ends of the carbon-fluorine chain connected to hydrogen or a functional group, and the cyclic analogs of linear PFAS (OECD, 2018). The OECD (2018) study updated the report and identified 4,730 PFAS, including 267 fluoropolymers (by CAS[14] numbers, not structures); other PFAS definitions have been proposed (Buck et al., 2021).

In general, PFAS can be classified as non-polymers (consisting of a single molecule) or polymers (consisting of thousands of repeating units). The 4,730 PFAS reviewed in the OECD (2018) report were assigned to structure categories, and eight such structure categories with assigned codes and subcodes were used to identify various subcategories. A summary of the 4,730 PFAS is provided in Table 2-1. The majority of relevant substances (~53%) of 4,730 PFAS (OECD, 2018) were in three categories: series 400, 500, and 800 (fluoropolymers).

Table 2-1. Per- and Polyfluoroalkyl Substances (PFAS) Assigned to Eight Structure Categories

Series	Structure Category	Total number of substances	Percentage (%)	Comments
100	Perfluoroalkyl carbonyl compounds	514	10.9	Non-polymer
200	Perfluoroalkane sulfonyl compounds	629	13.3	Non-polymer
300	Perfluoroalkyl phosphate compounds	23	0.5	Non-polymer
400	Fluorotelomer-related compounds	1872	39.6	Non-polymer and polymer
500	Per- and polyfluoroalkyl ether-based compounds	365	7.7	Non-polymer and polymer
600	Other PFAA precursors and related compounds—perfluoroalkyl ones	314	6.6	Non-polymer
700	Other PFAA precursors or related compounds—semifluorinated	746	15.8	Non-polymer
800	Fluoropolymers	267	5.6	Polymer
Total		**4,730**	**100.0**	

Source: OECD, 2018, "Toward a new comprehensive global database of per- polyfluoroalkyl substances (PFASs): Summary report on updating the OECD 2007 list of per- and polyfluoroalkyl substances (PFASs)," OECD Series on Risk Management, No. 39, Organisation for Economic Co-operation and Development, Paris, France.

PFAA = perfluoroalkyl acid.

Of the 267 fluoropolymers identified in the OECD (2018) study, which has been cited widely in scientific literature (e.g., Glüge et al., 2020; Buck et al., 2021), the following categories (by structure) were identified (where frequencies are indicated in []):

- Ethylene tetrafluoroethylene (ETFE) [2]
- Fluorinated ethylene propylene (FEP) [3]
- Polytetrafluoroethylene (PTFE) [2], functionalized PTFE [74], and non-functionalized PTFE [1]
- Polyvinylidene fluoride (PVDF) [1] and non-functionalized PVDF [1]
- (Fluorinated) oxitane polymer [3]
- Polychlorotrifluoroethylene (PCTFE) [1]
- Terpolymer of tetrafluoroethylene-hexafluoropropylene-vinylidine fluoride (THV) [1]

[14] Unique registry number assigned to chemical compounds by the Chemical Abstracts Service (CAS).

- Vinylidene fluoride-hexafluoropropylene (VDF-HFP) [1] – survey
- Unspecified fluoropolymers [177].

The above fluoropolymers were also mentioned by the respondents to the Vanderbilt survey (Appendix A); however, PFA, fluorine Kautschuk material (FKM), and ECTFE were also indicated in these survey results. A search was performed (by CAS number) for the 177 unspecified fluoropolymers from the OECD (2018) study; the results indicated that 46 of the substances were identified as PTFE and another two as PVDF (i.e., categories already enumerated above). The above fluoropolymers, supplemented by the additional, important substances indicated by the Vanderbilt survey responses or from literature, form the foundation of this evaluation. Of further note, the set of fluoropolymers in this report is consistent with the fluoropolymers discussed in the Henry et al. (2018) and Korzeniowski et al. (2023) articles; these fluoropolymers dominate the world market for such materials (CEH, 2022).

Buck et al. (2021) indicated that less than 6% of the 4,730 PFAS (and 38 fluoropolymers) identified in the OECD (2018) study were "commercially viable globally," suggesting that grouping and categorizing PFAS using criteria based on composition and structure could be used to identify appropriate groups of PFAS for risk assessment, "thereby dispelling assertions that there are too many PFAS chemistries to conduct proper regulatory risk assessments for the commercially relevant substances." A group of 38 commercially viable fluoropolymers (not identified by name, CAS number, or structure because of the double-blind nature of the study) was indicated by Buck et al. (2021). Authors from Buck et al. (2021) suggested that considering the set of fluoropolymers in the Henry et al. (2018) and Korzeniowski et al. (2023) articles would also provide a reasonable basis for this study,[15] which is consistent with the approach in this report, as described later in Sections 2.4 and 4.0.

With tens of thousands of chemicals in commerce and more introduced every year, the EPA, through its computational toxicology research, developed the web-based CompTox Chemistry Dashboard (EPA, 2023c). This dashboard is a publicly available application that provides access to a chemical's toxicity, chemistry, and exposure information, with the focus being to support the mission to evaluate chemical safety and protect human health and the environment. As per the list released in August 2022 (EPA, 2022a), 15,000 PFAS are reported (where fluoropolymers are not indicated as such). This number was derived based on a threshold of a minimum of 30% fluorine (without hydrogens) in a molecular formula with sufficient fluorination levels to *potentially* impart PFAS-type properties. For example, a chemical structure with a molecular formula of $C_6HF_9O_6$ has 43% fluorine (9F/(6C+9F+6O), without hydrogen). The EPA also added PFAS as a class to the list of unregulated contaminants that will be monitored in drinking water across the U.S. (87 FR 68060, "Drinking Water Contaminant Candidate List – Final") and provided a list of 10,239 PFAS (EPA, 2022b) that meet the definition of PFAS used in this report. Note that EPA only proposed to regulate six PFAS (PFOS, PFOA, PFH_xS, HFPO-DA, PFNA, and PFBS) that have been demonstrated to have possible negative health effects (88 FR 18638, "PFAS National Primary Drinking Water Regulation Rulemaking"). The EPA studies address PFAS in general and not specifically fluoropolymers.

2.3 The Science of Fluoropolymers, Properties and Uses

Fluoropolymers possess a unique combination of characteristics, such as heat, chemical and electrical resistance, durability, and unique dielectric properties, which enables the material to perform under harsh operating conditions. This section provides information on (1) chemical types/groupings and physical forms (e.g., sheeting, coatings, solutions, thin films, fibers, additives), and (2) properties, including beneficial physical/chemical properties (e.g., non-stick, heat-resistant, hydrophobicity, chemically inert) and additional properties that may limit use such as expansive aspects, radiation degradation, and thermal.

[15] Personal communication with the authors of Buck et al. (2021) on September 26, 2023.

Fluoropolymers can be classified into homopolymers – repeatedly joined monomers of the same chemical structure, and copolymers – alternating monomers, including those (e.g., terpolymers) consisting of different types of monomers. Fluoropolymers can be further classified based on the degree of fluorination as perfluoropolymers (e.g., FEP and PFA), where fluorine substitutes for hydrogen in *all* possible bonds to carbon, and polyfluoropolymers (e.g., PVF and ETFE), where hydrocarbon functional groups are incorporated into the backbone of the polymer.

Fluoropolymers are a group of polymers within the class of PFAS also including low molecular weight monomers and oligomers that can be emitted during the use, production, processing, or treatment of fluoropolymers (ITRC, 2022). Typical properties of fluoropolymers for the sectors pertinent to this report and specific requirements or functions of each industrial application are summarized in Table 2-2 and Table 2-3, respectively.

Table 2-2. Summary of Fluoropolymers and General Properties

Fluoro-polymer	Starting year	Melting temperature (°C)	Tensile modulus (MPa)	Break elongation (%)	Dielectric strength (kV/mm)	Appl. temp (°C)	Main Applications
PTFE	1947	317-337	550	300-550	19.7	260	Chemical processing, wire and cable
PCTFE	1953	210-215	60-100	100-250	19.7	200	Barrier film, packaging and sealing
FEP	1960	260-282	345	~300	19.7	200	Cable insulation
PVF	1961	190-200	2,000	90-250	12-14	110	Lamination, film, and coating
PVDF	1961	155-192	1,040-2,070	50-250	63-67	150	Coating, wire, cable, electronic
ECTFE	1970	235-245	240	250-300	80	150	Flame resistant insulation
PFA	1972	302-310	276	~300	19.7	260	Chemical resistant components
ETFE	1973	254-279	827	150-300	14.6	150	Wire and cable insulation
THV	1996	145-155	82-207	500-600	48-62	93	Barrier film and insulation

Source: Teng, H., 2012, "Overview of the Development of the Fluoropolymer Industry," *Applied Sciences*, 2(2), pp 496–512.

ECTFE = ethylene chlorotrifluoroethylene.
ETFE = ethylene tetrafluoroethylene.
FEP = fluorinated ethylene propylene.
PCTFE = polychlorotrifluoroethylene.
PFA = perfluoroalkoxy.
PTFE = polytetrafluoroethylene.
PVDF = polyvinylidene fluoride.
PVF = polyvinyl fluoride.
THV = tetrafluoroethylene-hexafluoropropylene-vinylidene fluoride (TFE-HFP-VF2).

Table 2-3. Typical Applications of Fluoropolymers for Different Industry Sectors (2 pages)

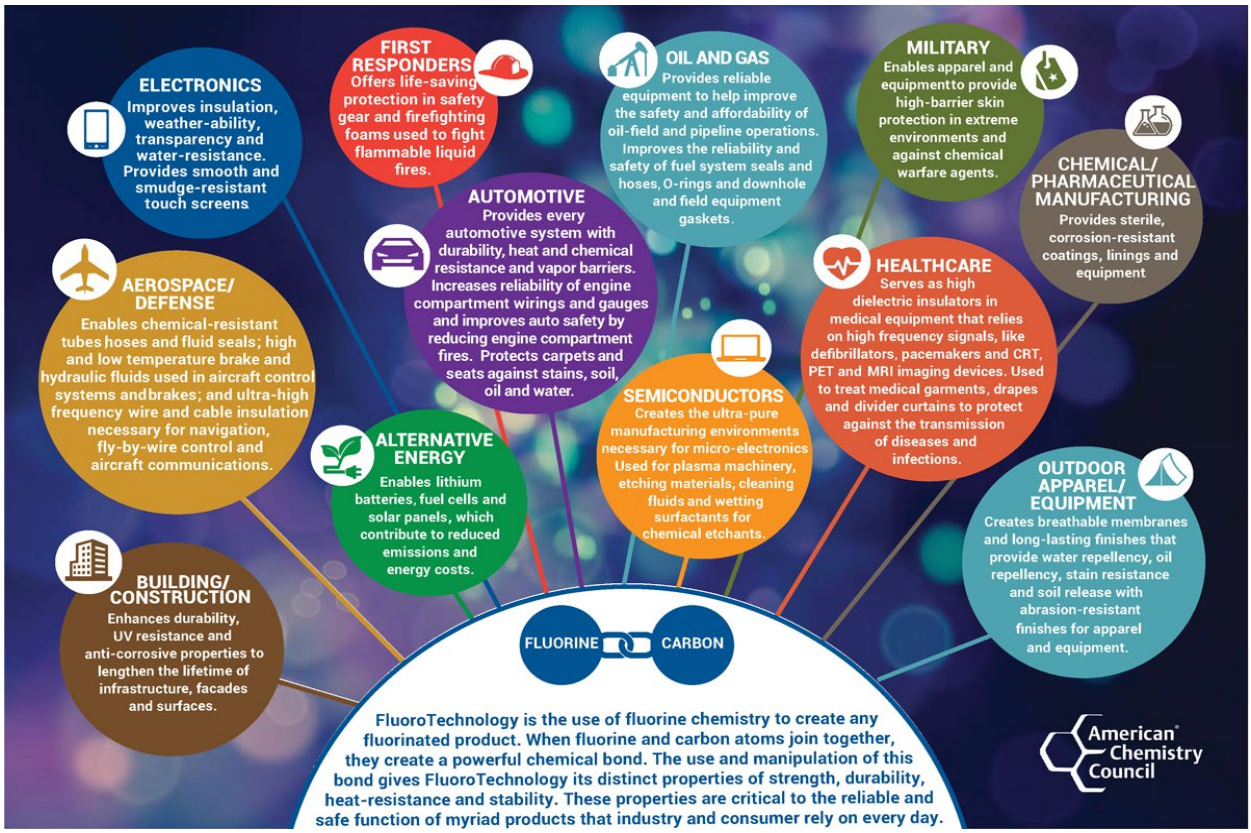
Industries	Functions	Forms
Automotive	Mechanical property, thermal property, chemical property, and friction property	O-rings, gaskets, valve stem seals, shaft seals, linings for fuel hoses, power steering, and transmission
Chemical	Chemical resistance, mechanical property, thermal property, and weather stability	Coatings for heat exchangers, pumps, diaphragms, impellers, tanks, reaction vessels, autoclaves, containers, flue duct expansion joints, and heavy-wall solid pipe and fittings
Electrical/electronic	Dielectric constant, flame resistance, and thermal stability	Electrical insulation, flexible printed circuits, ultrapure components for semiconductor manufacture
Architectural and domestic	Weatherability, flame retardancy, friction property, thermal stability	Water-repellent fabric, architectural fabric, non-stick coatings for cookware, and fiberglass composite for construction

Table 2-3. Typical Applications of Fluoropolymers for Different Industry Sectors (2 pages)

Industries	Functions	Forms
Engineering	Mechanical property, thermal stability, chemical stability, weatherability, and surface energy	Seats and plugs, bearings, non-stick surfaces, coatings for pipes, fittings, valve and pump parts, and gears
Medical	Surface energy, biological stability, mechanical property, chemical resistance	Cardiovascular grafts, ligament replacement, and heart patches

Source: Teng, H., 2012, "Overview of the Development of the Fluoropolymer Industry," *Applied Sciences*, 2(2), pp 496–512.

The unique characteristics of fluoropolymers can enhance product durability, sustainability, and safety. Products that are lighter and longer-lasting will generally have lower life cycle costs, embodied energy, transportation-related emissions, and safety risks. Fluoropolymers are found in many commercial and industrial applications, consumer products, and medical equipment. Examples include fuel tubes and hoses that significantly reduce fugitive emissions; release films in carbon-fiber-reinforced composite structural components for lightweight automotive and aerospace applications; gaskets and seals across many industries; and coatings, lining, piping, fuel tubes, batteries, semiconductor equipment, data transmission cables, cell phones, and wind turbines. Industry applications of fluoropolymers used in a wide range of products are summarized in Figure 2-6.



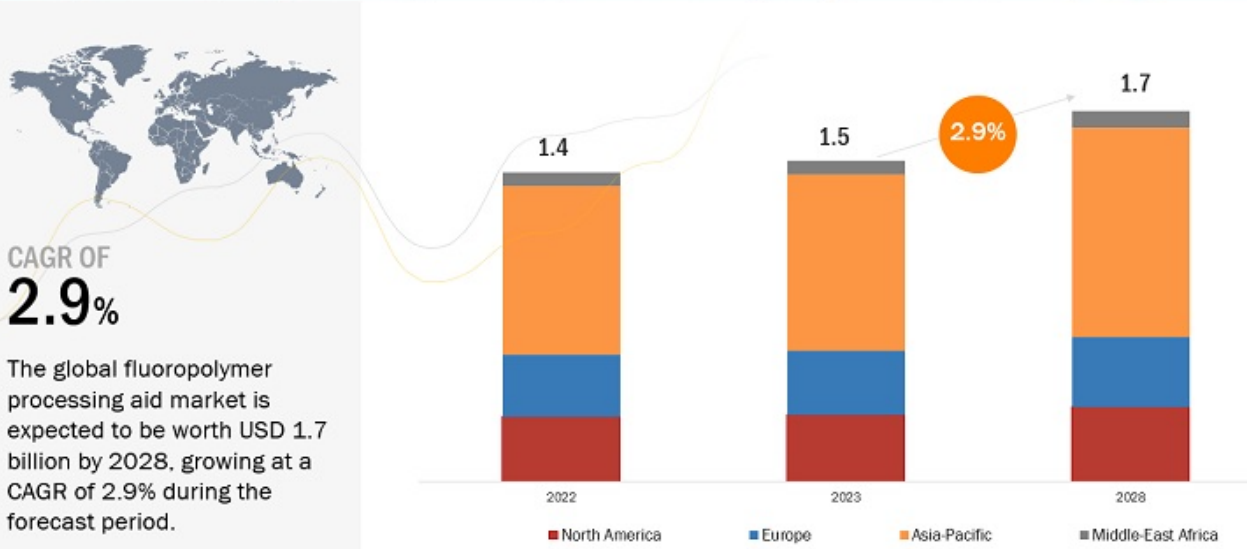
Source: Sullivan, H., 2021, "Dyeing, Printing & Finishing: PFAS – A Textile Perspective," *Textile World.*

Figure 2-6. Fluoropolymer and Fluorotechnology End Uses by Industry

2.3.1 Fluoropolymer Processing Aids Used in Polymer (Non-fluorinated Polymer) Processing

A well-known and economically significant use of selected fluoropolymers (FKM, PVDF, and PVDF copolymer) is as fluoropolymer processing aids (FPA), or synonymously fluorinated polymer processing aids, as an integral part of the processing of polyethylene (PE) products (Seiler et al., 2017), with lesser amounts of fluoropolymers also used for processing other polyolefins like polypropylene (PP) and polyethylene terephthalate (PET), where PE, PP, and PET are *not* fluoropolymers. FPAs act as lubricants, reducing friction, preventing melt fracture, improving surface finish, and facilitating processing. The most common FPAs are (1) vinylidene fluoride-hexafluoropropylene (VF2-HFP) copolymer and (2) vinyl fluoride-hexafluoropropylene (VF-HFP) copolymer with additives such as polyethylene oxide (PEO). FPAs are generally prepared using emulsion polymerization of VF2 and HFP in an aqueous reaction medium with an initiator and water-soluble fluorosurfactant[16] capable of emulsifying both the initiator and reaction mass during the polymerization.

FPAs were originally developed to aid in the processing of linear low-density polyethylene (LLDPE) for blown films and tubing, where the addition of very small amounts of fluoropolymers (0.1 – 2.0 wt%) to polyolefins was discovered to provide processing benefits. The use of FPAs has expanded to many types of polyolefins and various types of melt processing because of (1) the effectiveness of FPAs as a melt processing/extrusion aid, and (2) growing demands for consumer goods and packaging and for plastics and composites in the automobile industry, even with the high cost of FPAs and potential regulatory concerns (MarketsandMarkets, 2023). As indicated in Figure 2-7, the FPA market was estimated at $1.5B for 2023 and projected to increase to $1.7B in 2028, driven largely by increased consumption of polymers such as PE, PP, and PET used in containers and packaging in the food and beverage industries.



CAGR = compound annual growth rate. USD = United States dollar.

Source: MarketsandMarkets, 2023, "Fluoropolymer Processing Aid Market by Polymer Type (PE, PP, PVC), Application (Blown & Cast Film, Wires & Cables, Pipes & Tubes, Fibers & Raffia), and Region (Europe, North America, Asia Pacific, MEA, South America) – Global Forecast to 2028," CH 8634, MarketsandMarkets Research Pvt. Ltd, Pune, India.

Figure 2-7. Fluoropolymer Processing Aid Market – Global Forecast to 2028

[16] Fluorosurfactants and fluorochemicals are forms of PFAS.

2.4 Properties of Fluoropolymers Used in the Sectors of this Study

This section outlines important properties for fluoropolymers used in the sectors of interest (as defined in Section 1.0) for this report, which include:

- Aerospace and automotive
- Battery, solar, and wind energy
- Building construction and infrastructure
- Chemical processing, storage, and disposal
- Electronics and semiconductors.

Because of the large quantity and ubiquity of fluoropolymers in the marketplace, the above list is not intended to be exhaustive but instead captures a high-level review of the breadth and depth of fluoropolymer activity.

2.4.1 Properties of Fluoropolymers Used in Aerospace and Automotive Applications

Exceptionally strong durability and resistance to extreme temperatures (from -200 °C to +200 °C), corrosion, oxidation, and ultraviolet (UV) radiation make fluoropolymers ideal for use in various environments in the aerospace and automotive sectors. Because of their resistance to heat, cold, smoke, fire, humidity, fluids, fuels, compression, and vibration, fluoropolymers prolong the useful life of various components and help improve reliability and engine efficiency. Compared to traditional steel and aluminum, fluoropolymers weigh significantly less and have superior strength and durability that help reduce payloads that ultimately provide added safety.

2.4.2 Properties of Fluoropolymers Used in Battery, Solar, and Wind Energy

Examples of fluoropolymer properties related to uses in the battery, solar, and wind energy sector (discussed further in Section 4.5) include:

- **Solar panels** – Fluoropolymers are used in both frontsheets for solar panels, as a result of their stability in UV light, low permeability, weather resistance, and ability to transmit light in the visible range, and in backsheets. A backsheet in a solar panel needs to be weather resistant, have mechanical strength, and provide electrical insulation over a wide range of operating temperatures. As with the frontsheet, the backsheet needs to maintain these properties over a wide range of operating temperatures.
- **Wind turbines** – Fluoropolymers are used in wind turbines for weather and corrosion-resistant properties.

2.4.3 Properties of Fluoropolymers Used in Building Construction and Infrastructure

Fluoropolymers, with their unique combination of properties, provide solutions for many challenging applications in building materials. Fluoropolymers are applied as coatings and are used in building materials that provide resistance to fire, water, and corrosive chemicals. Fluoropolymer coatings can also enable significant energy savings and can reduce building cooling costs and improve energy efficiency and use, up to 22% (Plastics Europe, 2023a). The non-wetting, non-stick properties and lightweight nature of fluoropolymers can extend the life of a building even in harsh/extreme environments and thus reduce maintenance. Fluoropolymers provide durable, thermally stable building materials that will enhance the overall stability of the structure. Such unique properties help in designing novel architectural designs that require flexibility and thin, lightweight materials that reduce energy use. Further, the very low surface energy provides dirt adhesion resistance that helps maintain solar reflective qualities, thereby preserving its energy efficiency and reducing maintenance costs (i.e., a high level of dirt adhesion resistance requires less frequent cleaning).

Fluoropolymer films and paints in the materials used for stadiums, domes, and glass fabric roofs provide enhanced stability. Fluoropolymer paints are used in bridge and offshore bearing pads for the lowest friction coefficient of all plastics (ACA, 2023).

2.4.4 Properties of Fluoropolymers Used in Chemical Processing, Storage, and Disposal

For chemical processing applications, important properties of fluoropolymers include stability, high continuous use temperature, weatherability, chemical resistance, fire resistant properties, release properties, biological inertness, low friction, cryogenic properties, flexibility, electrical properties, low dielectric constant, and low dissipation factor. The Vanderbilt survey responses indicate other critical properties of fluoropolymers, including specific gravity, melting point, tensile strength, elongation of break, compressive strength, and flex life. Other important chemical processing properties (e.g., mechanical strength, cryogenic, ultra-high purity) can be realized by choosing a specific fluoropolymer.

2.4.5 Properties of Fluoropolymers Used in Electronics and Semiconductor Processing and Components

Fluoropolymers are specialty materials that can be used to provide chemical and heat resistance, electrical insulation, strength, and durability to other materials. Depending on the selected fluoropolymer, the material can be used to extend the lifespan of components, improve fire safety, increase transmission speeds, and enable the creation of smaller, more powerful, and more integrated electronic products. For the semiconductor industry, fluoropolymers are used to enable pipes, vessels, valves, and pumps used in semiconductor manufacturing to withstand harsh etching and processing conditions, while maintaining purity requirements critical to this industry (West, 2020).

2.5 Fluoropolymer Distinctions

Research continues on whether or not fluoropolymers are polymers of low concern (Henry et al., 2018; Lohmann et al., 2020). To better explain fluoropolymer usage, scientists defined distinctions among three sets of fluoropolymers: (1) fluoropolymer substances, (2) fluoropolymer products, and (3) fluoropolymers in finished articles (Lohmann et al., 2020). The details of the definitions are provided in Table 2-4. The distinction is important mainly because fluoropolymers are diverse in their production (how they are produced), how they are transported or shipped, and how they are used; these distinctions are important to consider when assessing their potential ecological and human health hazards and risks.

Table 2-4. The Fluoropolymer Distinction

Fluoropolymer	Details	Examples
Fluoropolymer substance	Chemical structure of a fluoropolymer	PTFE: $(-CF_2-CF_2-)_n$, FEP: $(-CF_2-CF_2-)_n-(-CF_2-CFCF_3-)_m$, PFA: $(-CF_2-CF_2-)_n-(-CF_2-CFOCF_3-)_m$
Fluoropolymer product	Actual fluoropolymer material produced (solid or liquid) in different grades as granulates, fine powders, or aqueous dispersions	• Teflon-granulate or Teflon-fine powder produced and sold by a chemical manufacturer • May contain non-polymeric PFAS impurities from the production process (raw materials or processing aids)
Fluoropolymer in finished articles	Fluoropolymer products that are incorporated in their finished articles	PTFE tape, waterproof clothing with a PTFE membrane, PTFE-coated cookware, lubricant liquid

Source: Lohmann et al., 2020, "Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS?," *Environmental Science and Technology*, 54(20), pp 12820–12828.

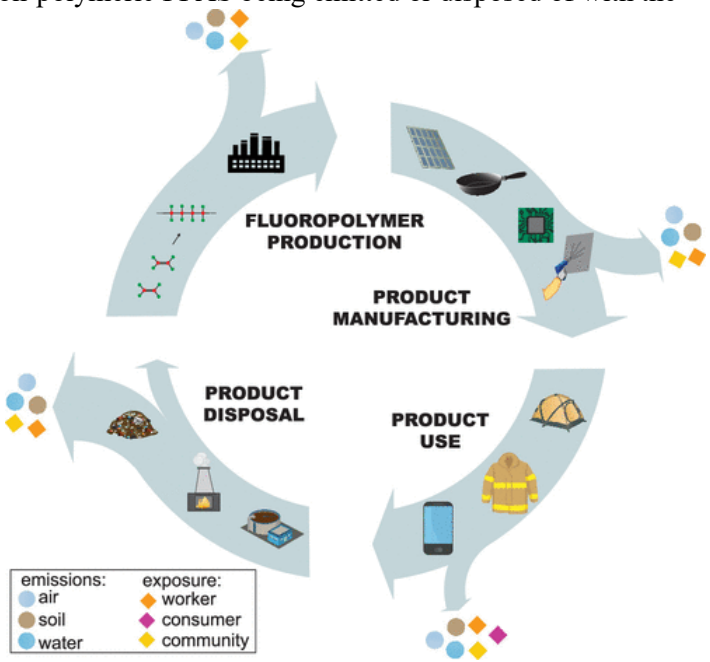
FEP = fluorinated ethylene propylene.
PFA = perfluoroalkoxy.
PFAS = per- and polyfluoroalkyl substances.
PTFE = polytetrafluoroethylene.

Increased attention on pollution caused by low molecular weight non-polymeric PFAS emissions is related to specific fluoropolymers during their life cycle (e.g., non-polymeric PFAS [low molecular weight] as processing aids in the production or emitted during product manufacture, usage, and disposal).

2.6 Fluoropolymers Production (Polymerization)

Synthesis of some fluoropolymers may require low molecular weight non-polymeric PFAS as polymerization aids, dispersion agents, or foaming agents. Specifically, in emulsion polymerization, non-polymeric PFAS act as surfactants or emulsifiers that help to improve the dispersion of monomers and enable polymerization in aqueous solution. Non-polymeric PFAS polymerization aids are important nonreactive additives that are used in fluoropolymer synthesis. In some fluoropolymers, the non-polymeric PFAS act as raw materials.

In either type of fluoropolymer synthesis, most of the polymerization aid is recycled or recovered from the solution, with the remaining fraction of non-polymeric PFAS being emitted or disposed of with the effluent wastewater or waste. Typical polymerization aids used in industry are PFOA, PFNA, and HFPO-DA. Significant fluorosurfactant polymerization aid is incorporated into the polymer during the polymerization process; however, much of this unbound polymerization aid is removed during heat treatment of the resulting powdered fluoropolymer. Under typical manufacturing conditions (Lohmann et al., 2020), a low concentration of the processing aid may remain incorporated with the fluoropolymer and be released during use (Drohmann et al., 2021); the fluoropolymer itself may also be degraded (e.g., at high temperature but too low for complete destruction, aggressive conditions), with the resulting low molecular weight PFAS degradation products (potentially including microplastics) emitted into the environment during its life cycle (Lohmann et al., 2020). A conceptual diagram of low molecular weight PFAS emissions during the fluoropolymer life cycle is presented in Figure 2-8.



Source: Lohmann et al., 2020, "Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS?," *Environmental Science and Technology*, 54(20).

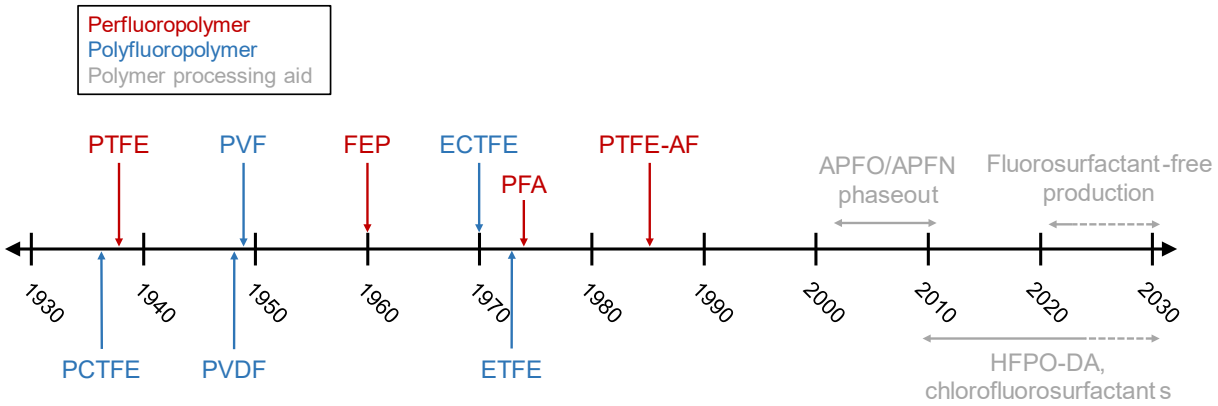
Figure 2-8. Conceptual Diagram Showing the Low Molecular Weight Per- and Polyfluoroalkyl Substances (Non-polymers) Emissions During Fluoropolymer Production, Manufacturing, Usage, and Disposal

In the production of flexible fluoropolymer products via radiation or electron beams, remaining non-polymeric PFAS could potentially be released. For example, fluoropolymers such as ETFE, PVDF, and ECTFE can be chemically etched via irradiation to induce reactive free-radical sites or functionalization directly on the polymer chains, which renders reactive sites on the polymer for linking to other polymers and typically results in improved mechanical and physicochemical properties (Gardiner, 2014; Teng, 2012). Such methods will improve performance of these fluoropolymers as engineering thermoplastics in demanding applications. As a result of radiation or electron-beam processing, non-polymeric PFAS (low molecular weight) may be formed as by-products of the etching process, with subsequent potential for release.

3.0 FLUOROPOLYMER MANUFACTURING

Fluoropolymers find use in many sectors of commercial and industrial applications and are manufactured in a wide variety of chemistries and physical forms to accommodate specific end uses. Although the term fluoropolymer may refer to any chemical substance formed by reaction of fluorinated monomeric precursors to form a macromolecular repeating structure, in the context of this report, the discussion in this section is constrained to treatment of fluoropolymer plastics, including both thermoplastic (rigid materials formed by heating or machining) and elastomeric (flexible material) forms. In this context, fluoropolymer plastics refer to water-insoluble, solid-state materials (either hard or soft), composed of fluoropolymers and useful for fabrication of physical articles. Many of these materials share similar synthetic production routes and chemical properties (discussed in Section 2.0). Fluoropolymer plastics are distinct from fluorinated side-chain polymers, which are formed through polymerization of non-fluorinated polymeric backbones with various perfluorocarbon side chains. Also distinct from fluoropolymer plastics are PFPEs, which are typically produced as oligomeric formulations for use in applications such as high-temperature, chemically resistant lubricant oils and greases (Glüge et al., 2020).[17]

The commercial production of fluoropolymer plastics began after the 1938 discovery of PTFE as an unintentional reaction product of the refrigerant candidate TFE (Plunkett, 1986). PTFE was found to be exceptionally resistant to chemical attack and highly thermally stable and was initially used for applications in the Manhattan Project because of these unique properties (i.e., the uranium hexafluoride used in the separation process is highly reactive). PTFE was marketed commercially as Teflon by DuPont starting in the late 1940s, and development and commercialization of additional fluoropolymer plastics continued through the 1980s, as shown in Figure 3-1.



Based on information from McKeen and Ebnesajjad (2023a).

Figure 3-1. Timeline of Fluoropolymer Development (Major Fluoropolymer Plastics and Polymer Processing Aids)

Many forms of fluoropolymer plastics required the use of fluorosurfactant emulsifiers as polymer processing aids during production. These low molecular weight fluorochemicals, including PFOA and PFNA, were eventually found to be of concern due to their exceptionally long half-lives in biological and environmental systems, water solubility, and toxicity at low levels (Prevedouros et al., 2006).

[17] Fluorinated side-chain polymers and PFPEs are taxonomically distinguished in this report from fluoropolymers and may have different life cycle characteristics and environmental impacts than fluoropolymer plastics, which are the focus of this study. Fluorinated side-chain polymers and PFPEs, which are considered distinct categories, are thus not included as part of the evaluation in this report.

In recent years, the fluoropolymer industry has introduced low molecular weight fluorochemical replacements for PFOA and PFNA as polymer processing aids (Figure 3-1), although these replacements (including chlorofluorosurfactants and HFPO-DA) also have significant environmental implications (McCord et al., 2020; Sun et al., 2016). Most recently, several fluoropolymer manufacturers have introduced fluorosurfactant-free production methods to address environmental safety concerns (Reich, 2008; Solvay, 2022).

3.1 Fluoropolymer Plastic Forms

Fluoropolymer plastics are produced in several physical and chemical forms, depending on the polymer chemistry and the desired end-use (McKeen and Ebnesajjad, 2023; Gardiner, 2014). The four primary classes of fluoropolymer plastic production forms are:

- **Crystalline, non-melt-processable**: PTFE (Teflon) is the most important commercial example of this type of fluoropolymer. These fluoropolymers are produced in several physical forms, including granular, powdered, aqueous dispersion, or paste. The materials are highly crystalline and undergo thermal decomposition at temperatures below their flow transition and, therefore, cannot be processed into useful shapes via conventional thermoplastic extrusion and molding techniques. Fabrication of finished parts from non-melt-processable polymers, such as PTFE, typically requires techniques similar to those used in metal sintering and results in an opaque and somewhat porous material.
- **Crystalline, melt-processable**: Most of the major fluoropolymer plastics shown in Figure 3-1 fall into this category. These polymers can be processed into final shapes using conventional thermoplastic extrusion and molding techniques, making them more economical than the non-melt-processable polymers. These fluoropolymers can be further classified as perfluoropolymers, such as FEP and PFA, where fluorine substitutes for hydrogen in all possible bonds to carbon, and polyfluoropolymers such as PVF and ETFE, where hydrocarbon functional groups are incorporated into the backbone of the polymer. Typically, crystalline, melt-processable fluoropolymers are either opaque or translucent and cannot be produced in transparent form. These materials can be extruded or molded into practically any shape, including tubes and films.
- **Amorphous, melt-processable**: These fluoropolymers were introduced in the mid-1980s and include, most notably, Teflon amorphous fluoropolymer (AF) (Figure 3-1), which offers the chemical resistance of perfluoropolymers such as PTFE in a form that can be readily processed via thermoplastic extrusion and molding techniques. In addition, the amorphous, low-crystallinity nature of the macromolecular polymer structure makes these polymers more transparent than their crystalline analogs, with excellent optical properties. Semicrystalline materials, such as the terpolymer THV, bridge the gap in properties between amorphous and crystalline melt-processable polymers.
- **Fluoroelastomers**: Elastomeric forms of fluoropolymers are produced by a combination of multiple monomers, including those that form straight-chain segments and bulkier monomeric components that break up the crystallinity of the polymer at regular intervals. These polymers are engineered to exist below their glass transition temperatures in typical operating conditions, making them easily deformable and recoverable from strain (Drobny, 2016).

3.2 Overview of Fluoropolymer Production

Fluoropolymer production begins in all cases with the availability of precursor monomers. In nearly all cases, these monomers are based on a vinyl group substructure (Figure 3-2), wherein an ethylene functional group serves as the site for attack of free-radical-based initiators that induce polymerization.

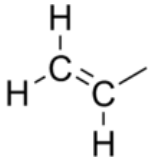
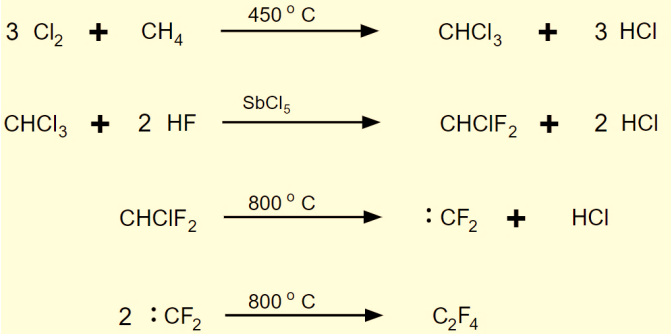


Figure 3-2. Vinyl Group Substructure

Variations on the chemical substituents bonded to the vinyl core structure lead to different polymer properties in fluoropolymers. The simplest monomer in fluoropolymer production is TFE (C_2F_4 in Figure 3-3), which is directly analogous to the hydrocarbon monomer ethylene used in production of low- and high-density polyethylene. While ethylene (and other hydrocarbon vinyl monomer feedstocks) are easily isolated from petrochemical feedstocks through cracking during refining, fluorochemical monomers such as TFE are considerably more difficult to prepare.



Source: Mierdel, K., A. Jess, T. Gerdes, A. Schmidt, and K. Hintzer, 2019, "Energy and Resource Efficient Production of Fluoroalkenes in High Temperature Microreactors," *ChemEngineering*, 3(4), 77.

Figure 3-3. Production of Tetrafluoroethylene (TFE | C_2F_4) Through the R22 Process

The complexity of monomer production contributes to the significantly higher cost of fluoropolymer production relative to the analogous hydrocarbon polymers (e.g., polyethylene and polypropylene). An example of this cost difference is production of TFE through the so-called R22 route (Mierdel et al., 2019), wherein multi-step synthesis of the final TFE monomer proceeds through synthetic routes, including chlorinated hydrocarbons and hydrofluoric acid, to produce the intermediate difluorochloromethane (R22), which was formerly used as a refrigerant before being recognized as a potent contributor to high global warming potential and ozone depletion in the upper atmosphere. Further treatment by pyrolysis yields TFE through an unstable difluorocarbene intermediate (Figure 3-3). Apart from the elaborate and resource-intensive synthetic route necessary to prepare it, production of TFE via the R22 route produces waste products that must be disposed of, including carbon tetrachloride and hydrochloric acid (Mierdel et al., 2019). As discussed in Section 3.3, TFE is required in nearly all fluoropolymer plastic production methods.

Production of fluoropolymer plastics proceeds at-scale through industrial processes appropriate to the particular formulation. In most cases, industrial synthesis of fluoropolymers is based on free-radical polymerization using peroxide-based catalysts such as ammonium persulfate or potassium permanganate (Gardiner, 2014). For some polymers, small quantities of crosslinkers or other additives are introduced at the polymerization stage to adjust final properties. In nearly all cases, polymerization of fluoropolymer plastics proceeds under aqueous conditions either (1) through suspension polymerization whereby monomers are directly added to an aqueous solution with catalysts, or (2) via emulsion polymerization whereby a fluorosurfactant such as ammonium perfluorooctanoate (APFO), ammonium perfluorononanoate (APFN) (Prevedouros et al., 2006), HFPO-DA, also known as GenX (Strynar et al., 2015), or chlorofluorosurfactants (McCord et al., 2020) are introduced along with the monomer to form a fine dispersion prior to polymerization. In both cases, the resulting polymers are insoluble in aqueous solution and are readily isolated by settling or filtration (Gardiner, 2014).

Many melt-processable fluoropolymer plastics are di-block or tri-block copolymers, requiring careful control of the various monomer ratios to obtain the desired physicochemical properties. In addition, additives and chain-transfer agents can be added to adjust the molecular weight of the produced resins (Gardiner, 2014) in an analogous manner to the production of hydrocarbon thermoplastics. Perfluoro-polymers, such as PTFE, are typically recalcitrant to reactive crosslinking, due to their extraordinarily inert fluorine-carbon bond structure, and thus, these polymers often exhibit lower tensile strength and are subject to creep and flow under pressure.

Polyfluoropolymers such as ETFE can be crosslinked via introduction of chemically reactive crosslinking additives or via irradiation to induce reactive free-radical sites directly on the polymer chains (Gardiner, 2014). This introduction of sites typically results in improved mechanical and physicochemical properties such that these polyfluoropolymers are often used as engineering thermoplastics in demanding applications (Section 2.6).

Crystalline fluoropolymers are insoluble in nearly all known solvents and, therefore, must be processed into final form via either sintering (e.g., for PTFE) or thermal molding/extrusion (e.g., for thermoplastic fluoropolymers). Some amorphous fluoropolymers are soluble in select organic solvents, enabling such fluoropolymer plastics to be solvent-cast into thin (and optically transparent) films (Gardiner, 2014).

The primary manufacturers of fluoropolymer plastic resins as of 2014 were DuPont, Chemours, Asahi Glass/AGC, Solvay, 3M, Dyneon (a 3M and Hoechst joint venture), Honeywell, Arkema, and Daikin (Gardiner, 2014). Production and consumption of fluoropolymers reached approximately 270,000 tons per year by 2015, with most of this consumption accounted for by PTFE (140,000 tons/year) (Mierdel et al., 2019).

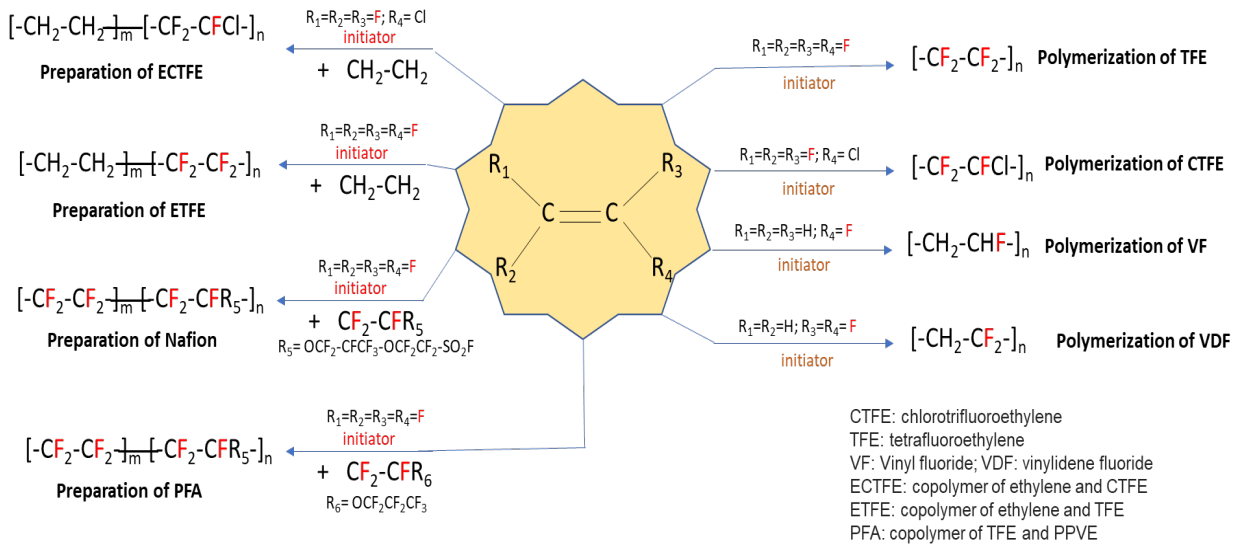
The market for fluoropolymers was expected to grow to 475,000 tons per year by 2022, with a compounding annual growth rate of 6.5% over the period 2016 – 2022. The largest consumer and user of PTFE in the world is China, accounting for 44% of consumption and 50–55% of production, respectively, in 2017. The U.S. is a net importer of PTFE, and several tens-to-thousands of tons of PTFE oversupply are typically in the global market, contributing to price depression worldwide. Melt-processable fluoropolymer plastic consumption worldwide is dominated by China and the U.S., with each accounting for approximately 30% of consumption, while western countries and Japan account for most of the corresponding production capacity (McKeen and Ebnesajjad, 2023a).

North America is the second largest fluoropolymers market (second to the Asia-Pacific region), which accounts for approximately 25% revenue share of global consumption in 2019. North American fluoropolymer consumption was estimated to be 92 kilotons (kt) and $1.4B in 2019. Fluoropolymer consumption is forecast to grow during the 2020 to 2025 period at a compound annual growth rate (CAGR) of 4.8% kt. The North American fluoropolymer market is forecast to grow during 2020 to 2025 at a CAGR of 5.0% to reach approximately $1.9B (PLS080B, *Fluoropolymer Materials: Technologies and Global Markets*).

PTFE accounted for the largest portion of the U.S. fluoropolymer market in 2020, where it was extensively used in chemical processing, cookware and bakeware, and medical applications. North American fluoropolymer consumption is also being affected by the growing use of fluoropolymers in wire and cable applications, where fluoropolymers are used as jacketing and primary insulation material and for fiber optic cables. FEP and PVDF are the fastest-growing product types with respect to these applications. PVDF is also expected to grow relatively quickly in North America, as the material is increasingly being used in lithium-ion batteries and architectural coating applications (PLS080B).

3.3 Overview of Fluoropolymer Chemistry

The chemistry of fluoropolymer production is based on free-radical initiated polymerization of vinyl-based monomers, including TFE and related compounds (Figure 3-4). Details of production and synthesis methods for the most important fluoropolymer plastics in use today are described as follows.



Note: Based on information from Teng (2012).

Figure 3-4. Fluoropolymer Plastic Synthesis Begins with Vinyl Monomer Precursors, Proceeding Through Free-Radical-Initiated Polymerization to Form Final Polymers

3.3.1 Polytetrafluoroethylene (PTFE)

PTFE was the first commercial fluoropolymer, accidentally discovered in 1938 (Figure 3-1) (Plunkett, 1986; Teng, 2012). This homopolymer is chemically analogous to polyethylene, with all hydrogen atoms replaced by fluorine atoms. PTFE differs structurally from polyethylene in its helical polymer chain configuration, leading to a very high crystallinity (Teng, 2012). The very high fluorine-to-carbon ratio of this material and its dense structure gives PTFE the highest density of any fluoropolymer (Sastri, 2014). The high density and the corresponding rigidity of the polymer chain result in an exceptionally high melting point (320 °C) and a corresponding high viscosity near the melting point (Teng, 2012; McKeen and Ebnesajjad, 2023b). PTFE thermally decomposes at a temperature below its flow-point, such that it cannot be melt-processed through conventional thermoplastic extrusion and molding techniques.

Synthesis of PTFE is accomplished via peroxide-initiated polymerization of TFE monomers in aqueous solutions (Figure 3-5) (Teng, 2012; McKeen and Ebnesajjad, 2023b). The initial physical form of the polymer is dictated by the use or absence of dispersion agents such as fluorosurfactants. When PTFE is produced using emulsion polymerization without a fluorosurfactant, PTFE forms granules that can be isolated from the synthesis liquor by settling. These granules are useful for fabrication of parts via compression molding and ram extrusion (Teng, 2012).

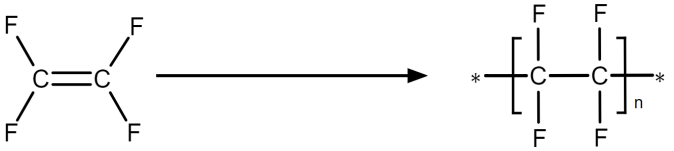


Figure 3-5. Production of Polytetrafluoroethylene from Tetrafluoroethylene Precursor

Emulsion polymerization of PTFE in the presence of a fluorosurfactant yields an aqueous dispersion of fine PTFE powders, which is then useful for fabrication of parts via paste extrusion or (in aqueous dispersion) to produce coatings or thin films by casting (Teng, 2012). For powdered PTFE, the fluorosurfactant is typically removed by heat-treating, while PTFE dispersions retain the fluorosurfactant as an impurity (Prevedouros et al., 2006).

The most commonly used fluorosurfactant for PTFE emulsion polymerization was APFO until the early 2000s, when this compound was replaced in the Chemours process by HFPO-DA (Figure 3-1). Discharge of fluorosurfactant from PTFE and other fluoropolymer production, and its presence as an impurity in fabricated products, has led to widespread environmental contamination and has motivated a move toward fluorosurfactant-free production methods. Representative commercial PTFE resins and manufacturers include Teflon (DuPont), Polyflon[18] (Daikin), Dyneon[19] PTFE (Dyneon), and Fluon[20] (Asahi Glass/AGC).

3.3.2 Polychlorotrifluoroethylene (PCTFE)

A close structural analog to PTFE, the homopolymer PCTFE, was the second fluoropolymer to be commercialized as Kel-F[21] by the M. W. Kellogg Company in 1953 (Teng, 2012), although it was first reported in 1937, before PTFE (McKeen and Ebnesajjad, 2023a). This plastic is a polyfluoropolymer, wherein one of the fluorine atoms of TFE is replaced by a chlorine atom. Relative to PTFE, this substitution renders the resulting polymer less crystalline due to the incorporation of the bulkier chlorine atom and disruption of the tightly packed polymer chain (Teng, 2012; McKeen and Ebnesajjad, 2023f). This material was the first truly extrudable and thermoplastic fluoropolymer. PCTFE is produced by the same synthetic route as PTFE, with aqueous suspension or emulsion polymerization methods (Figure 3-6).

PCTFE is somewhat more expensive to produce than PTFE, due to the added expense of the chlorinated monomer, and is typically used in specialty applications. The material is not as solvent-resistant as PTFE but exhibits enhanced engineering properties such as less susceptibility to creep and cold-flow (Teng, 2012; McKeen and Ebnesajjad, 2023f).

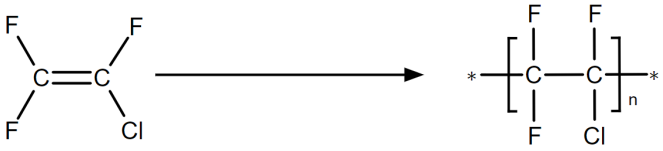


Figure 3-6. Production of Polychlorotrifluoroethylene from Chlorotrifluoroethylene

Although 3M no longer manufactures PCTFE as Kel-F, it is currently in production by Daikin as Neoflon,[22] by Honeywell as Aclar,[23] and by Arkema as Voltalef[24] (Teng, 2012).

3.3.3 Polyvinyl Fluoride (PVF)

The hydrofluoropolymer PVF was introduced in 1961 by DuPont. This homopolymer is very similar in structure to polyethylene, with only a single substitution of hydrogen to fluorine in the monomer structure (Teng, 2012; McKeen and Ebnesajjad, 2023e). As with the other fluorinated homopolymers described above, PVF is synthesized in an aqueous solution by free-radical initiated polymerization (Figure 3-7). However, the production of PVF requires higher pressure than, for example, PTFE (Teng, 2012). Because the vinyl fluoride precursor is asymmetric, PVF can polymerize in two orientations (head-to-tail and head-to-head), leading to irregularities and structural defects in the resulting polymer material (McKeen and Ebnesajjad, 2023e).

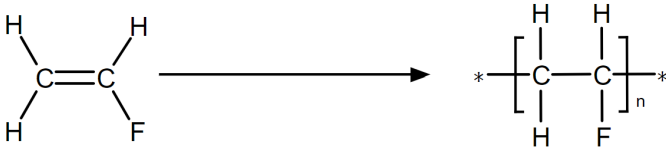


Figure 3-7. Production of Polyvinyl Fluoride from Vinyl Fluoride

[18] Polyflon is a registered trademark of Daikin Industries, Ltd., Osaka, Japan.
[19] Dyneon is a registered trademark of 3M Company, St. Paul, Minnesota.
[20] Fluon is a registered trademark of AGC Chemicals, Exton, Pennsylvania.
[21] Kel-F is registered trademark of 3M Company, St. Paul, Minnesota.
[22] Neoflon is a registered trademark of Daikin Industries, Osaka, Japan.
[23] Aclar is a registered trademark of Honeywell International Inc., Charlotte, North Carolina.
[24] Voltalef is a registered trademark of Arkema S.A., Colombes, France.

As with other homopolymer fluoropolymer plastics, PVF can be prepared via suspension or emulsion polymerization. PVF is not as chemically resistant as PTFE and PCTFE but exhibits good melt-processibility and can be cast into films that are easily functionalized by exposure to radiation and electron beams (Teng, 2012). Currently, the only commercial PVF is produced in film form by DuPont under the brand name Tedlar.[25]

3.3.4 Polyvinylidene Fluoride (PVDF)

Polymerization of vinylidene fluoride (VDF) to form PVDF was first reported in 1948 by DuPont (McKeen and Ebnesajjad, 2023e). This homopolymer is prepared by aqueous free-radical initiated emulsion or suspension polymerization in a similar manner to that used for other vinylic homopolymer fluoropolymer plastics such as PTFE (Figure 3-8). The resulting polyfluoropolymer is easily melt-processable and moldable using conventional thermoplastic handling methods.

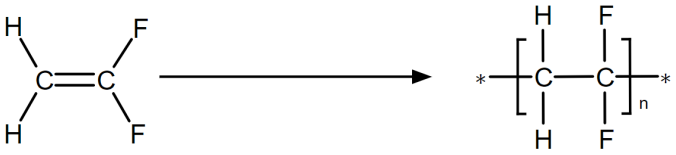


Figure 3-8. Production of Polyvinylidene-Fluoride from Vinylidene Fluoride

PVDF is less chemically resistant than PTFE but exhibits excellent mechanical properties and can be crosslinked by ionizing radiation (Teng, 2012), making it the second most highly produced fluoropolymer plastic after PTFE (McKeen and Ebnesajjad, 2023e). The largest producer of PVDF is Arkema, through their Kynar[26] product line (Teng, 2012; McKeen and Ebnesajjad, 2023e). Historically, Arkema used APFN as a surfactant in their production method; however, the use of fluorosurfactants in Kynar production has been phased out due to environmental concerns (Reich, 2008). Solvay produces PVDF as Solef[27] and also historically used APFN as a polymer processing aid. Solvay has recently announced their intention to move to a fully fluorosurfactant-free PVDF production process in 2026, while employing a perfluoroether surfactant in the interim period (Solvay, 2022). The third major producer of PVDF is Daikin, as Neoflon PVDF (Teng, 2012).

3.3.5 Ethylene-Chlorotrifluoroethylene (ECTFE) Copolymer

Copolymers between hydrocarbon-based and fluorochemical vinyl monomers were introduced as commercial products in the 1970s starting with the development of ECTFE and its subsequent production by Ausimont. This polymer has an alternating ethylene and chlorotrifluoroethylene (CTFE) structure, as shown in Figure 3-9.

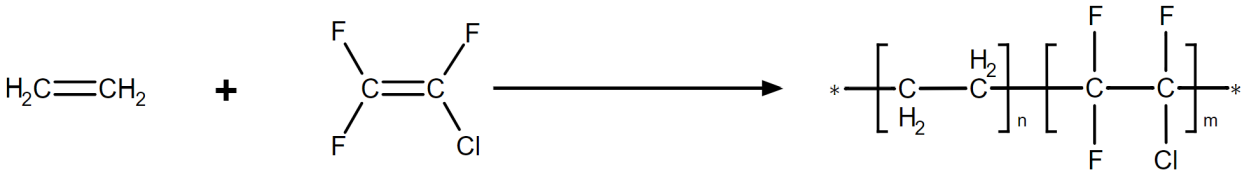


Figure 3-9. Production of Ethylene-Chlorotrifluoroethylene from Ethylene and Chlorotrifluoroethylene

Polymerization of this copolymer is performed under aqueous conditions using a peroxide-based free-radical catalyst together with a chain transfer agent (usually halogenated), which serves to control the resulting polymer molecular weight (Teng, 2012). No fluorosurfactants are reported to be used in this process.

[25] Tedlar is a registered trademark of DuPont, Wilmington, Delaware.
[26] Kynar is a registered trademark of Arkema S.A., Colombes, France.
[27] Solef is a registered trademark of Solvay S.A., Brussels, Belgium.

The polymeric production of ECTFE results in a zig-zag structure, which yields moderate crystallinity (50-60%) and stability over a wide range of temperature conditions. As a melt-processable thermoplastic, ECTFE can be extruded and molded into a variety of shapes, including sheets and filaments. ECTFE is more dimensionally stable than PTFE and other perfluoropolymers, exhibits high tensile strength (Teng, 2012), and can be chemically crosslinked using ionizing radiation (Gardiner, 2014). ECTFE is currently manufactured as Halar[28] by Solvay, primarily for use in cable and wiring insulation (Teng, 2012).

3.3.6 Ethylene-Tetrafluoroethylene (ETFE) Copolymer

Unlike many other fluoropolymers, the copolymer of ethylene and TFE (Figure 3-10) developed by DuPont in 1973 and marketed as ETFE is not typically produced under aqueous conditions.

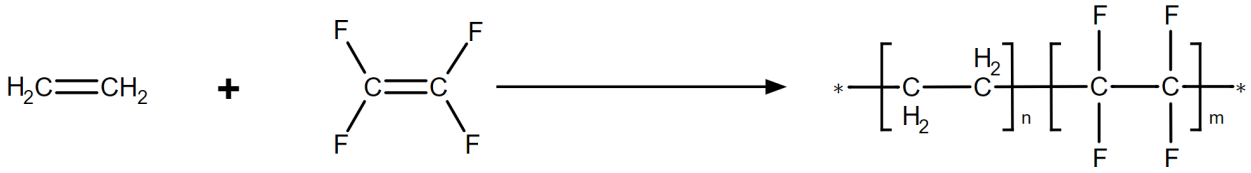


Figure 3-10. Production of Ethylene Tetrafluoroethylene from Ethylene and Tetrafluoroethylene

This copolymer is typically prepared in a solvent (usually a chlorofluorocarbon liquid) with a fluorinated peroxide initiator (Teng, 2012) but without an emulsifier. Like ECTFE, ETFE forms a zig-zag polymer structure, yielding a crystallinity below 60% and a variable melting temperature depending on the ratio of ethylene to TFE.

Among all copolymers of TFE, ETFE exhibits some of the best engineering properties, as it can be fabricated into finished products using the full range of thermoplastic processing techniques. For example, ETFE can be blow molded, extruded, injection molded, or compression molded (Teng, 2012). This copolymer is moderately chemically resistant and like many ethylene copolymers can be crosslinked by ionizing radiation (Gardiner, 2014; Teng, 2012). ETFE is marketed commercially by DuPont as Tefzel,[29] by Asahi Glass/AGC as Fluon, by Solvay as Halon[30] ETFE, by Daikin as Neoflon ETFE, and by Dyneon as Dyneon ETFE.

3.3.7 Fluorinated Ethylene Propylene (FEP) Copolymer

The need to create a perfluoropolymer with the chemical resistance of PTFE but with the melt-processability of conventional hydrocarbon-based thermoplastics led to development of a FEP copolymer by DuPont in 1960. This copolymer of TFE and hexafluoropropylene (HFP) yields a perfluorinated structure that is very similar to PTFE but with a trifluoromethyl functional side-group on the polymeric chain (Figure 3-11) (Gardiner, 2014; Teng, 2012).

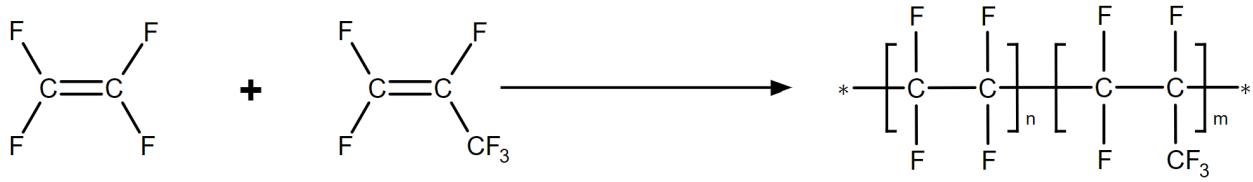


Figure 3-11. Production of Fluorinated Ethylene Propylene from Tetrafluoroethylene and Hexafluoropropylene

[28] Halar is a registered trademark of Solvay S.A., Brussels, Belgium.
[29] Tefzel is a trademark of Chemours, Wilmington, Delaware, for its brand of ETFE fluoropolymer resins.
[30] Halon is a registered trademark of Allied Corporation, Morristown, New Jersey.

This polymer is a structural analog of the hydrocarbon plastic polypropylene. As with PTFE, the synthesis of FEP typically involves free-radical polymerization in an aqueous medium, usually in the presence of a fluorosurfactant dispersing agent – commonly HFPO-DA (McKeen and Ebnesajjad, 2023c). As a copolymer, careful control of the monomer ratio and reaction conditions is necessary to generate a polymer with acceptable use properties. FEP typically contains approximately 5 mol% HFP, which is sufficient to disrupt the regular crystal structure of pure PTFE and yield a crystallinity below 70% (Teng, 2012; McKeen and Ebnesajjad, 2023c). The resulting copolymer is somewhat more translucent than PTFE and can be melt-processed but retains its exceptional chemical inertness and insolubility with superior mechanical properties relative to PTFE (Teng, 2012). Some specific FEP commercial products include Teflon FEP (Dupont), Neoflon FEP (Daikin), and Dyneon FEP (Dyneon).

3.3.8 Perfluoroalkoxy (PFA) Polymer

Additional work by DuPont to generate melt-processable analogs of PTFE resulted in development of a PFA polymer, which is a perfluorinated copolymer of TFE and a fluorinated vinyl ether such as perfluoropropylvinylether (PPVE) (Figure 3-12).

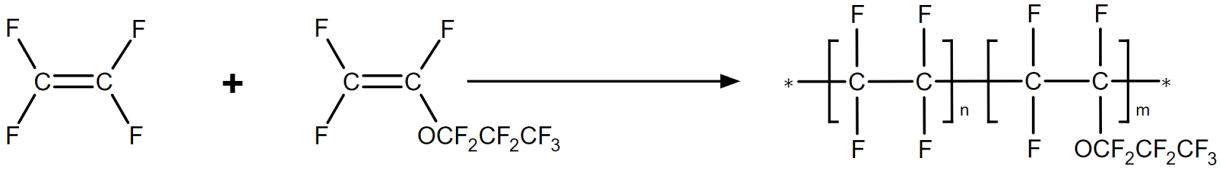


Figure 3-12. Production of Perfluoroalkoxy from Tetrafluoroethylene and Perfluoropropylvinylether

The incorporation of PPVE into PFA represents the first incorporation of oxygen-containing ether functional groups into perfluoropolymers and yields a fluoropolymer plastic with exceptional chemical resistance and processability (Teng, 2012; McKeen and Ebnesajjad, 2023d). As with most other fluoropolymer plastics, the dominant method used to prepare PFA is dispersion or suspension polymerization with fluorosurfactants such as HFPO-DA. Commercial PFA formulations typically have approximately 3.5–4% vinyl ether monomer incorporated into the structure. As with FEP, this branched monomer incorporation is sufficient to lower the crystallinity of the polymer sufficiently to allow ready-melt processibility (McKeen and Ebnesajjad, 2023d).

In addition to PPVE, additional vinyl ether monomers such as perfluoroethylvinylether (PEVE, Chemours) and perfluoromethylvinylether (PMVE, Solvay) have been produced and marketed (McKeen and Ebnesajjad, 2023d). PFA polymers can be made in exceptional purity for sensitive applications requiring low levels of impurities and additives (e.g., semiconductors). Commercial PFA formulations include Teflon PFA (DuPont), Aflon[31] PFA (Asahi Glass/AGC), Dyneon PFA (Dyneon), Neoflon PFA (Daikin), and Hyflon[32] PFA (Solvay) (Teng, 2012).

3.3.9 Amorphous Perfluoropolymer

The limited solubility in solvents, poor optical clarity, and relatively high deformability under stress inherent to crystalline or semicrystalline perfluoro- and polyfluoropolymers described above limited their applications in specialized scenarios (Teng, 2012). The first amorphous perfluoropolymer was developed by DuPont in 1985 by copolymerization of TFE and perfluoro-2,2-dimethyl-1,3-dioxole (PDD) (Figure 3-13). Consistent with other fluoropolymer production methods, the synthesis is carried out in aqueous media with a peroxide-based initiator.

[31] Aflon is a registered trademark of AGC Inc. (formerly Asahi Glass Co., Ltd.), Tokyo, Japan.
[32] Hyflon is a registered trademark of Solvay S.A., Brussels, Belgium.

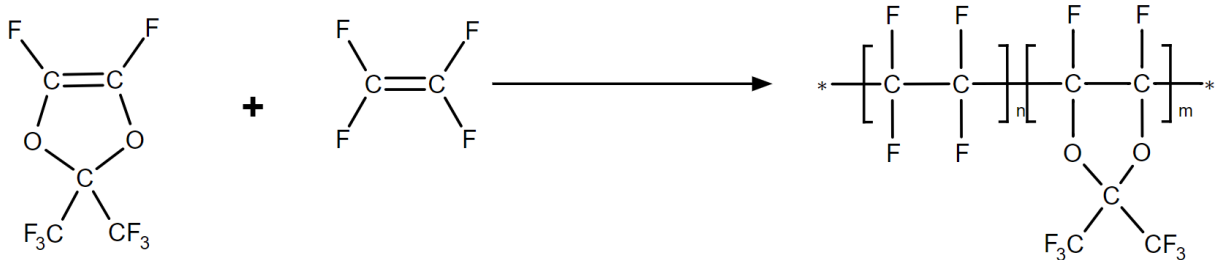


Figure 3-13. Production of Teflon Amorphous Fluoropolymer from Tetrafluoroethylene and Perfluoro-2,2-Dimethyl-1,3-Dioxole

Once polymerized, these materials have very low refractive indices, making them suitable for use in optical applications such as spectrometer windows and transparent tubing and fiber cladding. Amorphous fluoropolymers are also soluble in several organic solvents, rendering them viable for thin-film casting and use in dip-coating of circuits and other specialized applications. The DuPont product is branded as Teflon AF, while Solvay markets an analogous copolymer of TFE and 2,2,4-trifluoro-5-trifluoromethoxy-1,3-dioxole (TTD) as Hyflon AD. Asahi Glass/AGC produces an amorphous homopolymer of perfluoro-3-butenylvinylether (PBVE) as Cytop.[33]

3.3.10 Sulfonated Perfluorinated Ionomer (Nafion)

The fluoropolymer plastics discussed previously are neutral polymers, carrying no net charge. The development of the copolymer Nafion by DuPont in the 1960s yielded the first ionic fluoropolymer, or ionomer (Teng, 2012). This polymer is synthesized by copolymerization of TFE and the ionogenic monomer based on perfluoroalkylvinylethersulfonyl fluoride chemistry (Figure 3-14).

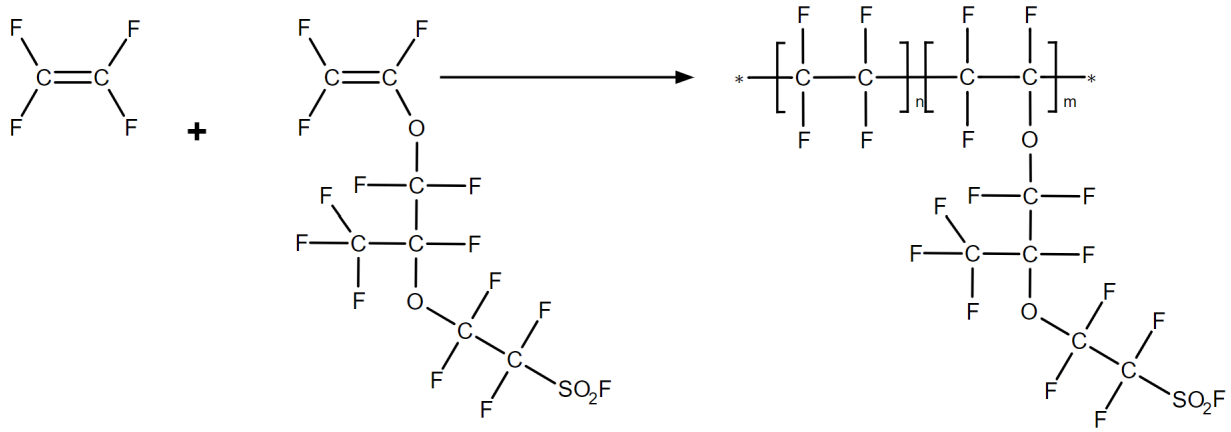


Figure 3-14. Production of Nafion from Tetrafluoroethylene and Perfluoroalkylvinylethersulfonyl Fluoride

Polymerization of this material under aqueous conditions, with the addition of concentrated sodium hydroxide, yields sulfonic acid functional groups from hydrolysis of the sulfonyl fluoride (Teng, 2012). The resulting polymer is soluble in hot aqueous alcohol and such preparations are suitable for the production of thin films.

The primary form of sulfonated perfluorinated ionomers is used to make ion-conductive membranes, which exhibit chemical resistance while offering high ion-conductivity (Teng, 2012). These materials are not typically melt-processed or extruded due to their intended uses in membrane technology. To date, the primary producer of these perfluoroionomer materials is DuPont, as Nafion.

[33] Cytop is a trademark of AGC Inc., Tokyo, Japan.

4.0 COMMERCIAL USES OF FLUOROPOLYMERS AND COMPETING TECHNOLOGIES

Throughout various industries, fluoropolymers are often essential to maintaining the effectiveness, safety, and robustness of a wide range of products across many industry sectors. A consistent theme throughout this section is that no industrially scaled materials are currently available and viable to fill the role of fluoropolymer plastics if required for multiple performance characteristics, as described in Section 2.0. While other polymers and non-polymers can resist chemical attack, be used at temperatures exceeding 260 °C, resist UV radiation, have low weight, and have considerable strength and durability, finding alternative materials that can meet multiple or all these requirements for the intended application is difficult. This section outlines various potential options for individual needs in the following industrial sectors:

- Chemical processing, including applications critical to DOE waste storage and processing
- Microelectronics and semiconductors
- Building construction and infrastructure
- Aerospace and automotive
- Battery, solar, and wind energy.

The fluoropolymers listed in Table 4-1 (Korzeniowski et al., 2023) are those that tend to dominate the fluoropolymer marketplace, especially for the sectors of interest in this report, and are specifically mentioned in the Vanderbilt survey results. Because there is no strict or regulatory definition of PFAS (and thus of fluoropolymers) and the definition is still evolving (Buck et al., 2021), this report captures what the subject matter expert team considered the most significant set of fluoropolymers based on literature and the survey results. For example, 267 fluoropolymers (by CAS numbers) were identified in the OECD (2018) study, which has been cited widely in scientific literature (e.g., Glüge et al., 2020; Buck et al., 2021). Of those fluoropolymers of economic significance identified in OECD (2018),[34] the fluoropolymers listed in Table 4-1 are in agreement with OECD (2018), where most of the fluoropolymers that could be identified were PTFE (although more than a hundred could not be identified – OECD [2018] indicated there was more work to do). Of further note, the set of fluoropolymers listed in Table 4-1 is consistent with the fluoropolymers discussed in Henry et al. (2018) and Korzeniowski et al. (2023); authors from the Buck et al. (2021) report who looked at commercial viability indicated that the fluoropolymers in Table 4-1 dominate the world market for such materials.[35]

Table 4-1. Selected Fluoropolymers and Example Uses for Sectors of Interest in the Vanderbilt Study (2 pages)

Industries end uses	Transportation		Chemical		Telecommunications		Infrastructure construction and architecture	Renewable energy		
	Auto-motive	Aero-space	Oil and gas	Chemical process industry (CPI)	Electronics and semiconductors	Internet and wireless communi-cations		Energy production	Hydrogen production	Energy storage
Fluoropolymer Thermoplastics										
PTFE	●	●	●	●	●	●	●	●	●	●
ETFE	●	●	●	●	●	●	●	●		●
FEP	●	●	●	●	●			●		
PFA	●	●	●	●	●			●		
PVDF homopolymer	●	●	●	●	●	●	●	●	●	●
PVDF copolymer	●	●		●	●	●	●		●	●
ECTFE copolymer		●	●	●	●	●	●			
ECTFE terpolymer			●	●						
PCTFE		●			●					
FEVE	●	●			●		●			

[34] OECD (2018) did not consider global commercial viability according to Buck et al. (2021).
[35] Personal communication with the authors of Buck et al. (2021) on September 26, 2023.

Table 4-1. Selected Fluoropolymers and Example Uses for Sectors of Interest in the Vanderbilt Study (2 pages)

Industries end uses	Transportation		Chemical		Telecommunications		Infrastructure construction and architecture	Renewable energy		
	Auto-motive	Aero-space	Oil and gas	Chemical process industry (CPI)	Electronics and semiconductors	Internet and wireless communi-cations		Energy production	Hydrogen production	Energy storage
EFEP	●			●	●					
CPT	●				●					
THV	●	●		●	●		●	●		●
Fluoropolymer Elastomers										
FEPM	●	●	●	●	●		●	●		
FKM	●	●	●	●	●		●	●	●	●
FFKM		●	●	●	●					
Specialty Fluoropolymers										
Amorphous		●		●	●	●			●	●
Ionomer	●			●	●			●	●	●

Source: Based on Henry et al., 2018, "A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers," and Korzeniowski et al., 2023, "A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers," *Integrated Environmental Assessment and Management*.

CPT = chlorotrifluoroethylene-perfluoroalkoxy-tetrafluoroethylene.
ECTFE = ethylene chlorotrifluoroethylene.
EFEP = ethylene-tetrafluoroethylene-hexafluoropropylene.
ETFE = ethylene tetrafluoroethylene.
FEP = fluorinated ethylene propylene.
FEPM = trifluoroethylene-propylene copolymer.
FEVE = fluoroethylene-vinyl ether.
FFKM = TFE-PMVE perfluoroelastomer.
FKM = fluorine Kautschuk material.
PCTFE = polychlorotrifluoroethylene.
PFA = perfluoroalkoxy polymer.
PTFE = polytetrafluoroethylene.
PVDF = polyvinylidene fluoride.
THV = TFE-HFP-VF2.

4.1 Chemical Processing

This section describes fluoropolymers used in chemical processing, storage, and disposal. For example, chemical processing industries often handle corrosive chemicals during the manufacturing of diverse products. Fluoropolymers often replace stainless steel and exotic alloys in processes that involve highly reactive chemicals, where fluoropolymers also meet purity requirements, which are essential in semiconductor, food, and biopharmaceutical production. Examples of industries using fluoropolymers include chemical manufacturing, plastics manufacturing and processing, semiconductor manufacturing, pharmaceutical and biopharmaceutical industries, and food processing (Ebnesajjad and Khaladkar, 2018, p. 1). Their unique characteristics also make replacing fluoropolymers difficult and often cost prohibitive, as fluoropolymers are typically used if alternate polymers or other materials cannot tolerate the stringent conditions required.

4.1.1 Forms of Fluoropolymers Used in Chemical Processing, Storage, and Disposal

Fluoropolymers can generally be found in several forms (Biering, 2023):

- Granulates are the most common form of fluoropolymers and are available commercially as solid granules or pellets, which can be processed using various techniques (e.g., extrusion or compression molding) to create a wide variety of parts and components.
- Some fluoropolymers are melt-processable materials; these fluoropolymers can be melted and processed using techniques like extrusion and injection or blow molding, which offer more versatility in terms of design and manufacturing because these materials can be easily shaped into complex geometries.

- Thin, flexible, and strong fluoropolymer films, which can be produced by various methods (e.g., casting, extrusion, or skiving), are suitable for use in applications such as electrical insulation, gaskets, and seals.
- Fluoropolymer emulsion-modified paste is a viscous, semi-solid material that can be made into films, thin wall heat-shrink, or industrial tubing, pipe seal tape, and membranes where product materials can be sintered or non-sintered depending on end-use.
- Dispersions are liquid suspensions of fluoropolymer particles in a solvent or aqueous medium; these dispersions can be applied as coatings or used to impregnate other materials and are typically used in applications that require a thin, uniform layer of the resulting material.

Examples of the forms (typically rods, tubes, and sheets) of fluoropolymers used in chemical processing that tend to dominate in the fluoropolymer marketplace (Vincent, 2023) or are specifically mentioned in the Vanderbilt survey results include:

- **Polytetrafluoroethylene (PTFE**)/Teflon is offered commercially primarily in three forms – granular resins, fine powders, and aqueous dispersions (Drobny, 2009) – that can be processed into rods, tubes, sheets, heat shrink, O-rings to produce gaskets, seals, and linings that are suitable for chemical applications due to the material's inertness; high resistance to corrosion, solvents, and chemicals; and ability to withstand operating temperatures up to 260 °C.
- **Ethylene tetrafluoroethylene (ETFE)**/Tefzel/Texlon[36]/Fluon is a thermoplastic copolymer offered commercially in the form of powders that can be processed into rods, tubes, and sheets where ETFE coatings supply chemical inertness similar to fluoropolymers like PTFE but also provide mechanical strength and resistance to abrasion. Because of its resistance to petroleum, ETFE is increasingly being used for fuel tubing in the automotive industry and for gaskets, O-rings, and hose linings.
- **Fluorinated ethylene propylene (FEP)**/Teflon FEP/Neoflon/Dyneon FEP materials are offered commercially in the form of varying melt viscosity resins and aqueous dispersions (Drobny, 2009) that can be processed into rods, tubes, and sheets that are used to line chemical processing equipment and tubing.
- **Perfluoroalkoxy fluorocarbon (PFA)**/Teflon PFA is offered commercially in the form of an aqueous dispersion or copolymer resin (Drobny, 2009) that can be extruded into rods, tubes, sheets, and foams and to coat components and tubes that are suitable for chemical processing due to its high resistance to most chemicals and its anti-stick properties.
- **Polyvinylidene fluoride (PVDF)**/Kynar is offered commercially in the form of aqueous dispersions or resins (Drobny, 2009) that can be processed into rods, tubes, and sheets that are used to produce flexible, heat-shrinkable tubing and components like pumps and sensors for chemical processing.
- **Ethylene chlorotrifluoroethylene (ECTFE)**/Halar is offered commercially as resin or hot cut pellets (Drobny, 2009) that can be processed into rods, tubes, sheets, and films. The oil, gas, and chemical industries use ECTFE to line vessels, tanks, and other components.
- **Ethylene-tetrafluoroethylene-hexafluoropropylene (EFEP)**/Neoflon is a melt-processable fluoropolymer derived from ETFE that is typically supplied in pellet form. EFEP has good chemical resistance and high clarity for applications in which transparency is important, for example, in the chemical processing industry in which liquid levels must be viewed through valves or pipes.

[36] Texlon is a registered trademark of Vector Foiltec GmbH, Siegsdorf, Germany.

- **A terpolymer of tetrafluoroethylene, hexafluoropropylene, and vinylidene fluoride (THV)**/Dyneon THV is a melt-processable fluoropolymer that is available in nine commercial grades (five dry grades in pellet or agglomerate form and four aqueous dispersions) that differ in monomer ratios and consequently in melting points, chemical resistance, optical properties, and flexibility (Drobny, 2009). The chemical resistance and low permeation of THV make it suited for chemical processing particularly where tight radius bends of the tubing require high flexibility without cracking.
- **Trifluoroethylene-propylene copolymer (FEPM)** originally designated copolymers of **tetrafluoroethylene (TFE) and propylene (P)**/Alfas[37]/Viton Extreme,[38] where the primary form TFE/P (commercially available in the form of pellets) provides a unique combination of chemical, heat, and electrical properties resisting both acids and bases, along with steam, amine-based corrosion inhibitors, hydraulic fluids, alcohol, and petroleum fluids. TFE/P typically retains its chemical resistance even in high temperatures.
- **Fluorine Kautschuk material (FKM)**/Viton[38]/Fluorel[39] /Dai-el[40]/Tecnoflon[41] is commercially available in latex form or as sheets, ribbons, and pellets and can be fabricated into O-rings, expansion joints, diaphragms, blow-out preventers, valve seats, gaskets, hoses, safety clothing and gloves, stack and duct coatings, tank linings, drill bit seals, and V-ring packers for typical chemical and petrochemical applications (McKeen, 2013, pp 195-196).
- **Perfluoroelastomer (FFKM)**/Kalrez[42]/Tecnoflon[41]/Chemraz[43] is available in the form of pellets, fine powder, granules, and sheets for uses in chemical processing, including O-ring agitator shaft and pump seals, mechanical pump seals at elevated temperatures and high pressures, pipeline seals, and outlet valve seals (McKeen, 2013, p. 197).

4.1.2 Critical Properties for Fluoropolymers Used in Chemical Processing, Storage, and Disposal

The properties important for use of fluoropolymers in chemical processing, storage, and disposal applications include (Ebnesajjad and Khaladkar, 2018; Korzeniowski et al., 2023):

- Low coefficient of friction (non-stick properties)
- Chemically stable, inert, and nontoxic
- Biocompatible for medical applications and bioinert
- High resistance to solvents, chemicals, and corrosion (i.e., nonleachable/good release properties)
- Stable at low and high operating temperatures (i.e., high temperature resistance and high continuous use temperature) and cryogenic properties
- Electrical properties, low dielectric constant, and low dissipation factor
- Flame resistant
- Recyclable
- Weather resistance/weatherability; UV, radiation, and arc resistant
- Low deformation under stress and remains flexible at low temperatures.

[37] Alfas is a registered trademark of Asahi Glass Company, Tokyo, Japan.
[38] Viton/Viton Extreme are trademarks of The Chemours Company FC, LLC (formally DuPont), Wilmington, Delaware.
[39] Fluorel is a trademark of 3M Company, St. Paul, Minnesota.
[40] Dai-el is a registered trademark of Daikin Industries, Osaka, Japan.
[41] Tecnoflon is a registered trademark of Solvay S.A., Brussels, Belgium.
[42] Kalrez is a registered trademark of DuPont Performance Elastomers, Wilmington, Delaware.
[43] Chemraz is a registered trademark of Greene Tweed, Selma, Texas.

The Vanderbilt survey responses indicate other critical properties of fluoropolymers, including specific gravity, melting point, tensile strength, elongation of break, compressive strength, and flex life.

A summary of important properties related to chemical processing for selected fluoropolymers (Korzeniowski et al., 2023) is provided in Table 4-2. The fluoropolymers in Table 4-2 (that correspond to those that tend to dominate the marketplace as indicated in Section 2.0) provide resistance to chemicals—providing a barrier material for lining process vessels and lines in aggressive environments; most can also be used over a broad range of operating temperatures. Other important chemical processing properties (e.g., mechanical strength, cryogenic, ultra-high purity) can be realized by choosing a specific fluoropolymer.

Table 4-2. Selected Fluoropolymers and Properties of Interest Related to Chemical Processing

Properties and functionality	Durable			Inert – Stable					Functional						
	Mechanical strength	Wear resistance	Flexibility	Resistance to chemicals	Weatherability	Cryogenic properties (lower than -50 °C)	High operating temperature range	High limiting oxygen index	Electrical insulator	Ionic conductivity	Piezo-electrical properties	Barrier properties	Non-stick properties	Ultra-high purity grades for clean applications	Polymer processing additives
Fluoropolymer Thermoplastics															
PTFE		●		●	●		●	●	●			●	●	●	●
ETFE	●			●			●		●			●	●		
FEP				●	●		●	●	●			●	●	●	
PFA			●	●			●	●	●			●	●	●	
PVDF homopolymer	●	●		●	●		●	●			●	●		●	●
PVDF copolymer	●	●		●	●		●	●			●	●			●
ECTFE copolymer	●	●		●	●	●	●	●	●			●			
ECTFE terpolymer		●		●	●		●	●				●			
PCTFE	●	●		●	●	●	●	●				●	●	●	
FEVE	●	●	●	●	●		●	●				●			
EFEP	●	●		●	●	●	●	●				●	●		●
CPT				●	●	●	●	●				●	●	●	
THV			●	●	●		●	●				●			●
Fluoropolymer Elastomers															
FEPM	●	●	●	●	●		●	●	●			●			
FKM	●	●	●	●	●		●	●				●	●		●
FFKM	●	●	●	●			●	●	●			●		●	
Specialty Fluoropolymers															
Amorphous			●	●			●	●	●	●		●		●	
Ionomer			●	●				●	●	●		●	●		

Source: Based on Korzeniowski et al., 2023, "A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers," *Integrated Environmental Assessment and Management*.

CPT = chlorotrifluoroethylene-perfluoroalkoxy-tetrafluoroethylene.
ECTFE = ethylene chlorotrifluoroethylene.
EFEP = ethylene-tetrafluoroethylene-hexafluoropropylene.
ETFE = ethylene tetrafluoroethylene.
FEP = fluorinated ethylene propylene.
FEPM = trifluoroethylene-propylene copolymer.
FEVE = fluoroethylene-vinyl ether.
FFKM = TFE-PMVE perfluoroelastomer.
FKM = fluorine Kautschuk material.
PCTFE = polychlorotrifluoroethylene.
PFA = perfluoroalkoxy polymer.
PTFE = polytetrafluoroethylene.
PVDF = polyvinylidene fluoride.
THV = TFE-HFP-VF2.

4.1.3 Fluoropolymer Applications Used in Chemical Processing, Storage, and Disposal

Typical fluoropolymer applications tend to exploit one or a combination of important fluoropolymer properties (e.g., chemical resistance, good mechanical properties, thermal stability, and cryogenic properties) that differentiate them from other plastics, polymers, metal alloys, and other alternative materials. Typical chemical processing uses include gaskets, T's, bellows, spacers, high-pressure hoses and tubing, coatings, fluid handling systems, vessel liners, and valve, pipe, and fitting liners (Ebnesajjad and Khaladkar, 2018, p. 5).

In chemical processing, fluoropolymers have exceptional resistance to chemical attack and are often used as barrier materials. These materials are often used to fabricate linings for carbon steel vessels and for piping and other fluid handling components (where construction of whole vessels, pipe, or components would often be cost prohibitive). Fluoropolymers provide durable, low maintenance, and economical alternatives to exotic metal alloys and may also offer thermal stability for use at high temperatures. As they do not react with process streams, fluoropolymers help prevent contamination during chemical processing (Ebnesajjad and Khaladkar, 2018, pp 5-6).

Applications for corrosion control are typically classified as follows (McKeen, 2013, p. 271):

- Barrier (linings)
- Self-supporting structures
- Others (e.g., seals, gaskets, column internals[44]).

Fluoropolymers, which have the highest chemical resistance and maximum-use temperature range among polymers, are often used for barriers (linings) and other applications such as column internals, seals, gaskets, and occasionally to construct self-supporting structures (Ebnesajjad and Khaladkar, 2018, p. 15). Corrosion resistance is a function of the level of fluorine; thus, fully fluorinated fluoropolymers (e.g., PTFE, FEP, PFA, and methyl fluoroacetate [MFA]) that are resistant to solvents, esters, and ketones are preferred for more challenging applications. Of the partially fluorinated materials, ETFE is also resistant to solvents, esters, and ketones, although others (PVDF and PCTFE) may show mild effects or even degradation to solvents, esters, and ketones (Ebnesajjad and Khaladkar, 2018, p. 12).

Examples of general uses of fluoropolymers in chemical processing include (McKeen, 2013, pp. 271-273):

- **Chemical reactors** – Vessels, mixers, and pipes are frequently coated (via liquid or powder) with thick fluoropolymer films (40+ mils) where the most chemically resistant and highest-temperature-rated material is PFA.
- **Ducts for corrosive fumes and fire resistance (semiconductor industry)** – Ductworks in a semiconductor fabrication plant carry corrosive and flammable materials, and fluoropolymer-coated metal (using ETFE or ECTFE) has replaced fiber-reinforced plastic (FRP) (resin-impregnated fiberglass that is not sufficiently fire resistant) in many of these applications.

Specific examples of chemical applications of the fluoropolymers (Table 4-1 and Table 4-2) that dominate the marketplace for fluoropolymers, are mentioned in the Vanderbilt survey responses, and cover those in widely cited articles (OECD, 2018; Henry et al., 2018; Korzeniowski et al., 2023; and Buck et al., 2021) include:

- **PTFE** – Non-stick properties and heat resistance make PTFE appropriate for bearings, insulators, surface coatings, and conveyor belt rollers in the food processing and service industry. PTFE gaskets and linings are suitable for chemical applications due to the material's chemical resistance; its high temperature resistance also makes PTFE useful for insulating external aircraft fittings and jet engines in the aerospace industry.

[44] "Column internals" refers to packings and internal structures in petroleum and chemical processing reactors and separations columns to provide increased surface area and regulate internal flows.

- **ETFE** – Resistance to corrosive chemicals and high temperatures make ETFE appropriate for the construction of chemical processing equipment, storage tanks, and piping systems; ETFE is also used to make chemical pumps, valves, and gaskets. Because of its resistance to petroleum, ETFE is increasingly being used for fuel tubing in the automotive industry and for gaskets, O-rings, and hose linings. The electrical industry uses the material for insulating wires and components like connectors.
- **FEP** – Used to line chemical processing and storage equipment, tubing, pipes, and fittings, FEP coatings are one of the important coating materials in the chemical industry because they can store and transport harsh chemicals.
- **PFA** – The main applications of PFA are chemical-resistant components for valves, pumps, and pipes due to its high resistance to most chemicals and its anti-stick properties. PFA is also widely used in the semiconductor manufacturing industries for high purity and chemical-resistant moldings. Its purity and U.S. Food and Drug Administration approval also make PFA ideal for sensitive applications like pharmaceutical and semiconductor handling processes.
- **PVDF** – Offered commercially in a broad range of melt flow rates (in the forms of latex and fine powders from emulsion processes and as granules), PVDF can be compounded with a variety of additives to improve either processing or end-use performance properties (McKeen, 2013, pp 145-147). PVDF components are used extensively in the following:
  - ***Nuclear waste processing*** (radiation and hot-acid resistant) (Section 4.1.4 discusses related DOE fluoropolymer applications)
  - ***General chemical processing industry*** (extreme chemical and temperature applications)
  - ***PVDF resins*** used in a wide range of components, including pipes, fittings, and valves; pump assemblies; tubing (flexible and rigid); tanks and vessels; nozzles; membranes and filter housing; and polymer processing aids
  - ***PVDF powder-coating systems***, which allow formation of a thick spray coating of the resin to be applied to metals for optimum corrosion resistance; PVDF powder coatings can be applied without primer.
- **ECTFE** – In the semiconductor industry, ECTFE is suitable for coating ductwork to prevent contamination and corrosion. The oil and gas and chemical industries use ECTFE to line vessels, tanks, and other components.
- **EFEP** – A melt-processable fluoropolymer derived from ETFE, EFEP has good chemical resistance and high clarity for applications in which transparency is important; for example, in the chemical processing industry in which liquid levels must be viewed through valves or pipes.
- **THV** – A melt-processable fluoropolymer, THV comprises three different monomers: tetrafluoroethylene, hexafluoropropylene, and vinylidene fluoride. Chemical resistance and low permeation make THV suited for chemical processing particularly where tight radius bends of the tubing require high flexibility without cracking.
- **FEPM** – FEPM originally designated copolymers of TFE and P, where the primary form TFE/P provides a unique combination of chemical, heat, and electrical properties resisting both acids and bases, along with steam, amine-based corrosion inhibitors, hydraulic fluids, alcohol, and petroleum fluids. TFE/P typically retains its chemical resistance even in high temperatures.
- **FKM** – Typical chemical and petrochemical applications of FKM, a family of fluoropolymer rubbers, include O-rings, expansion joints, diaphragms, blow-out preventers, valve seats, gaskets, hoses, safety clothing and gloves, stack and duct coatings, tank linings, drill bit seals, and V-ring packers (McKeen, 2013, pp 195-196).

Other industrial applications of fluorocarbon elastomers include valve seals, hose (rubber-lined or rubber-covered), wire and cable covers (in steel mills and nuclear power plants), diaphragms, valve and pump linings, reed valves, rubber-covered rolls (100% fluorocarbon elastomer or laminated to other elastomers), electrical connectors, pump lining and seals, and seals in food-handling processes approved by the U.S. Food and Drug Administration (McKeen, 2013, p. 196).

- **FFKM** – Perfluoroelastomer FFKM compounds contain higher amounts of fluorine than standard FKM. Examples of FFKM applications in the chemical industry include O-ring agitator shaft seals in an oxidation reactor operating at high temperatures and in contact with 70% acetic acid; mechanical process pump seals pumping alternately acetone, dichloromethane, and methyl isocyanate at elevated temperatures; pipeline seals exposed to chloromethyl ether or dichlorophenyl isocyanate at elevated temperatures; outlet valve seals exposed to a 50/50 mixture of methylene chloride/ethanol; mechanical pump seals handling a mixture of ethylene oxide and strong acids at high temperature and pressure; O-rings in a pump handling 99% propylene at low temperatures; and O-ring pumps for pumping chromate-inhibited water at high temperature (McKeen, 2013, p. 197).

4.1.4 Fluoropolymer Applications Critical to U.S. Department of Energy Waste Storage and Processing

Within DOE, the wide usage of polymer products includes fluoropolymers. Similar to other chemical processing organizations, the need for fluoropolymers within the DOE complex is driven by the unique properties of the materials described in Sections 2.0 and 3.0. Sealing components are a major use of fluoropolymers in radioactive waste processing systems. Metal or ceramic seals may be used for some seals; however, polymers are frequently used due to common design, low cost, compliance, and lower sealing stresses. The most used fluoropolymer sealing component is PTFE; however, ethylene propylene diene monomer (EPDM) is used when the heat and chemical resistance of PTFE is not required, or additional elasticity is required.

Valve seats, which are where valves contact the containing vessel and maintain the seal around the valve, are often made of stiffer polymers based on the needs of the valve. Common polymer components of seat valves include ETFE (a fluoropolymer), ultra-high molecular weight polyethylene (UHMWPE), and polyetheretherketone (PEEK). An important limitation of PTFE is that it is unsuitable for high-level waste processing due to the considerable degradation of PTFE when exposed to those conditions, and ETFE is only suitable for short-term processing. PEEK has shown significantly higher resistance to degradation and may provide an alternative to current technologies.

Elastomers are often used to seal containment vessels in radioactive material packages. For example, O-rings of fluoroelastomer are used to seal the stainless-steel containment vessels in Model 9975 shipping packages designed to transport plutonium-bearing materials. New liquid processing equipment and transfer systems have been developed using chlorinated and fluoropolymer-based plastics, such as chlorinated polyvinyl chloride (CPVC) end plates, commercial-grade plastic piping and valves for internal glovebox transfer systems, and PVDF slab tanks for process storage.

Fluoropolymers are widely used in DOE national laboratories, and an exhaustive list would encompass dozens of specific uses. Examples include:

- PFA fluoropolymer (Teflon) resin vessels used for product consistency tests (PNL-10497, *Product Consistency Testing of Three Reference Glasses in Stainless Steel and Perfluoroalkoxy Resin Vessels*)
- Fluoropolymer distillate receiver vials for Hanford waste tank mercury analyses (PNNL-29555, *Mercury Speciation and Quantification of Hanford 241-AP-107 Tank Waste Feed and Treated Samples*)

- Fluoropolymer bottles for preservation and storage of mercury and methylmercury (MeHg) tank waste samples (PNNL-32726, *Measurement of Total, Elemental, and Methyl Mercury in Hanford Tank Waste*; SRNL-STI-2019-00056, *Total Mercury Analysis Comparison: Deployment of Analytical Method for the Savannah River Site Liquid Waste System*)
- Hanford tank waste corrosion testing of fluoropolymer-lined kettles (PNNL-11064, *Hanford Waste Vitrification Plant Technical Manual*)
- Teflon fluoropolymer vessel used for hydrogen generation rate flow-system measurements (SRNL-STI-2019-00411, *Investigation of Thermolytic Hydrogen Generation Rate in Tank 28 and Tank 39 Samples*)
- PVDF membrane disc filter for measurement of sulfur solubility from glass samples (PNNL-28838, *Enhanced Hanford Low-Activity Waste Glass Property Data Development: Phase 2*)
- PVDF filter for crystalline silicotitanate (CST) equilibrium batch contact testing (SRNL-STI-2020-00128, *Characterization and CST Batch Contact Equilibrium Testing of Modified Tank 9H Process Supernate Samples in Support of TCCR*).

The historical significance of the precursor of DOE is also important to understanding the legacy of fluoropolymer use within the DOE complex. During the Manhattan Project, under the direction of the U.S. Army Corps of Engineers (transferred to the Atomic Energy Commission in 1946, which later became DOE), the first atomic bomb was produced. PFAS (including fluoropolymers) were first produced on an industrial scale for use in uranium separation activities during the Manhattan Project. PTFE was used for valves and gaskets due its resistance to chemical attack from highly reactive uranium hexafluoride (UF_6) at the Oak Ridge K-25 Gaseous Diffusion Plant, which was the largest industrial facility ever constructed at the time.

4.1.5 Potential Competing Technologies and Alternatives for Fluoropolymers in Chemical Processing, Storage, and Disposal

The Fluoropolymer Group of Plastics Europe requested Chemservice to develop a Regulatory Management Option Analysis (RMOA) for fluoropolymers to evaluate possible regulatory management options that could address concerns related to a chemical substance or group of substances (Drohmann et al., 2021). Under an RMOA, the expected impacts of relevant regulatory management options are analyzed against a selection of criteria and factors based on the following guidance (Drohmann et al., 2021, p. 125):

- *Guidance for the preparation of an Annex XV dossier for restrictions* (ECHA, 2007)
- *Guidelines for an Industry Risk Management Option Analysis* (Eurometaux, 2017)
- *Integrated Regulatory Strategy Annual Report* (ECHA, 2019).

In terms of alternatives to fluoropolymers, Drohmann et al. (2021, p. 84) states:

> *The information on alternatives is based on general feedback on alternatives and on specific examples provided by the supply chain of [fluoropolymers] FPs. As a result, it does not necessarily cover all applications and/or all products. The alternatives mentioned as part of the consultation include steel and other metals; high nickel alloys, polypropylene, polyvinyl chloride (PVC), glass, ceramics, mica, polyether sulfone, polyimide, ethylene propylene diene monomer (M-class) rubber (known as EPDM rubber), nitrile [butadiene] rubber (NBR), hydrogenated nitrile [butadiene] rubber (HNBR), acrylic rubber (ACM), ethylene-acrylic rubber (AEM rubber), fluorosilicone (FVMQ), graphite, aramid, slip agents. Each would only be a possible alternative for some of the applications of FPs.*

In sectors such as chemical, power, pharmaceuticals or transport, FPs provide resistance to a wide range of low and high temperatures and universal chemical resistance. This "universal" resistance to chemicals is a crucial characteristic of FPs that is not present in any of the alternatives, according to consultation feedback. There are alternatives that are more or less resistant to specific chemicals, but there is not one that is universally suitable.

A high-level alternatives analysis was performed as part of the RMOA for sectors related to this report (as defined in Section 1.0) and considered the following (Drohmann et al., 2021, p. 84-85):

- Technical implications (e.g., lower performance, increased weight and associated impacts, and reduced durability and reliability)
- Economic implications (e.g., regression of advanced technologies, reduced ability of Europe to compete and attract high and medium technology manufacturing, efficiency losses, higher initial [investment] costs, and higher maintenance costs)
- Environmental/health implications (e.g., potential for higher risk of staff exposure to hazardous substances, higher safety risks, and increases in emissions).

Some of the above criteria (e.g., economic impact on Europe) would only loosely be considered relevant to this report; however, the results begin to depict the types of alternatives that have been considered for fluoropolymers. Table 4-3 provides an overview of the results of the RMOA (Drohmann et al., 2021, Table 40) focused on the chemical industry sector.

Table 4-3. Overview of Chemical Industry Alternatives (2 pages)

Alternative/s	Example potential application	Overview of likely technical economic and environmental implications
Stainless steel, copper	Pipes, liners, tubing	Fluoropolymers are commonly used as liners in stainless-steel pipes and valves. Stainless steel is not corrosion resistant as a replacement for these applications; possible for certain very specific components. However, metals are likely to result in: • Increased weight and size/design of components • Inferior resistance to corrosion and/or abrasion • Inferior non-stick and non-friction properties • Lack of flexibility. Rapid corrosion and abrasion (on metal dynamic applications) would be the consequence. Other implications include costly redesigns, higher maintenance costs, higher design costs, and higher safety and environmental risks.
High-performance nickel alloys	Pipes, desulfurization heat exchangers, and filters	Various grades are available for specific applications, which are often quoted as highly resistant to corrosion. Fluoropolymers are generally more resistant to chemicals and at higher temperatures. Alloys are likely to be more costly, especially nickel-chromium-molybdenum alloys. This "universal" resistance to chemicals is a crucial characteristic of fluoropolymers that is not present in any of the alternatives. There are alternatives that are more or less resistant to specific chemicals but not one that is universally suitable. If there were no fluoropolymers, not only would the alternatives have inferior performance, a specific alternative would have to be developed for each manufacturing process, with potential differences across the industry. Only titanium and tantalum could have similar resistance, but their cost is very high, and they do not have the other required properties. Therefore, they are not considered as alternatives by industry.

Table 4-3. Overview of Chemical Industry Alternatives (2 pages)

Alternative/s	Example potential application	Overview of likely technical economic and environmental implications
Polypropylene and PVC	Commonly used in pipes and liners	Low resistance to chemical attack and temperature hence lower corrosion prevention. Unsuitable for demanding applications, unless coated or reinforced (for instance with fluoropolymers).
Glass and ceramics	Historically used in several applications	Brittle, considerably heavier and more difficult to transport. Lack of chemical resistance to strong bases and hydrofluoric acid.
Polyethersulfone and polyimide	Seals	Their thermal resistance is similar to that of some fluoropolymers. It is understood that chemical resistance may be inferior. They are also rigid, posing design difficulties.
Rubbers and silicones such as NBR, HNBR, ACM, AEM rubber, or FVMQ	Seals, O-rings, and other applications	Suitable for other applications and resistant to specific chemicals. They have generally lower resistance to temperature changes, abrasion, and chemicals compared to fluoropolymers.
Graphite and aramid	Gaskets	Aramid is sensitive to acids (i.e., cannot prevent corrosion) and ultraviolet light. Graphite, while chemically resistant, is brittle.
Zinc stearate, calcium stearate	Polymerization additives	While the stearates can be used as processing additives in polymers, their effect is limited both on melt fracture elimination and pressure reduction. High loadings are required, which in turn impacts other film properties, rendering the alternatives not acceptable in the packaging sector.
Polysulfone (PSF) and polyethersulfone (PES)	Water filtration membranes	These materials can be used in certain applications, but they are less resistant to chemicals resulting in shorter membrane life. They are too stiff to be used as submersible membranes in bioreactors, where they are clearly not an alternative.
Boron nitride and other inorganic solids	Lubricants	Reduced chemical stability (e.g., hydrolysis), downgraded lubricity, expensive.

Source: Extracted from Table 40 of Drohmann et al., 2021, *Regulatory Management Option Analysis for Fluoropolymers*, Plastics Europe, Association of Plastics Manufacturing, Brussels, Belgium.

ACM = acrylic rubber.
AEM = ethylene acrylic elastomer.
FVMQ = fluorosilicone.
HNBR = hydrogenated nitrile butadiene rubber.
NBR = nitrile butadiene rubber.
PES = polyethersulfone.
PSF = polysulfone.
PVC = polyvinyl chloride.

The replies from direct uses of fluoropolymers (Drohmann et al., 2021) indicated that one case out of the 42 analyzed would provide a viable alternative (i.e., evaluated against the criteria of technical feasibility, economic feasibility, availability, and hazards and risks of the alternative [Drohmann et al., 2021, p. 84]) for one minor and very specific use of fluoropolymers in the manufacture of leather products to provide anti-soiling properties, although resulting in certain performance decrease. However, this alternative for leather manufacturing is not part of the sectors of interest for this report. Information from Table 4-3 does suggest that there may be specific or even niche chemical industry applications where alternatives may exist:

- Stainless steel or copper may provide possible alternatives for certain, very specific applications although with inferior properties, redesigns, and higher maintenance and design costs.
- High performance nickel alloys are alternatives for specific applications needing resistance to corrosion; however, at higher costs and inferior corrosion resistance at higher temperatures.
- Polypropylene and polyvinyl chloride (PVC) may present alternatives for less demanding applications.

- Polyethersulfone (PES) and polyimide may provide comparable thermal resistance at the cost of inferior chemical resistance and potential design difficulties.
- Polysulfone (PSF) and PES can be alternatives for water filtration membranes but are less resistant to chemicals, resulting in shorter membrane life and higher maintenance and replacement costs.

In the cases evaluated in the RMOA (Drohmann et al., 2021, p. 85), 16 replies from the direct uses indicated that alternatives are not available "that would meet the technical conditions required for the specific application and which render the specific [fluoropolymers] FPs of interest unique." In addition, three direct users indicated that alternatives had not been tested, and as many as 12 did not provide information on alternatives.

In the Vanderbilt survey results, of the 16 responses, five provided no information related to alternatives. The responses pertaining to fluoropolymer alternatives ranged from "none" to "We have been researching for the last 20 years and have not found alternatives yet." However, the two following responses to the Vanderbilt survey are of interest considering the results from the RMOA (Drohmann et al., 2021):

- No alternative chemicals have been found to replace PTFE powder as additives in critical applications requiring high temperature and chemical stability.
- No alternatives have been found, even with the intense development actions, for polymeric PFPE and PTFE. For PTFE only, some options might be available, but no real alternatives are currently being evaluated. However, these options might fall under other regulations (e.g., microplastics).

These results suggest that alternatives may exist for specific applications in less challenging temperature and corrosion environments but possibly at the cost of lower performance and higher design, maintenance, and replacement costs.

4.2 Microelectronics and Semiconductor Processing and Components

Microelectronics and semiconductor components are found in a variety of products that are used daily, from common consumer goods to complex machinery. Fluoropolymers find extensive use in the fabrication and production of microelectronics and semiconductors. The use of fluoropolymers in this industry is primarily due to two specific requirements: (1) physical and electronic properties of the polymers make them uniquely suited for incorporation into electronic and semiconductor devices, and (2) the high purity and chemical inertness of many fluoropolymer plastics render them useful for handling solutions necessary within semiconductor manufacturing processes (Drohmann et al., 2021; Glüge et al., 2020). As noted below, few if any viable alternatives for fluoropolymers are used in microelectronics and semiconductor processing.

4.2.1 Forms of Fluoropolymers Used in Microelectronics and Semiconductor Processing and Components

As shown in Table 4-1, nearly all fluoropolymers are used to some degree in the fabrication and manufacturing of electronics and semiconductors. Several of the most important applications, and the specific fluoropolymers used in those contexts, are described below.

Electrical Wiring

The primary use of fluoropolymer plastics in the electronics industry is for insulation of wiring and cabling in scenarios where resistance to high temperatures, chemical corrosion, and mechanical stress is paramount (Drohmann et al., 2021). The primary fluoropolymers used as insulation in wire insulation for electronics include PVDF, FEP, ETFE, ECTFE, and PCTFE (Glüge et al., 2020). The following applications are notable:

- **PVDF** – Used in heat-shrinkable cable splice insulation and in wiring within computers and industrial process controls in cases where low-frequency signals are carried (Gardiner, 2014)
- **FEP** – Fire resistance and physical durability make FEP well-suited for insulation of cables routed within a plenum or other electronic device component exposed to vibration, movement, or heat stress (Gardiner, 2014)
- **ECTFE and ETFE** – Used in specialty applications for electronics within the aerospace and automotive industries due to their high flexibility and flame-retardant nature (Gardiner, 2014).

Printed Circuit Boards

Fabrication of printed circuit boards requires layering of typically copper conductor paths on an electrically resistive polymeric layer atop a fiberglass substrate. Many circuit boards use fluoropolymers as the dielectric layer for this application. Specifically, PTFE and an ETFE copolymer with 1,1'-oxybis(ethene) are reportedly used for this application (Glüge et al., 2020).

Piezoelectric Devices

Electronic devices designed for measuring electromagnetic radiation or for producing or detecting sound (e.g., speakers and microphones) make use of piezoelectric materials, which change their electrical properties (i.e., resistance) as a function of mechanical or thermal stress. Films of PVDF and copolymers of PVDF and trifluoroethylene (TrFE) are particularly useful as piezoelectric elements in sensors and transducers (Drohmann et al., 2021; Glüge et al., 2020).

Semiconductor Photoresist

Production of semiconductors on silicon wafers using photolithography require the application of a photoresist or light-sensitive polymer. Functionally, exposure to light via the application of a mask renders the photoresist layer either more (positive photoresist) or less (negative photoresist) soluble in the developer solution that is subsequently applied in the process. Two novel fluoropolymer photoresists are known to be used in semiconductor fabrication – both of these are copolymers with TFE (Glüge et al., 2020):

- 2-Propenoic acid, 1,1-dimethylethyl ester, polymer with 4,5-difluoro-2,2-bis(trifluoromethyl)-1,3-dioxole and tetrafluoro ethene: $-(C_7H_{12}O_2)_x-(C_5F_8O_2)_y-(C_2F_4)_m-$, CAS #851389-08-7
- Propanoic acid, 3-[1-[difluoro[(1,2,2-trifluoro ethenyl)oxy]methyl]-1,2,2,2-tetrafluoroethoxy]-2,2,3,3-tetrafluoro-, methyl ester, polymer with 4,5-difluoro-2,2-bis(trifluoromethyl)-1,3-dioxole and 1,1,2,2-tetrafluoroethene: $-(C_9H_3F_{13}O_4)_x-(C_5F_8O_2)_y-(C_2F_4)_m-$, CAS #86179-28-4.

Semiconductor Antireflective Coatings

Artifacts of internal and external reflection of light during the photolithography process in semiconductor manufacturing can be reduced by the inclusion of antireflective coatings either as a topcoat above a reflective substrate or as an undercoat below the photoresist. These coatings are typically polymers with very low refractive indices and good liquid barrier properties (Ober et al., 2022).

Several fluoropolymers are used for these applications. Unlike many other fluoropolymer uses described for electronics and semiconductors, these are functional ionomers with either carboxylic acid or sulfonic acid functional groups (Glüge et al., 2020; Ober et al., 2022):

- **Topcoat**: 2-Propenoic acid, polymer with 2-ethenylnaphthalene and 4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,11-heptadecafluoro-2-hydroxyundecyl 2-propenoate: -($C_{14}H_9F_{17}O_3$)$_x$-($C_{12}H_{10}$)$_y$-($C_3H_4O_2$)$_m$-, CAS #934505-67-6
- **Undercoat**: 2-Propenoic acid, 4,4,5,5,6,6,7,7,7-nonafluoro-2-hydroxyheptyl ester, polymer with 2-propene-1-sulfonic acid: -($C_{10}H_9F_9O_3$)$_x$-($C_3H_6O_3S$)$_y$-, CAS #910114-99-7
- **Undercoat**: 2-Propenoic acid, 4,4,5,5,6,6,7,7,7-nonafluoro-2-hydroxyheptyl ester, polymer with 2-methyl-2-[(1-oxo-2-propen-1-yl)amino]-1-propane sulfonic acid: -($C_{10}H_9F_9O_3$)$_x$-($C_7H_{13}NO_4S$)$_y$-, CAS #910114-98-6
- **Undercoat**: 2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl ester, polymer with 2-methyl-2-[(1-oxo-2-propen-1-yl)amino]-1-propane sulfonic acid and 2,2,2-trifluoroethyl 2-propenoate: -($C_{10}H_9F_9O_3$)$_x$-($C_7H_{13}NO_4S$)$_y$-($C_5H_5F_3O_2$)$_m$-, CAS #172083-53-3.

Semiconductor Manufacturing Process Equipment

The photolithographic process for semiconductor manufacturing requires extremely high purity of all chemical reagents used in the process, along with the use of highly aggressive and corrosive chemicals, including organic solvents and strong acids (Drohmann et al., 2021; Korzeniowski et al., 2023; Glüge et al., 2020). Few materials are available that can withstand these aggressive conditions without releasing leachable or extractable constituents into the process solutions, thereby introducing contaminants. Because of this, fluoropolymers find essential use in semiconductor manufacturing equipment and facilities.

- **PTFE**, **PVDF**, **PFA**, **FEP**, and **ETFE** are used as molds, reaction vessels, and piping within semiconductor manufacturing facilities to handle aggressive process fluids (Glüge et al., 2020, Drohmann et al., 2021).
- **ECTFE** and **PCTFE** are used as liners for high-purity water systems within the semiconductor manufacturing process to avoid contamination from corrosion of water piping by ultrapure water (Korzeniowski et al., 2023).
- A unique terpolymer of chlorotrifluoroethylene, perfluoroalkoxy-vinyl-ether, and tetrafluoroethylene, known as **CPT**, is of particular use in fabricating multi-layer tubes with **PFA** – used to increase the liquid barrier performance of tubing for transporting strong acids – relative to use of PFA alone (Korzeniowski et al., 2023).
- Fluoroelastomers such as **FKM** and **FFKM** are used for valve seats and O-rings within liquid handling systems delivering high-purity or corrosive chemicals in semiconductor manufacturing processes (Korzeniowski et al., 2023).

4.2.2 Potential Competing Technologies and Alternatives for Fluoropolymers in Electronics

Because of the very stringent chemical, physical, and in some cases electrical requirements of materials used to fabricate microelectronics and semiconductors, very few viable replacement materials can be identified for fluoropolymers within such applications. Table 4-4 provides an overview of the results of the RMOA (Drohmann et al., 2021, Table 40) focused on the electronics sector, describing some possible alternatives in specific applications and the trade-offs inherent in such alternatives.

Table 4-4. Overview of Electronics Alternatives

Alternative/s	Example potential application	Overview of likely technical economic and environmental implications
Polyolefin with flame retardant	Cable insulation	These materials do not offer the same resistance to temperature range as fluoropolymers (maximum limits differ but the minimum working temperature of polyolefins is higher than that of fluoropolymers, reducing their performance in cases where coolants are used to decrease the temperature of data processing systems). Polyolefins also have inferior fire resistance, often requiring a flame retardant. Flame retardants commonly increase dielectric constant and dielectric loss, which reduce data communication rates. The use of polyolefins would likely result in weaker data processing and slower signal return, reflecting inferior purity, friction properties, and stability compared to fluoropolymers. If an alternative is found at some point, the industry states at least 10 years may be required to replace equipment and adapt manufacturing methods and processes.
Non-conductive plastics	Historically used in semiconductor manufacture	Unviable. The modern semiconductor industry has stringent requirements, and fluoropolymers are the only material that can currently protect the processing equipment in which semiconductors are etched and cleaned from the chemicals used in the manufacturing process while at the same time offering the highest purity. Microprocessors and chips need to be increasingly small, yet powerful, preventing metallic contamination and corrosion to maximize chip yields.

Source: Extracted from Table 40 of Drohmann et al., 2021, *Regulatory Management Option Analysis for Fluoropolymers*, Plastics Europe, Association of Plastics Manufacturing, Brussels, Belgium.

4.3 Building Construction and Infrastructure

The resistance of fluoropolymer compounds to environmental degradation makes these compounds desirable in construction applications as weatherproofing materials, insulation materials for wire and cables, and liners for corrosion-resistant pipes, and in many other applications. While fluoropolymer compounds are generally more expensive than alternative materials, the extended lifetime and superior performance of these compounds make them desirable for applications in construction and infrastructure.

4.3.1 Forms of Fluoropolymers for Use in Construction and Infrastructure

Fluoropolymers are used in a wide variety of applications across construction and infrastructure. This section describes critical uses of fluoropolymers across these industries.

Fluoropolymer materials are used extensively for enhanced durability and extended lifetime of materials. Due to the strength of the carbon-fluoride bond of the fluoropolymers, these materials are resistant to UV degradation, have exceptional weatherability and durability, and in many applications, are expected to have functional lifetimes exceeding 50 years (Darden and Takayanagi, 2007).

Weatherproofing

Environmental exposure of structures leads to rapid corrosion, degradation, and deterioration (Sirojiddin and Yulchiyeva, 2023). This destructive impact can lead to financial losses, decreased lifespan of structures, and compromising safety. Fluoropolymer coatings provide a lightweight barrier to prevent degradation of structural materials. Specific examples of fluoropolymers used as weatherproofing materials include:

- **Fluoroethylene-vinyl ether (FEVE)** – FEVE fluoropolymer resins are used to manufacture bridge, architectural, and other industrial weatherproof coatings (Korzeniowski et al., 2023).

- **PVDF** – PVDF dispersions and coatings are applied to architectural structures to provide weather resistance (Dallaev et al., 2022). The long lifetime of PVDF coatings (50+ years) is also desirable for building facades to maintain color and gloss, and its chemical resistance makes PVDF suitable as an anti-graffiti coating for building exteriors (Korzeniowski et al., 2023).
- **ETFE** – ETFE has high corrosion resistance, high tensile strength, high impact strength, and is resistant to degradation through exposure to UV radiation. ETFE is used as a transparent structural material – owing to its resistance to discolor when exposed to UV radiation (Lamnatou et al., 2018).

Pipes and Insulation

Fluoropolymers are crucial components in cable insulation and piping applications. In cable insulation, fluoropolymers provide electrical insulation, have high dielectric strength, and are resistant to chemicals. In pipes, these materials offer exceptional chemical resistance, temperature stability, and non-stick properties, making them ideal for transporting corrosive chemicals and maintaining high purity in industrial processes.

- **PVDF** – The weather and temperature (up to 120 °C) resistance of PVDF, coupled with its chemical inertness and high flexibility, make it useful as a pipe liner for a wide range of applications, including ultrapure water pipelines, nuclear power, chemical production and synthesis, and boiler service pipes (Dallaev et al., 2022). The low mass and high coefficient of resistance to heat transfer of PVDF also make it useful for insulation of electrical wires.
- **ECTFE** – A copolymer of ethylene and chlorotrifluoroethylene, ECTFE is a thermoplastic fluoropolymer often used for manufacturing corrosion-resistant pipes (Dallaev et al., 2022).
- **FEPM** – Used in a range of applications, including wire and cable applications as insulating materials, FEPM exhibits heat resistance, chemical resistance, and high electrical resistivity (Dallaev et al., 2022).

Sealants and Adhesives

Fluoropolymers offer superior chemical resistance, ensuring the longevity and reliability of seals and bonds in various industries.

- **PTFE** – The resistance of PTFE to wear, extreme temperatures, and chemical resistance make it desirable as sealant materials (Sui et al., 1999).
- **FFKM** – Perfluoroelastomers have high chemical and temperature resistance and are impermeable to gas and liquid permeation. FFKM is widely used as sealing materials in oilfield applications (Korzeniowski et al., 2023).

Other Specific Applications

- **Anti-vandal coatings** – PVDF is used as an anti-graffiti coating, offering protection by forming a durable and chemically resistant barrier. The chemical and UV resistance of PVDF make it effective for preserving the aesthetics of public buildings, transportation vehicles, and signs (Silagy et al., 2000).
- **Wastewater systems** – Fluoropolymers are used for lining pipes, tanks, and treatment facility structures to prevent corrosion due to wastewater and industrial chemicals. PTFE gaskets, seals, and pump components ensure watertight and chemical-resistant connections. Tanks and vessels lined with PTFE, PVDF, or ETFE are used for storage and treatment of corrosive wastewater (Korzeniowski et al., 2023).

- **Drinking water and water treatment** – The corrosion resistance and temperature stability of fluoropolymers make them useful in drinking water infrastructure applications. PTFE and PFA gaskets, coatings, and fittings prevent corrosion of infrastructure and contamination of drinking water. The long lifetime of fluoropolymers minimizes the need for maintenance and upkeep of drinking water infrastructure. The low friction properties of fluoropolymers make them useful in pumps, minimizing wear and tear and extending the lifetime of the pump equipment. Fluoropolymer membranes and filters are also used for treatment of water; PTFE, for example, has been used for oil/water separation due to its low surface free energy, chemical resistance, and its intrinsic hydrophobicity (Bongiovanni et al., 2020).
- **Electrical grid** – Fluoropolymers are used for insulation for wires, cables, and high-voltage components. PTFE, ETFE, PVDF, and ECTFE are often used to insulate wires and cables due to their insulation properties and high-temperature resistance.

4.3.2 Fluoropolymer Replacement Materials for Use in Construction and Infrastructure

Table 4-5 provides an overview of the results of the RMOA (Drohmann et al., 2021, Table 40) and other sources (as noted) focused on the architecture sector.

Table 4-5. Overview of Architecture Alternatives (2 pages)

Alternative/s	Example potential application	Overview of likely technical economic and environmental implications
Steel or glass	Insulation materials, pipes, and tubes	Steel and glass alternatives are heavier and more inflexible than fluoropolymers. Steel is not resistant to corrosion, leading to higher maintenance costs. Glass is more fragile to hail or other impact. These alternatives are not able to meet the design requirements of fluoropolymers.[a]
Polycarbonate sheets	Weatherproofing, architectural material	Polycarbonates are resistant to temperature and can withstand force; they tend to yellow in external applications in contrast to fluoropolymers. PVC/PES membranes for architectural applications are common; however, the membranes are often coated with a protective layer (often made of PVDF, a fluoropolymer) providing UV-resistance and weatherability. Without this coating, they offer lower performance due to not being resistant to denting or certain chemicals.[a]
Mica	Insulation material, cables	Rigid and brittle, mica has lower chemical resistance than fluoropolymers. Performance could be improved with additional insulation (additional weight, similar brittleness).[a]
EPDM rubber reinforced with lead	Underground cables and submersible pumps	This alternative has higher weight and lower chemical and temperature resistance compared to fluoropolymers. Due to inaccessibility of these cables/ pumps, durability is essential, implying increased downtime and higher maintenance costs.[a]
Slip agents	Cable applications	These additives are designed to reduce friction and provide appropriate lubrication during polymer processing (e.g., adhering a film to a metallic surface). While these slip agents perform well for the elimination of melt fractures, die build-up and higher energy consumption may be problematic in some applications.[a]
Silicone	Weatherproof coatings, seals	Silicone-based coatings offer good adhesion, durability, and water repellence. Silicone maintains its flexibility and elasticity over a wide range of temperatures (-60 °F to 230 °F) and is highly resistant to many chemicals; therefore, it is a suitable material for use in sealants in pipelines and wastewater systems.[b] While silicone is a useful replacement, fluoropolymers exhibit superior resistance, durability, and performance; therefore, fluoropolymers are generally a preferred material in many applications.

Table 4-5. Overview of Architecture Alternatives (2 pages)

Alternative/s	Example potential application	Overview of likely technical economic and environmental implications
Polyurethane	Weatherproofing, coating, seals	Polyurethane can be used as an alternative for waterproofing or for sealants and gaskets; however, compared to fluoropolymers, it offers poor chemical, temperature, and UV resistance.[c]

[a] Extracted from Table 40 of Drohmann et al., 2021, *Regulatory Management Option Analysis for Fluoropolymers*, Plastics Europe, Association of Plastics Manufacturing, Brussels, Belgium.

[b] Aibada et al., 2017, "Review on Various Gaskets Based on the Materials, their Characteristics and Applications," *International Journal on Textile Engineering and Processes*, 3(1), pp 12–18.

[c] Somarathna et al., 2018, "The use of polyurethane for structural and infrastructural engineering applications: A state-of-the-art review," *Construction and Building Materials*, 190, pp 995–1014.

EPDM = ethylene propylene diene monomer.
PES = polyethersulfone.
PVC = polyvinyl chloride.
PVDF = polyvinylidene fluoride.
UV = ultraviolet.

4.4 Automobiles and Aerospace

Fluoropolymers play a vital role in the automotive and aerospace industries, possessing several essential characteristics such as high heat and chemical resistance, low permeability, a low coefficient of friction, and excellent mechanical properties. These attributes are instrumental in ensuring safety, enhancing fuel efficiency, and reducing carbon emissions within these sectors. Consequently, the pursuit of alternative or competing technologies necessitates a delicate balance. Safety features and technological performance must be maintained, while considering potential toxicity concerns associated with fluoropolymer manufacturing and end-of-life disposal. The challenge lies in the complexity of achieving real substitutions on a large scale. The deep-rooted reliance on fluoropolymers in the traditional automotive and aviation industries has somewhat hindered their exploration of novel materials and technologies. Additionally, finding equivalent products to replace fluoropolymers in each specific field proves to be a formidable task. Section 4.4.4 provides a summary of alternative materials and competing technologies for fluoropolymer applications in various automotive and aerospace contexts. Note that based on available information, none of these alternatives have been implemented on a large scale.

4.4.1 Forms of Fluoropolymers Used in Automotive and Aerospace

Fluoropolymers come in both plastic and elastomeric forms in diverse formats, including powders, granules, pellets, aqueous dispersions, and lattices (Drobny, 2007). In the transportation sector, PTFE and fluoroelastomer are the two major types of resins, constituting 27.9% and 43.8% of the fluoropolymer volume in 2020, respectively (PLS080B). PTFE comes in three primary forms: granular, fine powder or coagulated dispersion PTFE, and aqueous dispersion PTFE (Ramboll, 2023; Drobny, 2007).

In the transportation sector, PTFE granules are used in seals, gaskets, valves, protective linings, expansion joints, pipes, and fittings due to their exceptional resistance to extreme temperatures and chemicals. PTFE powder is used for various purposes in transportation, including coating for fuselages and wings, gaskets, O-rings, shaft seals, drive belts, window/door seals, window wipers, pump heads, gears, valves, bushings, bearings, slides, and other wear components.

PTFE aqueous dispersions can also be formulated into a range of coatings that are easily applicable to different components, such as weld nuts/pierce nuts, air conditioning pistons, intake valves, and more (Drobny, 2007). PTFE micropowders, available in dry form or as aqueous dispersions, serve as additives to oils and greases, enhancing their lubricating properties.

4.4.2 Critical Properties of Fluoropolymers Used in Transportation

Fluoropolymers offer a set of critical properties for their role in transportation applications:

- **Chemical and thermal resistance** – Fluoropolymers are resistant to a wide variety of lubricants and fuels at elevated temperatures over the vehicle's lifetime, therefore guaranteeing the highest possible safety (PLS080B).
- **Low permeation rate** – Fluoropolymers serve as highly effective barrier materials against evaporative emissions. This capability contributes significantly to improved fuel efficiency and reduced greenhouse gas emissions.
- **Low surface energy** – Fluoropolymers used in coatings possess a unique resistance to the adhesion of foreign substances. This property effectively reduces friction and prevents the buildup of contaminants.
- **Low coefficient of friction** – Fluoropolymers enhance lubrication and facilitate low friction between surfaces. This property is pivotal for minimizing wear and enhancing efficiency.
- **Extreme condition resistance** – Fluoropolymers are used for insulation of electrical and data transmission cables in the aerospace industry due to their predictable operational life, ability to operate from cryogenic temperature (extremely low temperature) to 226 °C, and relative resistance to oxygen and humidity. Additionally, solid lubricants like PTFE are frequently used in aerospace applications under extreme conditions, including both high and low temperatures, and in vacuum environments (McCook et al., 2005).
- **Dielectric property** – Fluoropolymers are useful in preventing electrical fires in cables due to their dielectric properties.

4.4.3 Fluoropolymer Applications Used in Automotive and Aerospace

Due to the various applications in the automotive industry, fluoropolymer applications are categorized into three sectors: conventional vehicles, emerging energy (low-emission and zero-emission) vehicles, and agricultural machinery.

Applications of Fluoropolymers in the Automotive Industry

Conventional Vehicles **(Drohmann et al., 2021; Henry et al., 2018; PLS080B; Wang et al., 2013)**

- **Engine components**
  - Fluoropolymers are known for their thermal and chemical resistance, which has led to their application in parts like fuel lines, hoses, and turbocharger hoses made from PTFE, FEP, and PFA. These hoses are integral for fuel transport, and their multi-layered structure infused with fluoroelastomers ensures durability. Innovations involve the integration of PTFE liners with fiberglass braids to withstand high temperatures.
  - Seals, rings, and packings, typically made from fluoropolymers like FKM, FEPM, and FFKM, serve vital functions – from protecting engine parts from contaminants to ensuring valve lubrication and durability.
  - Cylinder head gaskets and air intake manifold gaskets, both comprising fluoroelastomers, are used to seal cylinders and direct air to engines respectively, emphasizing their importance in ensuring engine efficiency.

- **Electrical, electronics, and sensors**
  - Fluoropolymers, particularly in lambda, NO_x, or oxygen sensors, are instrumental in reducing greenhouse gas emissions. Their unique properties make them ideal for sensor cables exposed to high temperatures.
  - PTFE is used in switches, ensuring structural integrity while offering waterproof and dustproof protection. The role of PTFE in millimeter wave radar antennas emphasizes its importance in high-frequency transmission systems.
  - Display device coatings benefit from the use of fluoropolymers to offer resistance to surface contamination and environmental factors.
- **Materials and adhesives** – PTFE adhesive tapes are applied to multiple vehicle components, owing to their superior resistance properties. Processes like nickel-phosphorus plating also incorporate PTFE to enhance material hardness, while treatments like the Geomet method employ a PTFE-containing film for adjusted friction.
- **Brake system** – In hydraulic systems, PTFE is fundamental in ensuring leak-free and durable hoses. Its role extends to anti-lock braking system brake lines, optimizing brake efficiency.
- **Venting products** – Crucial for lighting, electronic systems, and other components, vents employ fluoropolymers to offer protection against contaminants and to maintain optimal functioning amidst temperature and pressure fluctuations.
- **Vehicle parts and lubrication** – Door hinges, seat adjusters, and various car parts rely on PTFE and ETFE for reliability and minimized friction. Greases and lubricants use fluoropolymers like PTFE and PFPE as base oils due to their superior resistance and lubricity properties.

Low-Emission and Zero-Emission Vehicles

Fluoropolymers are used in low-emission and zero-emission energy vehicles. PVDF is used in lithium-ion battery binder, providing mechanical strength, flexibility, and thermal stability features over its operational life (Zhong et al., 2021). In fuel cells, fluoropolymer membranes are used to enable the movement of protons from the anode to the cathode side of the fuel cell and facilitate the electrochemical reactions that produce electricity (Sales et al., 2023; Améduri, 2018).

Agricultural Machinery

In agricultural equipment, fluoropolymers serve as protective coatings and linings, effectively preventing material buildup and clogging in critical components like hoppers and chutes. These durable coatings play a similar role in the automotive industry, where they are used for seals, gaskets, electrical insulation, high-temperature components, and bearing and bushing applications, enhancing the performance and longevity of these vital automotive parts.

Applications of Fluoropolymers in Aerospace Industry

Wires and cables insulated with fluoropolymers are used in data transmission in aircraft and spacecraft. Fluoropolymers like PTFE, ETFE, and PVDF are also used in in-flight connectivity. These materials enable multiple protocols to run through a single antenna, reducing the need for multiple antennas. In addition, fluoropolymers are important in aircraft interiors because of their broad temperature and UV resistance, flexibility, durability, chemical resistance to solvents and hydraulic fluids, and low smoke generation and flame resistance (Drohmann et al., 2021).

4.4.4 Competing Technologies

Table 4-6 provides a list of potential substitutes for fluoropolymers; however, each of these alternatives may only be suitable in specific applications where fluoropolymers are traditionally employed. No one-size-fits-all replacement exists that universally covers all fluoropolymer applications. Note that these replacements also often come with limitations, as fluoropolymers offer a range of critical properties essential for the automotive and aerospace industries.

Table 4-6. Overview of Automotive and Aerospace Alternatives (3 pages)

Alternative	Example potential applications	Overview of likely technical, economic, and environmental implications
Automotives		
General mineral oils or non-fluoropolymer-based thickener	Grease and lubricant	• Mineral oils – lower heat and low-temperature resistance compared to fluorinated oils and may not coexist well with rubber and resins • Thickeners (e.g., calcium, lithium, aluminum, and barium soaps) and non-soap materials (e.g., bentonite and urea) – inadequate heat resistance, water resistance, and shear stability[a]
Mica-insulation sensor cables	Sensor cables for oxygen and nitrogen sensors	Not able to resist extreme conditions; less accurate measurement[b]
PA or EVOH	Hoses, cables, tubes, and wire solutions	Increased elastic modulus by a factor of 2 with EVOH and fuel permeability by a factor of 140 with PA[a]
PEEK	Fuel hoses, lines, gaskets, seals, cables, cable liners, wire insulation (both in automotive and aerospace)	• Similar temperature resistance (260 °C), lower chemical resistance, rigid, and inferior electrical and data transmission properties • Cost concerns when compared to fluoropolymers such as ETFE and PTFE or a fluoroelastomer (FKM)[b,c]
Polysilazanes, Xirallic,[d] epoxy-based e-coats, aliphatic diisocyanate-based polyurethane coating	Coating	Comparable performance, including being "marketed as providing excellent weather resistance and can resist yellowing or paint degradation due to sunlight, gloss retention, resistance to water, oil and chemicals such as salt which adds to vehicle corrosion and scratch resistance"[a]
PU and PAN	Internal pressure regulator	• Limited water resistance compared to fluoropolymer materials due to high surface tension • Potential water-related issues in specific applications[a]
Silicone rubbers	Gaskets, cables, and hoses	• Offer a range of properties suitable for other applications (e.g., used in various applications in modern vehicles such as paint additives, air bag coatings, and radiator seals) • While offering a range of properties suitable for these applications, silicone materials do not have the specific combination of properties required in fluoropolymer applications[b]
Silicone, EPR, or EPDM rubber	Greenhouse gas emission control; lambda sensor cables	Reduced extreme heat resistivity and mechanical conditions[c]

Table 4-6. Overview of Automotive and Aerospace Alternatives (3 pages)

Alternative	Example potential applications	Overview of likely technical, economic, and environmental implications
Stainless steel, aluminum, or copper	Fuel lines in antique cars that do not need to meet modern standards; protection for plastic fuel lines	• Used in metal fuel lines for antique cars that do not have to meet modern standards (these fuel lines are prone to leakage during crash tests) • Difficult for other polymeric alternatives to meet fuel permeation standards, thus have limited application scope[b]
Steel, high-temperature polymers, or UHMWPE	Door hinges and seat height adjustment bearing	Alternative materials pose challenges, including frequent regreasing, assembly issues, rigidity, and low temperature resistance[c]
Various elastomeric materials, including NBR, ACM, AEM, HNBR, UHMWPE, POM, PU, PEEK, and EPDM	Seals, rings, and packing	• Limitations in friction, heat resistance, temperature ranges, or chemical resistance for alternatives • Lower performance compared to fluoroelastomer-based systems (FKM, FEPM, FFKM)[a,c]
XLPE or TPE	Cold air intake systems; control elements in car interiors	Limited chemical resistance when compared to fluoropolymers[b]
Low-Emission and Zero-Emission Vehicles		
Aluminized Mylar;[e] low-density PE; rubber or rubber composites; non-woven materials, elastic fibers such as spandex, nylon, Lycra,[f] or elastane	Facing layer for battery management system	Comparable performance to fluoropolymers, including durability, ease of handling, favorable insulation properties and reaction to fire, combustion, and flame-resistance properties[g]
Binder-free lithium-ion batteries	Facing layer material in components and systems to manage thermal runaway issues in electric vehicle batteries	Comparable performance in producing lithium-ion cells, including cost, energy density, safety, and reliability compared to cells manufactured using fluoropolymers as binders[h]
EVOH	Hose barrier layer for ethanol and methanol-containing fuels	Comparable performance to fluoroelastomers and/or fluoropolymer plastics such as FKM[i]
White latex containing PVAC, CMC, PVA, polyacrylic acid and polyacrylate modifier	Electrodes for lithium-ion batteries	• Used as an alternative aqueous binder (for PVDF) in fabricating lithium-ion anodes • Comparable or better performance for this application when considering cost, environment, decomposition, initial coulombic efficiency, and stability[j]
Aerospace		
PVC and PE combined with HFFR; ceramics	Electric cables	• Polymeric materials lack necessary temperature range performance • Ceramics offer partial chemical protection but are inflexible and heavier[c]

[a] ECHA, 2023, "Submitted restrictions under consideration," European Chemicals Agency, Helsinki, Finland.
[b] Drohmann et al., 2021, *Regulatory Management Option Analysis for Fluoropolymers*, Plastics Europe, Association of Plastics Manufacturing, Brussels, Belgium.
[c] Chemservice, 2022, "Analysis of Alternatives to Fluoropolymers and Potential Impacts Related to Substitution in Different Sectors of Use," Version 1, Chemservice, Chicago, Illinois.
[d] Xirallic is a registered trademark of Merck KGaA, Darmstadt, Germany.
[e] Mylar is a registered trademark of the DuPont Teijin Corporation, Chester, Virginia.
[f] Lycra is a registered trademark of The LYCRA Company, Wilmington, Delaware.
[g] Evans et al., 2020, "Components and systems to manage thermal runaway issues in electric vehicle batteries," U.S. Patent US20210167438A1, Aspen Aerogels Inc., Northborough, Massachusetts.
[h] 24M, 2023, "A Better Way to Work With Lithium-Ion: Simpler, Safer, More Reliable Cell Manufacturing," 24M Technologies, Inc., Cambridge, Massachusetts.

Table 4-6. Overview of Automotive and Aerospace Alternatives (3 pages)

Alternative	Example potential applications	Overview of likely technical, economic, and environmental implications

[i] Miller et al., 2009, "Low-Permeation Flexible Fuel Hose," U.S. Patent US20090123683A1, Gates Corporation, Denver, Colorado.

[j] Lahiru Sandaruwan et al., 2022, "White Latex: Appealing "Green" Alternative for PVdF in Electrode Manufacturing for Sustainable Li-Ion Batteries," *Langmuir*, 38(29), pp 8934-8942.

ACM = acrylic rubber.
AEM = ethylene acrylic elastomer.
CMC = carboxymethyl cellulose.
ECHA = European Chemicals Agency.
EPDM = ethylene propylene diene monomer.
EPR = ethylene propylene rubber.
ETFE = ethylene tetrafluoroethylene.
EVOH = ethylene vinyl alcohol resin.
FEPM = trifluoroethylene-propylene copolymer.
FFKM = TFE-PMVE perfluoroelastomer.
FKM = fluorine Kautschuk material.
HFFR = halogen-free flame retardant.
HNBR = hydrogenated nitrile butadiene rubber.
NBR = nitrile butadiene rubber.
PA = polyamide.
PAN = polyacrylonitrile.
PE = polyethylene.
PEEK = polyetheretherketone.
POM = polyoxymethylene.
PTFE = polytetrafluoroethylene.
PU = polyurethane.
PVA = polyvinyl alcohol.
PVAC = polyvinyl acetate.
PVC = polyvinyl chloride.
PVDF = polyvinylidene fluoride.
TPE = thermoplastic elastomer.
UHMWPE = ultra-high molecular weight polyethylene.
XLPE = cross-linked polyethylene.

4.5 Lithium-Ion Batteries, Wind Turbines, and Solar Panels

Fluoropolymers have multiple uses in the clean energy sector, which includes lithium-ion batteries, wind turbines, and solar panels. These uses include ECTFE (wind turbines, solar panels); ETFE (solar); FEP (wind turbines); PTFE (lithium-ion batteries, wind turbines); PVF (solar); and PVDF and PVDF copolymers (lithium-ion batteries, wind turbines, solar panels).

4.5.1 Lithium-Ion Batteries: Fluoropolymer Uses and Properties

Lithium-ion battery components include electrodes, membrane separators, and electrolytes. In some cases, the separator and electrolyte are combined into an integrated, solid-state polymer electrolyte. Collectively, PTFE, PVDF, PVDF-HFP, PVDF-CTFE, and PVDF-TrFE are used in lithium-ion battery electrode binders, membrane separators, gel polymer electrolytes, and the battery pack. These components are described in more detail below.

Electrodes – Battery electrodes include a metal current collector (e.g., aluminum for cathode, copper for anode), and a porous composite that includes an active material in which lithium ions can be intercalated. The electrodes also use binders for cohesion of particles of the active material and to help the composite adhere to the current collector (Lingappan et al., 2021; Bicy et al., 2022). To be effective, binders need to have high mechanical strength, thermal resistance, chemical and electrochemical stability, and excellent binding to the active material (Arcella et al., 2014; Lingappan et al., 2021).

For these reasons, early lithium-ion batteries (e.g., 1980s) used PTFE as a binder in both cathodes and anodes. However, electrode manufacturing involves deposition of binder materials onto the current collector, as a slurry and homogeneous distribution of the binder is essential. This even distribution was difficult to achieve with PTFE (Lingappan et al., 2021). In the 1990s, PVDF battery binders were developed that offered the same advantageous properties as PTFE *and* could be evenly distributed in the slurry during electrode fabrication (Lingappan et al., 2021), although studies continue to investigate use of PTFE. Some studies also report use of a PVDF copolymer known as PVDF-HFP as a binder material; this binder material is reported to have greater mechanical strength relative to PVDF (Wang et al., 2018). Arkema products Kynar and Kynar-FLEX are examples of PVDF and PVDF-HFP, respectively, that are currently on the market (Stephan et al., 2006; Amin-Sanayei and He, 2015).

Separators – The separator is a membrane between the cathode and anode that prevents electrical shorting, while still allowing transfer of lithium ions between electrodes (Costa et al., 2013; Arcella et al., 2014). The separator is critical for lithium-ion batteries since short-circuiting of the separator inside the battery can lead to combustion of flammable lithium-ion battery electrolytes (Costa et al., 2013). To prevent electrical shorting and maximize the operation of the lithium-ion batteries, separators should be electrochemically stable, thermally stable, wettable, chemically stable in the battery electrolyte, and have high ionic conductivity and mechanical strength (Costa et al., 2013; Arcella et al., 2014). PVDF and copolymers PVDF-HFP, PVDF-CTFE, and PVDF-TrFE have all been reported for use in lithium-ion batteries (Costa et al., 2013).

Gel polymer electrolytes – Safety problems associated with lithium-ion batteries can be addressed through use of solid-state electrolytes that integrate the separator and electrolyte. In essence, polymers are used to gel the electrolytes yielding a solid-state "gel polymer electrolyte" that provides ionic conductivity, electrochemical stability, and thermal stability, while preventing the liquid electrolyte from leaking and decreasing safety concerns (Zhang et al., 2014). Notably, incorporation of the electrolyte or ionic liquid into the polymer provides the needed ionic conductivity, and in some cases, these ionic liquids are low molecular weight PFAS. Gel polymer electrolytes are prepared via multiple techniques, including polymerization in the presence of the ionic liquid and by soaking a polymer (post-polymerization) in ionic liquid. Different methods may lead to different gel polymer electrolyte morphologies. The latter is a key consideration for gel polymer electrolytes since they are solid-state systems that need to have porosity that will facilitate transport of ions through the matrix without leading to leakage of ionic liquids, which may short-circuit the lithium-ion battery (Stepniak et al., 2014). PVDF and PVDF-HFP are both reported for use in gel polymer electrolytes (Zhang et al., 2014; Liang et al., 2018; Liu et al., 2021).

4.5.2 Lithium-Ion Batteries: Non-fluorinated Alternatives

Electrodes – Alternative, non-fluorinated materials are currently on the market for use as electrode binders. Polymeric electrode binders are broadly subdivided into aqueous and nonaqueous binders, which is indicative of the solvents used during binder manufacturing. As noted above, slurry processing of binders is used during construction of electrodes, so aqueous binders use water as the solvent during processing, whereas nonaqueous binders use solvents such as n-methyl-2-pyrrolidone (NMP). Fluoropolymers are typically processed using NMP or other organic solvents, so they are considered nonaqueous binders (Lingappan et al., 2021). Examples of non-fluorinated, aqueous binders include carboxymethyl cellulose (CMC), PVC, polyacrylic acid (PAA), chitosan, and alignates (Lingappan et al., 2021). Binders such as CMC and PAA often also incorporate styrene butadiene rubber (SBR) to improve structural integrity and adhesion to the collector (Lingappan et al., 2021). For example, BASF markets a series of Licity[45] electrode binders that are reported as aqueous SBR co-polymers (BASF, 2023).

Separators – Similar to electrode binders, non-fluorinated polymers reported for use as lithium-ion battery separators include polyethylene, polypropylene, PEO, polyacrylonitrile (PAN), and polymethyl methacrylate (PMMA) (Costa et al., 2013; Costa et al., 2019). Separators also incorporate non-fluorinated fillers that increase the strength and conductivity of the membrane. Examples of fillers include ceramics (Al_2O_3, SiO_2, TiO_2), zeolites, carbon-based materials, and ferroelectric materials ($BaTiO_3$) (Costa et al., 2013). The above-mentioned polymers are well-referenced in the literature for use as separators, as evidenced by their inclusion in multiple review studies. Several additional materials are also being explored for use as separators as they reportedly offer more thermal stability and/or are more environmentally friendly (Costa et al., 2019). These materials include polyimide, poly m-phenylene isophthalamide (PMIA), PEEK, polybenzimidazole (PBI), polyetherimide (PEI), polystyrene-b-butadiene-b-styrene (SBS), cellulose, chitin, silk fibroin, and polyvinyl alcohol (PVA) (Costa et al., 2019).

[45] Licity is a registered trademark of BASF, Ludwigshafen, Germany.

Gel polymer electrolytes – Non-fluorinated polymers are documented for use as gel polymer electrolytes, including PEO and polyethylene glycol (PEG). However, use of non-fluorinated polymers does not mean that the overall gel polymer electrolyte is PFAS-free, because low molecular weight PFAS are still used as ionic liquids to increase the electrical conductivity (Costa et al., 2019).

4.5.3 Wind Turbines: Fluoropolymer Uses and Properties

As a result of their use in outdoor environments, wind turbines need to be resistant to weathering and corrosion. For example, icing of wind turbines can cause uneven weight distribution between wind turbines and change aerodynamic performance, which leads to mechanical vibrations and reduced efficiency of the turbine (Peng et al., 2012; Qin et al., 2020). One way to mitigate icing is the use of a hydrophobic coating (Peng et al., 2012; Qin et al., 2020). Rain can lead to corrosion, erosion, and scouring of the blades, which can also impact aerodynamics, reduce turbine efficiency, and eventually lead to loss in lift (Chen et al., 2019). To reduce the impacts of both precipitation and icing, "superhydrophobic" coatings are used on turbines. ECTFE, PTFE, PVDF, and FEP are reported to be used in wind turbines for weather and corrosion-resistant properties (Arcella et al., 2014; Améduri, 2018). PVDF, PTFE, and FEP are also reported in the literature for use as superhydrophobic coatings (Peng et al., 2012; Qin et al., 2020; Ellinas and Gogolides, 2022).

4.5.4 Wind Turbines: Non-fluorinated Alternatives

An extensive body of literature exists related to the development of superhydrophobic coatings; however, the field is much broader than its application to wind energy because superhydrophobic coatings have extensive applications in other areas such as automotive and solar. Studies have been published related to engineering of superhydrophobic surfaces that mimic the "lotus leaf effect", which is known as a natural superhydrophobic surface (Ensikat et al., 2011). These coatings rely on a combination of water-repelling chemical characteristics and a surface roughness that is optimized to reduce nucleation of water molecules, which is beneficial for reducing ice formation and adhesion to surfaces (Liu et al., 2023). Several non-fluorinated materials have been explored to achieve the lotus effect, including silica nanoparticles (Karmouch and Ross, 2010) and biochar-based materials that offer thermal benefits for deicing scenarios (Liu et al., 2023). At this stage, whether such non-fluorinated alternatives are commercially available and/or used in the wind energy sector is unclear.

4.5.5 Solar Panels: Fluoropolymer Uses and Properties

Solar, or photovoltaic, cells generally consist of a metal frame that holds a series of layers, including a frontsheet, encapsulant, active layer, and backsheet (Arcella et al., 2014). Uses of fluoropolymers in the frontsheet and backsheet collectively include ECTFE, ETFE, PVF, and PVDF (Arcella et al., 2014). Uses in the frontsheet and backsheet are described in more detail below.

Frontsheet – The frontsheet of a solar panel is a transparent layer that allows light to pass through while protecting the underlaying layers. As a result, a frontsheet needs to be transparent, weather resistant, and impact resistant; provide electrical insulation; and must maintain these properties over a wide range of operating temperatures. Frontsheets are often made of glass, but there is an increasing demand for solar panels that are more flexible and lighter. ECTFE (e.g., Halar manufactured by Solvay) and ETFE (e.g., Tefzel manufactured by The Chemours Company FC, LLC) are both documented for use in frontsheets as a result of stability in UV light, low permeability, weather resistance (i.e., superhydrophobic properties; described in Section 4.5.3), and ability to transmit light in the visible range (Arcella et al., 2014; Chemours, 2023; Singh et al., 2023; Solvay, 2023). Although studies have reported that PVDF is less suitable for lamination than ETFE and ECTFE (Singh et al., 2023), PVDF products are marketed for use as frontsheets in solar panels (e.g., SOLAR-THRU[46]) (AiT, 2021). Additionally, FEP (e.g., Teflon FEP) is intermittently reported as a frontsheet on some solar cells (e.g., DuPont, 2013; Ross et al., 2014).

[46] SOLAR-THRU is a trademark of AI Technology Inc., Princeton Junction, New Jersey.

Backsheet – The role of the backsheet in a solar cell is like that of the frontsheet except that transparency is not needed in conventional (i.e., non-transparent) solar cells. As a result, the backsheet needs to be weather resistant, have mechanical strength, and provide electrical insulation. As with the frontsheet, the backsheet needs to maintain these properties over a wide range of operating temperatures. PVF (e.g., Tedlar), PVDF, and ECTFE are all reportedly used in solar cell backsheets (DeBergalis, 2004; Arcella et al., 2014; DuPont, 2023).

4.5.6 Solar Panels: Non-fluorinated Alternatives

Section 4.5.4 addressed non-fluorinated alternatives for superhydrophobic coatings used in wind turbines, and because superhydrophobic coatings are also used in the frontsheets and backsheets of solar cells, this information also applies to the solar industry. However, development of non-fluorinated alternatives for use in solar cells will need to address the additional requirements of transparency (i.e., for the frontsheet) and minimizing dust retention (Luo et al., 2023).

As noted in Section 4.5.4, superhydrophobicity depends in part on optimization of surface roughness to minimize nucleation of water droplets. However, such roughness can increase retention of dust, which in turn reduces transparency, a key property needed for solar cells (Luo et al., 2023). Similar to superhydrophobic coatings for wind turbines, studies in peer-reviewed literature document development of non-fluorinated alternatives for use in solar cells (Allahdini et al., 2022; Luo et al., 2023). For example, Allahdini et al. (2022) published a study using alkoysilane binder, silica nanoparticles, and methyltriethoxysilane to collectively yield a hydrophobic (including icephobic) and self-cleaning surface for use in solar cells. Also similar to wind turbines, if such non-fluorinated alternatives are primarily at the research and development stage or are available commercially for use in solar cells is unclear.

Table 4-7 provides an overview of the results of the RMOA (Drohmann et al., 2021, Table 40) focused on the renewable energy sector.

Table 4-7. Overview of Renewable Energy Alternatives

Alternative/s	Example potential application	Overview of likely technical economic and environmental implications
Pb (lead acid) battery	Batteries	Lead batteries are about one-third heavier than lithium-ion batteries in which fluoropolymers are used.
High-temperature fuel cells	Fuel cells (stationary applications)	The key disadvantage, compared to PEM fuel cells, is that the high-temperature fuel cells can only be used in stationary applications.

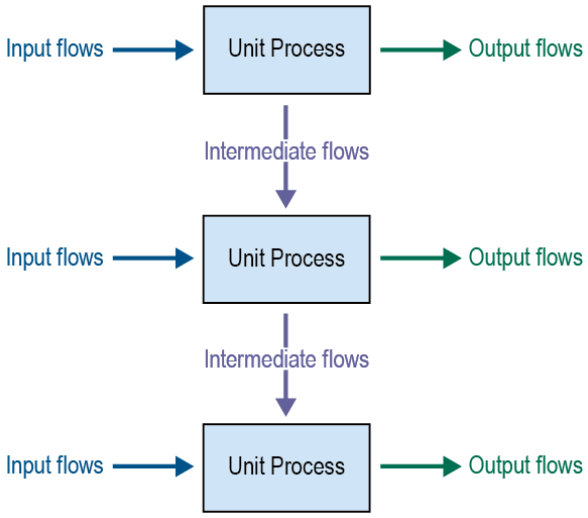
Source: Extracted from Table 40 of Drohmann et al., 2021, *Regulatory Management Option Analysis for Fluoropolymers,* Plastics Europe, Association of Plastics Manufacturing, Brussels, Belgium.

Pb = lead. PEM = polymer electrolyte membrane.

5.0 FLUOROPOLYMER LIFE CYCLE ASSESSMENT AND COST BENEFIT ANALYSIS

5.1 Life Cycle Assessment

Life cycle assessment (LCA) is a framework and tool that is increasingly used in decision-making and regulatory measures as the U.S. continues to identify sustainable products and energy solutions. The International Organization for Standardization (ISO) defines LCA as the "compilation and evaluation of the inputs, outputs and the potential environmental impacts of a product system throughout its life cycle" (ISO 14040:2006, ISO 14044:2006). LCA enhances the understanding of environmental impacts from the production and use of a product and can be used to identify environmental hotspots in a product's life cycle or to compare two product systems to identify which one is less detrimental to the environment. A product system comprises unit processes, each with its own input and output flows, that are linked via intermediate flows (Figure 5-1). Unit processes within a product system are often referred to as life cycle stages, such as raw material acquisition, manufacturing, use, recycling, and waste or end of life.

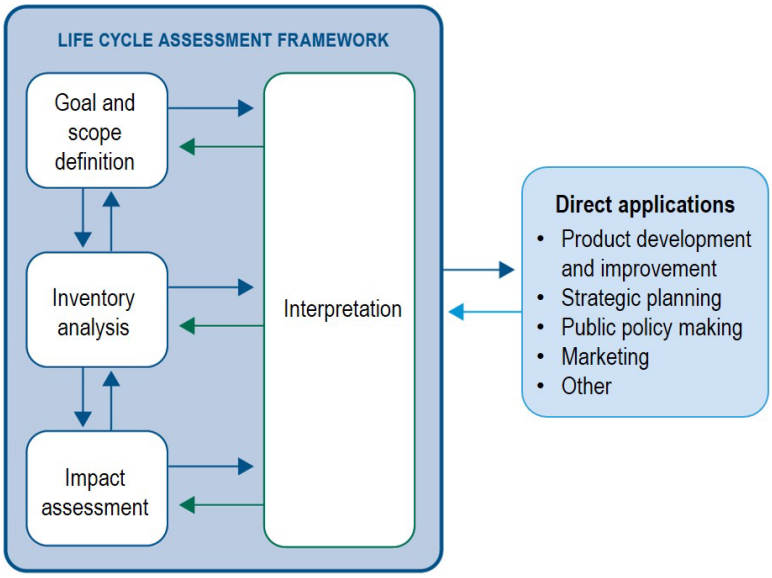


Source: ISO 14040:2006, "Environmental management — Life cycle assessment — Principles and framework."

Figure 5-1. Unit Processes within a Product System

ISO 14040 outlines the principles and defines the framework of an LCA, whereas ISO 14044 defines the requirements and guidelines (i.e., how to carry out an LCA study). The two standards represent the foundation that LCAs are built on and reviewed based on the provided guidance. Both ISO standards, though separate, are not mutually exclusive and the requirements of one are closely linked with the requirements of the other.

ISO 14040 outlines the four phases of completing an LCA as follows: (1) goal and scope definition, (2) inventory analysis, (3) impact assessment, and (4) interpretation. Figure 5-2 shows the iterative nature of LCA, where the interpretation phase can inform the scope of the study or the inventory included for analysis. The "goal and scope definition" phase is a critical step in LCA studies. During goal setting, the LCA practitioner identifies what the study is for, why the study is being done, who will see the study results, and how the study results will be used.



Source: ISO 14040:2006, "Environmental management – Life cycle assessment – Principles and framework."

Figure 5-2. Four Phases of Life Cycle Assessment

The scope of an LCA study defines the system being analyzed, the functional unit and system boundary of the study, and the impact categories and methodology selected for the study. The scope should also include information regarding the data being used in the study and any key limitations or assumptions. Notable steps in the goal and scope phase are defining the functional unit and setting a system boundary. A system will often have multiple functions; thus, defining the function of the system in the context of a particular study is critical. According to ISO 14040, "[t]he primary purpose of a functional unit is to provide a reference to which the inputs and outputs are related." As a result, the functional unit and system boundary are closely linked.

Setting the system boundary may change what functional unit is selected and can significantly influence the results of the impact assessment. A system boundary can include the entire life cycle of a product, which is referred to as cradle-to-grave, or the boundary can be truncated to only include specific sections of the life cycle, referred to as cradle-to-gate. For example, an LCA study of a chemical with a cradle-to-grave system boundary would include all life cycle stages from raw materials extraction through production, use, and disposal. Whereas a cradle-to-gate system boundary for the same study would end after production (i.e., the plant gate) and would not consider the use or disposal of that product. Clearly defining the system boundary provides context for the interpretation of a study's impact assessment results. Without this context, results may be misinterpreted, misleading, and can lead to misinformed decisions.

The life cycle inventory (LCI) phase of LCA includes "…data collection and calculation procedures to quantify relevant inputs and outputs of a product system" (ISO 14040). Inventory analysis can often result in refinement of the goal and scope, either as more data are discovered or as data gaps are identified. Data collected for LCA include raw material and energy inputs, product and waste outputs, and emissions to air, water, and soil. LCI data can be collected in several repositories, including both private and public options. Most notably, the Federal LCA Commons provides publicly available LCI data from several different organizations and institutions (FLCAC, 2023). Other notable databases include licensed options such as ecoinvent (Wernet et al., 2016) and GaBi (Sphera, 2023). The calculation component of inventory analysis includes both normalizing the data to a specific unit process and normalizing the data to the functional unit for the study. Dealing with unit processes and systems that produce more than one product is not uncommon. These additional products, referred to as co-products, are addressed during inventory analysis using a procedure called allocation. The allocation procedure in ISO 14044, Section 4.3.4.2, provides further detail on how to manage co-products within a system.

The third phase of LCA is the life cycle impact assessment (LCIA). Impact assessment "…involves associating inventory data with specific environmental impact categories and category indicators, thereby attempting to understand these impacts" (ISO 14040). LCIA can be performed using a variety of methods. EPA released and maintains its own impact assessment method called the Tool for Reduction and Assessment of Chemicals and Other Environmental Impacts (TRACI) (Bare, 2012). Impact assessment methods, like TRACI, comprise characterization factors (CF) that translate emissions into impacts. CFs characterize emissions using common equivalence units. For example, for the global warming potential (GWP) impact category, carbon dioxide (CO_2) has a CF of 1 kg CO_2 equivalents per kg (kg CO_2e/kg). Conversely, fossil methane (CH_4) has a CF of 29.8 kg CO_2e/kg. Therefore, CH_4 has a higher impact than CO_2, per unit of mass, in terms of GWP. The CFs are used to aggregate emissions into one category with a common equivalence unit, like CO_2 equivalents. CFs represent the potency of a specific emission, and that potency varies depending on the impact category and sometimes depending on the environmental compartment to which it is emitted (air, water, soil). Impact assessment methods rely heavily on modeling with varying levels of uncertainty to generate CFs.

Among the various impact assessment methods, there are two types of categories or indicators: midpoint and endpoint. Midpoint indicators represent individual environmental concerns, like GWP. Conversely, endpoint indicators represent aggregated environmental concerns like damage to human health.

A result of the aggregation that happens to reach endpoint indicators is increased uncertainty. This uncertainty is a result of the complexity associated with issues such as human health; various factors can impact human health, and the emission of one chemical cannot accurately indicate a health outcome. Thus, while providing a result that may have more meaning and connection to an audience, endpoint results have considerable uncertainty and should be presented with the associated limitations.

Optional components of the LCIA phase include sensitivity and uncertainty analysis. Uncertainty analysis is a way to determine the impact of assumptions, data gaps, and general uncertainties in the data. Sensitivity analysis can be used to determine the impact of specific changes to the data or the sensitivity of the data and results to changes. Additional details on how to perform impact assessments are provided in ISO 14044, Section 4.4.

Finally, the last phase of LCA, life cycle interpretation, includes completeness, sensitivity, and consistency checks, using the LCIA results to identify any limitations and provide conclusions. The interpretation phase connects the results of the LCI and LCIA back to the goal and scope of the study. This final phase of the LCA provides the practitioner an opportunity to interpret the results in the context of the defined goal and scope. This phase also affords an opportunity to refine the goal and scope, revisit the LCI, and recalculate the LCIA results as necessary.

In addition to this introduction to LCA, discussing what LCA is and is not is also important in the context of this report. Specifically, life cycle costing (LCC) is often confused with LCA. LCC is an economic framework that evaluates the total cost of a product system over its life. LCC can include the environmental costs, but still diverges from LCA by providing a primarily economic perspective. The Society of Environmental Toxicology and Chemistry (SETAC) published a code of practice for LCC that identifies the differences between LCC, LCA, and social LCA (SLCA) (Swarr et al., 2011). Economic and cost considerations within the scope of this report are discussed in Section 5.2.

LCA is not meant to replace detailed risk assessment of the toxicological or environmental effects of the emissions from product systems. LCA is meant to provide a high-level comparison between options, while risk assessments generally aim to quantify specific risks and to determine whether those risks fall within acceptable thresholds. While often complementary, these types of analyses do not exist within the framework of LCA. Impact assessment methods, and the impact categories within, provide a way to aggregate LCI results for interpretation in a meaningful way. The mechanisms and effects of the emissions accounted for during LCA are detailed in literature and the modeling used to develop LCIA methods. This report and the LCA section will largely avoid toxicological or environmental studies regarding fluoropolymers. These studies will be referenced if relevant inventory data and life cycle insights are provided.

5.1.1 Fluoropolymer Life Cycle Assessment Literature Review

Life cycle data are kept behind chemical industry walls due to confidentiality and proprietary concerns. The lack of data availability is compounded by missing CFs in existing LCIA methods. Thus, in cases where data exists for an LCA study, a way to turn the LCI data into impact results may not be available.

Hu et al. (2022) summarizes one of the key problems, as suggested above, when conducting an LCA of fluoropolymers: data availability. This 2022 study identifies 15 LCAs that include PVDF as an input and uses proxies to model its production and documents its own LCA of PVDF using stoichiometric methods. When specific data cannot be obtained for an LCA study, similar data can be used as a surrogate or proxy. For example, if data for a specific chemical is unavailable, data for a chemical with similar production technology and applications may be used as a proxy. This is common practice in LCA but must be done with care, as a proxy will introduce uncertainty into a life cycle model, and these proxies should be clearly documented for the audience of the LCA.

A majority of the 15 LCA studies examined lithium-ion batteries, where PVDF is a necessary component, and all 15 studies relied on proxies, such as PVF and PVC, to model PVDF. Notably, all but four of the studies obtained their proxy data from ecoinvent (Wernet et al., 2016). Depending on the selected proxy, the GWP results range from 1.6 kg CO_2e/kg of PVDF to 62 kg CO_2e/kg of PVDF.

These results highlight the uncertainty that is introduced when different proxies are used in LCA studies and the inability to identify what proxy may be representative of the input of interest. Ultimately, the Hu et al. (2022) study aims to conduct an LCA of PVDF synthesis and compare the results to those obtained using proxies. This analysis is achieved by providing the first known LCIs for PVDF production, relying on previously published literature and patents to stoichiometrically obtained input data for two synthesis routes. Note that the Hu et al. (2022) study seemingly excludes any direct emissions from and energy required for the manufacturing of PVDF. The LCI data presented in the study only focuses on the chemical inputs to PVDF production and the associated upstream emissions and energy requirements. Results from this LCA indicate that, in most cases, the use of proxies leads to significantly underestimating the environmental impacts when compared to the two PVDF cases presented in the Hu et al. (2022) study. The cumulative energy demands (CED) for both PVDF cases were significantly higher than any of the proxies under study. The same could be said for GWP except for the tetrafluoroethylene + polyethylene (TFE+PE) case, which has a higher GWP than all other proxies and the two PVDF cases. Using PVF as a proxy yielded a GWP and CED of 16.9 kg CO_2e/kg and 198.9 MJ equivalents (MJe) per kg, respectively. Conversely, the two PVDF cases based on stoichiometric methods had GWP and CED values of 54.7 and 55.8 kg CO_2e/kg and 858 and 756 MJe/kg, respectively. These results demonstrate the effect that using proxies can have on LCA results.

Holmquist et al. (2020) identifies CF availability as another key challenge to performing LCA studies of fluoropolymers and their monomers. Few CFs are available to characterize fluoropolymers and their PFAS monomers, and those that are available are not necessarily characterizing compounds of interest, such as PFOA. In addition, Holmquist et al. (2020) points out that these CFs do not consider the persistent and bioaccumulative nature of low molecular weight PFAS. To address these challenges, the study develops and proposes a framework for toxicity characterization, both ecosystem and human, which is specific to the complexity introduced with low molecular weight PFAS. The proposed framework contains two steps: (1) a translation table that converts PFAS inventory data into relevant degradation products, and (2) an impact characterization model to transform degradation product emissions into impact results. The amount of PFAS that degrades (i.e., transformation fractions) and the products it degrades into were determined using empirical studies of PFAS degradation. The impact characterization model represents a modified version of the USEtox model (Rosenbaum et al., 2008). While attempting to develop a robust framework for characterizing PFAS emissions, the authors acknowledge there are still limitations to the framework. These limitations do not lie within the proposed framework itself but are a result of limited understanding of the degradation mechanisms and ecosystem and the human toxicity effects of PFAS. Thus, the uncertainty in characterization frameworks like the one proposed can only be reduced through further empirical studies.

The study by Holmquist et al. (2020) provides a key example that, while efforts are being made to provide opportunities for better LCA studies of fluoropolymers and PFAS, there is still work that must be done. Notably, this study highlights the pervasiveness of uncertainty in LCA studies of fluoropolymers and PFAS, and this uncertainty was considered in the study conducted for this report. Another study, though not explicitly an LCA, developed CFs for textile chemicals such as fluoropolymers (Roos et al., 2018).

In a different study, Holmquist et al. (2021) leverages the characterization framework from Holmquist et al. (2020) and the CFs developed by Roos et al. (2018) to conduct an LCA of fluoropolymers used for textiles. The goal of the 2021 report is to quantify the effects of replacing fluoropolymers in the production of water-repellent shell jackets with alternative chemicals. In addition, this study aims to determine if the design and use of fluoropolymer-containing jackets affects the environmental impacts. The scope of this report (defined in Section 1.0) does not include textiles; however, this 2021 study includes LCI data for the production of fluoropolymers and thus is included in this literature review. The functional unit of the Holmquist et al. (2021) study is the life of the garment, where life span is based on studies of the use of water-repellent jackets. This consideration is notable because of the comparative nature of this LCA study. Establishing functional equivalence between fluoropolymers and their alternatives is one challenge in conducting a comparative LCA of these two products, which is discussed later in this section.

Once again, the Holmquist et al. (2021) study notes the challenge of modeling fluoropolymer production resulting from data availability and confidentiality. Like other studies reviewed here, the study uses fluoropolymer-specific LCI data where available and supplements with proxies where LCI data are unavailable. Upon investigation of the LCI data, the study appears to rely heavily on the use of proxies to fill data gaps. One notable outcome from the LCIA in the Holmquist et al. (2021) study is the identification that the impacts resulting from direct emissions from the studied system, with the exception of low molecular weight PFAS emissions, are small compared to the impacts resulting from energy use. The authors acknowledge, however, that the limitations associated with LCA studies of fluoropolymers may affect this finding. In addition, the authors note that considering how the fluoropolymer is used (i.e., the use and care of a shell jacket) is critical to evaluating its environmental performance. This is a key finding, as it indicates that fluoropolymers production requires significant energy use and that energy use contributes a large share of the environmental impacts. However, there also may be offsetting energy benefits from fluoropolymer use (e.g., reduced energy usage by aircraft because of weight reduction achieved using fluoropolymers). This result may indicate that there is no benefit, in the context of GWP, to using fluoropolymers over an alternative. However, as the authors note, the use of fluoropolymers is a critical consideration. Fluoropolymers have exceptional qualities that contribute to their longevity, and the lifetime of a product must be considered when evaluating the life cycle environmental impacts.

A D'Ambro et al. (2021) study characterizes emissions from a commercially operating fluoropolymer production facility. The study summarizes the emissions reported by a facility operated by The Chemours Company FC, LLC (Chemours) and uses that summary to model the transport of PFAS like GenX and other chemicals (D'Ambro et al., 2021). Chemours is a well-known producer of fluoropolymers like Teflon, the brand name version of PTFE, and polymerization aids like GenX, the brand name version of HFPO-DA. In 2017, the North Carolina Department of Environmental Quality (NC DEQ) found GenX in the Cape Fear River (NC DEQ, 2017). The NC DEQ identified the Chemours Fayetteville Works facility as the emission source of GenX and other PFAS to the Cape Fear River and surrounding water wells. As a result, Chemours was required to report air emissions from the Fayetteville Works facility (Chemours, 2018). Notably, Chemours reported 304.6 kg of HFPO-DA and 1,971 kg of hydrofluoric acid emissions during 2017.

These data are leveraged by D'Ambro et al. (2021) to evaluate the transport and fate of the reported air emissions using the Community Multiscale Air Quality (CMAQ) model. The new version of the CMAQ model, CMAQ-PFAS, predicted that approximately 95% of the PFAS air emissions from a fluoropolymer production facility like Fayetteville Works can be transported more than 150 km. Thus, only 5% of PFAS emissions are deposited within 150 km of a production facility. The remaining 95% of emissions can be transported across distances farther than 150 km. Although the D'Ambro et al. (2021) study does not include LCA or LCIA results, the model and results reported could be leveraged in an LCA study.

To address the emissions from the Fayetteville Works facility, the NC DEQ issued a permit on March 14, 2019 to Chemours to install a thermal oxidizer/scrubber system to reduce PFAS air emissions (NC DEQ, 2019). The permit included a 90-day testing period in which Chemours had to demonstrate a 99% reduction in air emissions. This treatment supplements carbon adsorbers that were installed in May 2018. In addition, Chemours implemented a water treatment system for the removal of PFAS, and the NC DEQ issued a discharge permit on September 15, 2022 (NC DEQ, 2022). The National Pollutant Discharge Elimination System (NPDES) permit sets emissions limits for a 180-day period of optimization, in addition to more stringent emissions limits after the 180-day period.

The LCA studies reviewed here highlight data gaps and limitations of conducting LCAs of fluoropolymer production. Note that the majority of the studies reviewed are not focused on fluoropolymers but are focused on low molecular weight PFAS, which are essential for and may be emitted during fluoropolymer production. While the review of LCA literature on fluoropolymers is the goal of this section, only one fluoropolymer LCA study was found in the literature, necessitating an equally important review of the LCA literature on PFAS due to their use in fluoropolymer production, emission during manufacturing, and the potential degradation of fluoropolymers into low molecular weight PFAS.

Product category rules (PCR) establish specific standards for LCAs of products and regulate how the results from such studies are communicated in documents like environmental product declarations. Currently, PCRs in the U.S. have largely been developed for products in the construction sector, such as concrete, flooring, and plumbing (Sustainable Minds, 2023). Due to the lack of data provided by manufacturers of fluoropolymers and fluoropolymer-containing products, the adherence to PCRs for products that may contain fluoropolymers, like coatings and electrical components, cannot be evaluated. Note that no PCRs for intermediate products, such as PTFE granules, have been identified. Based on the literature review provided in this section, developing a PCR for fluoropolymers may present significant challenges, such as data availability and missing impact assessment CFs.

As identified in this section, the area of concern regarding fluoropolymer production and use may not be the fluoropolymer itself, but the monomers, polymerization aids, and degradation products associated with fluoropolymers. The gap in LCA literature on fluoropolymer production is the result of several challenges. Due to the complexity of chemical transport in the environment, the expansive variety of chemical species, and the persistence of PFAS in the environment, the emissions from production, use, and end of life are incredibly hard to characterize. LCA studies rely on environmental and toxicological studies to provide a foundation on which LCIA methods and CFs can be developed. Although efforts are ongoing to collect these empirical data, fundamental challenges with data collection exist (Ankley et al., 2021). These challenges are compounded by the number of chemicals that fall within the PFAS spectrum and that PFAS often occur in mixtures. This lack of robust data makes it difficult to develop reliable LCIA models and CFs. These challenges and limitations are important to highlight and should be considered when reviewing the results of the LCA conducted for this report.

5.1.2 Case Study Selection

According to the market reports cited in this review, PTFE makes up over 50% of the total market volume of fluoropolymers (PLS080B). Section 4.0 highlights the nearly ubiquitous nature of PTFE. Thus, PTFE was selected as the fluoropolymer for the LCA conducted for this report. To perform a comparative analysis, stainless steel was selected as the alternative technology. Note that the appropriate alternative technology selection for comparison is highly dependent on the application; thus, a specific application of fluoropolymer and alternative technology is addressed in the following section.

5.1.3 Goal and Scope

The goal of the LCA conducted qualitatively for this report is to elucidate the environmental impacts of fluoropolymer production and use in a specified sector. More specifically, this LCA comparatively evaluates PTFE and its alternative under one of the specified sectors: industrial use in chemical processing. The specific technology application being evaluated is PTFE-coated or PTFE-lined pipe vs. stainless steel or other pipe. The results from this study are meant to contribute to the knowledge base of fluoropolymers, their alternatives, and the associated environmental impacts, not to promote the use of either technology or make policy recommendations. The functional unit for this study is 1 m of piping to be used in an unspecified chemical plant. The system boundary for this qualitative LCA, as shown in Figure 5-3, is cradle-to-gate and focuses on the production life cycle stage of PTFE. A more robust cradle-to-grave LCA will require additional LCI data and effort.

Note that when reviewing the LCIA methods, fluoropolymers and PFAS mostly were absent from established methods. As noted in Section 5.1.1 in the literature review, efforts are being made to fill these gaps (Holmquist et al., 2020; Roos et al., 2018). The frameworks and CFs reviewed above can be leveraged to perform a robust LCIA. However, the application of these methods is difficult in the context of a cradle-to-grave LCA of fluoropolymer production because of the significant gaps in available data.

Even with the progress made in characterizing fluoropolymer and PFAS emissions, considerable uncertainty is still associated with the human health and ecotoxicity impact categories. The level of uncertainty associated with these categories can produce misleading results that can lead to misinformed decision-making. This potential issue is especially true for fluoropolymers in that they do not have the empirical data to support robust impact assessment models and methods. To provide factual and reliable information, this study has omitted the human health and ecotoxicity impact categories from the LCIA, which have been deemed outside the scope of this report (defined in Section 1.0).

Based on the above findings and the scope of this report, this LCIA only includes the GWP impacts associated with the known chemical inputs into PTFE production and the associated upstream energy consumption. The CFs for the 100-year time horizon from the Intergovernmental Panel on Climate Change's Sixth Assessment Report (IPCC, 2023) were used to determine the GWP. Due to the significant data gaps identified, emissions of low molecular weight PFAS and other fluoropolymer degradation products were not considered.

5.1.4 Life Cycle Inventory

After thoroughly reviewing publicly available data and proprietary third-party databases, no complete LCI dataset was found for the production of PTFE. Notably, the results from the Vanderbilt industry survey did not yield any production or emissions data. The survey responses included only what is publicly available, such as the monomers and chemicals used in production, but did not include any quantities. This lack of transparency has been ubiquitously acknowledged in the literature and can be cited as the reason for lacking LCI data.

Third-party databases (e.g., ecoinvent) contain LCI data for chemicals used upstream of fluoropolymer production, such as TFE in the case of PTFE as the fluoropolymer. However, these databases are licensed data and therefore not available to the general public. The publicly available LCI data for PTFE production that do exist are either based off proxy data, stoichiometric calculations, or arbitrary emissions estimates; there are no ground-truth data sources. Additionally, because emissions of PFAS are not currently regulated in the U.S., no emission limits can be leveraged for LCI analysis of fluoropolymer production.

Raw Material Extraction

Figure 5-3 illustrates the PTFE production process. Rectangles and circles represent key life cycle stages and key inputs, respectively. Red arrows represent potential opportunities for PFAS emissions. PTFE is made from the polymerization of TFE, which is synthesized from chloroform and hydrogen fluoride. Hydrogen fluoride is produced via the reaction of sulfuric acid and the mineral fluorite. (Relevant raw material and market considerations are discussed in Section 5.2.)

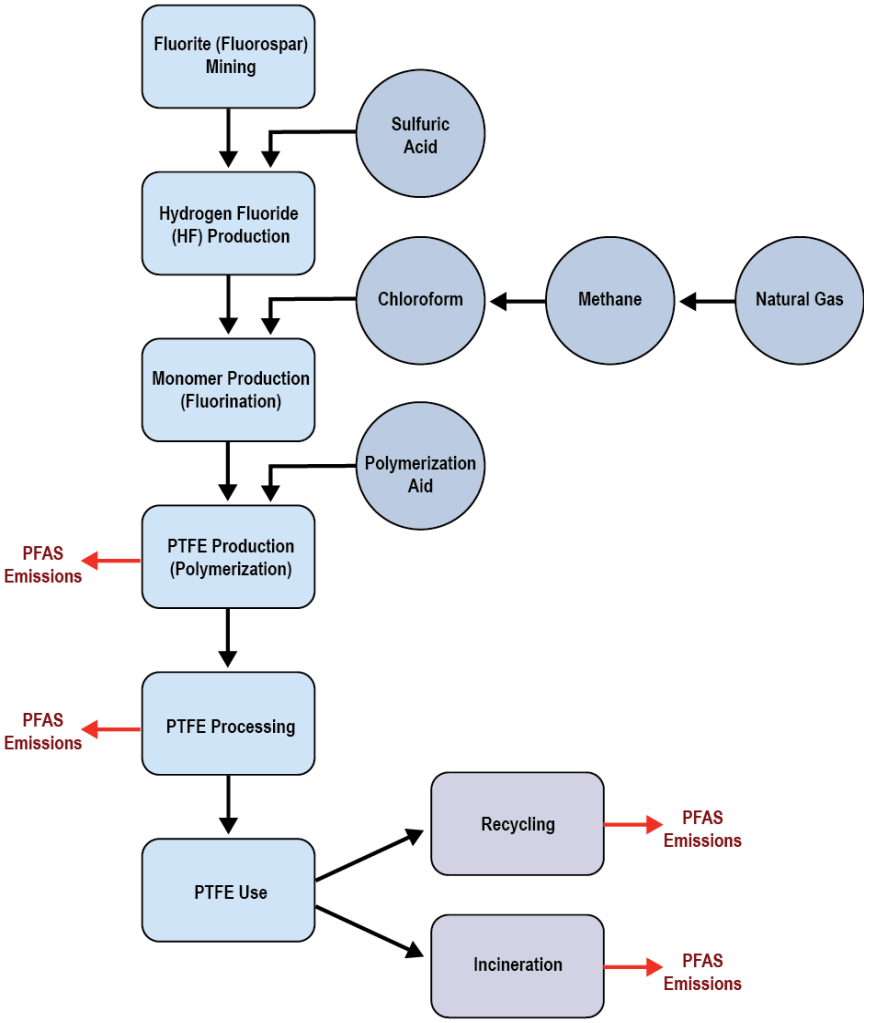


Figure 5-3. Polytetrafluoroethylene Production Process

Chloroform is produced from chlorine and methyl chloride or methane. Methane is primarily sourced from natural gas extraction, while methyl chloride is produced using methanol and hydrochloric acid. Methanol is generally produced from syngas containing carbon monoxide and hydrogen. The primary source of hydrogen is natural gas, but the syngas may be the product of other processes using other fossil-based hydrocarbons.

Given the above, natural gas is assumed to be the primary resource for PTFE production and a likely source for energy requirements throughout manufacturing. More importantly, significant amounts of chlorine go into the process and represent the bulk of the mass in chloroform.

PTFE Production

The screening-level LCA is documented in Appendix B and summarized below. From a purely stoichiometric perspective, the material inputs and data sources considered for TFE production are:

- Natural gas: 0.32 kg natural gas/kg TFE (Rai et al., 2021)
- Chlorine (from a Chlor-alkali plant): 4.25 kg Cl_2/kg TFE (NREL, 2012)
- Sulfuric acid: 1.96: 1.96 kg H_2SO_4/kg TFE (NREL, 2012)
- Fluorite: 1.56 kg CaF_2/kg TFE (Lai et al., 2021).

The above inputs do not account for real-world yields or energy input for the TFE itself or chloroform. (Note that the main by-product of chloroform formation is hydrochloric acid.)

From an emissions perspective, the polymerization of TFE into PTFE may be a point of risk for low molecular weight PFAS emissions to the environment due to their use as fluorosurfactants or polymerization aids (D'Ambro et al., 2021). As noted in the literature review (Section 5.1.1), these emissions could be on the order of hundreds of kilograms per year, while production is in the thousands of tons (NC DEQ, 2019). Even with the relatively low emission rate when compared to the production volume of fluoropolymer, existing studies indicate that exposure to small amounts of low molecular weight PFAS can cause significant health effects (Fenton et al., 2021). Thus, small mass flows of low molecular weight PFAS emissions should not be considered negligible.

As previously noted, no known sources of LCI data were found for low molecular weight PFAS emissions from fluoropolymer production. In addition, impact categories like human health and ecotoxicity were excluded from the LCIA in this report due to concerns regarding the associated uncertainties. These points are important to reiterate such that the following is clear: toxicity impact categories and low molecular weight PFAS emissions were not included in this report due to uncertainty and data gaps, not because they lack importance.

PTFE-Lined Pipe Production and Specifications

Using the dimensions for a commercially available PTFE-lined pipe for 1 m of 2-in. piping with a 5 mm-thick PTFE lining, the mass of steel is 5.4 kg/m and the mass of PTFE is 1.6 kg/m for a total of approximately 7 kg/m (Mersen, 2021). Given the performance of PTFE, the steel used for the PTFE-lined pipe is assumed to be of lower grade than stainless steel. The inventory for steel production was derived from the National Renewable Energy Laboratory (NREL) U.S. Life Cycle Inventory Database (USLCI) (NREL, 2012).

Stainless-Steel Pipe Production and Specifications

Many grades of stainless and specialty steels could be used in chemical plants; determining which steels are most likely to be used requires knowledge of all of the chemicals that PTFE-lined pipe are used to process and the stainless-steel alternatives that could be used in those situations. For simplicity, 304 stainless steel is assumed to provide similar performance characteristics for this application and is therefore used as a proxy. The amount of stainless steel for 1 m of 2-in. pipe is assumed to be the same as the PTFE-lined pipe: 5.4 kg/m. The inventory for stainless-steel production was derived from the NREL USLCI database (NREL, 2012).

Use Phase

Based on the reviewed literature and responses from industry, if the PTFE material is used as specified, no emissions are specifically associated with its use in chemical processing. This assumption has been applied here and results in no fluoropolymer-related emissions during the use phase.

End of Life

Various methods are employed for the reuse, recycling, and destruction of fluoropolymers (Améduri and Hori, 2023). Once the fluoropolymer is in its final form, most evidence points to very little breakdown of the fluoropolymer, which is expected, as one of its primary attributes is its stability and resistance to corrosion. Conversely, there is a risk of low molecular weight PFAS emissions from fluoropolymers at the end of life if the fluoropolymer-containing product is incinerated at temperatures less than 850 °C (Huber et al., 2009). Due to the scope of this report and the data scarcity regarding emissions during use and end-of-life treatment of fluoropolymers, the LCIA focuses on the impacts from PTFE production using a cradle-to-gate system boundary, thus end-of-life disposal emissions cannot be determined.

5.1.5 Life Cycle Impact Assessment Results

The GWP of the material inputs into TFE production, including upstream natural gas, chlorine for chloroform, and fluorite and sulfuric acid for hydrogen fluoride production, is estimated to be 10.65 kg CO_2e/kg TFE (Table 5-1). For 1 m of 2-in. pipe with a 5 mm-thick PTFE coating, the estimated 100-year GWP for just the material inputs is roughly 29.5 kg CO_2e/m PTFE-coated, non-stainless-steel pipe. In contrast, the GWP for 1 m of stainless-steel pipe is 41.3 kg CO_2e/m stainless-steel pipe. However, if the LCI data for PTFE production were available and the energy inputs into PTFE manufacturing were taken into account, this difference would likely be much smaller.

Table 5-1. Calculation of the Global Warming Potential of the Material Inputs into Tetrafluoroethylene Production

Product	PTFE-lined pipe	Stainless-steel pipe
Pipe diameter (in.)	2	2
Steel mass (kg/m)	5.4	5.4
PTFE mass (kg/m)	1.6	0
Global warming potential[a] (kg CO_2e/m)	29.5	41.3

[a] Global warming potential does not include LCI data for PTFE production, such as energy consumption.

LCI = life cycle inventory. PTFE = polytetrafluoroethylene.

This result, however, is just for the material inputs to the piping. With no operations emissions in the use phase of an LCA, such as per kg of chemical produced, both of these impacts would be divided by thousands of tons of production and would be expected to be dwarfed by the energy and feedstock requirements for creating the target chemical. One of the key advantages to PTFE is its stability. Even with a perfectly selected stainless steel, the stainless steel would potentially need to be replaced over the life of the chemical processing facility, providing a slight life cycle greenhouse gas emissions edge for the PTFE-lined pipe.

From a PFAS emission standpoint, as noted above, no clear way is apparent to compare these two scenarios through a human or ecotoxicity impact assessment because few such factors are available for low molecular weight PFAS and, furthermore, such considerations are outside the scope of this report. Note that a premature assessment would likely show higher toxicity impacts for stainless steel simply from nickel production.

5.1.6 Example Life Cycle Assessment Conclusions

For this specific case study, PTFE-lined pipe and stainless-steel piping would likely emit roughly the same amount of greenhouse gases for 1 m of piping. This result is a qualitative analysis informed by estimates of greenhouse gas emissions associated with just the material inputs. Such a result is far from a fully informed, cradle-to-grave LCA that would likely require two complete plant designs for processing specific chemicals – one design with PTFE and another without (i.e., using the selected alternative). Modifying the system boundary to include the use and end-of-life phases would require modification of the functional unit, and thus, the scale at which the comparison is being made. On a full life cycle basis, the greenhouse gas emissions associated with either PTFE-lined or stainless-steel pipes implemented in a chemical processing facility are likely to result in the same order of magnitude of emissions. This result is due to the expected high mass throughput for a chemical facility, which results in low emissions from amortized inputs (i.e., one-time emissions for construction are divided by a large amount of product).

There are known issues with some stainless-steel additives, like nickel, and known issues with low molecular weight PFAS emissions from PTFE production. A quantitative comparison of toxic emissions between the two scenarios is currently not possible due to the lack of LCI data for PTFE production and CFs for these emissions. However, in the case that CFs are available, a high amount of uncertainty is likely associated with those factors, making it difficult to draw any meaningful conclusions from an LCA.

A notable takeaway from this qualitative analysis is the data challenges associated with conducting LCAs of fluoropolymers. A lack of data available from fluoropolymer producers and unregulated emissions from fluoropolymer manufacturing has created information and data gaps. Current LCA studies that have circumvented these issues by using proxies have identified the limitations and uncertainties associated with this approach. Further investigation of these issues and fluoropolymer production may lead to a more comprehensive data set and more robust analysis.

5.2 Cost-Benefit Analysis

Cost-benefit analysis (CBA) is an approach used to evaluate the economic feasibility of projects, policies, or investments. CBAs are tools that aid individuals, organizations, and governments in assessing whether a particular course of action is justified economically. The basis of a CBA is to compare the costs associated with a project or action to the benefits it generates, considering monetary values and non-monetary factors.

The focus of this report is to develop a qualitative CBA, where costs encompass financial investments, ongoing operational expenses, and potential risks and drawbacks. A qualitative CBA also includes direct and indirect costs, such as labor, materials, and any potential negative impacts. Benefits encompass the positive outcomes that may result, including increased revenue, improved customer satisfaction, improved product performance, and the potential for new technology or products.

Qualitative CBAs are well-suited for scenarios where precise data are limited or where the CBA must be conducted quickly. Qualitative CBAs are generally more flexible and adaptable to a wide range of projects and can provide narrative assessments of costs and benefits. Additionally, qualitative CBAs also emphasize the strategic and contextual aspects of a decision, which aids decision-makers in aligning projects, policies, or investments with their broader objectives.

CBA is a valuable tool but also has limitations that should be addressed to avoid unreliable and/or inaccurate results. Limitations include subjectivity in assigning values to intangible benefits, data quality reliability, discount rate sensitivity, and the exclusion of ethical and social considerations. Therefore, while CBAs are a valuable analytical tool, these limitations should be adequately addressed to make the most informed data-driven decisions.

5.2.1 Cost-Benefit Analysis Background and Literature Review

The literature review uncovered no cases of a comprehensive, quantitative CBA of a fluoropolymer compared to a well-defined alternative technology. This analysis assessed the context, requirements, and market conditions relevant to the industries and applications where fluoropolymers are currently used and reviewed literature for existing CBA studies. Some partial CBAs are summarized below. Replacing fluoropolymers would incur costs associated with research and development, innovation, testing, production process modification, retooling of manufacturing facilities, and potential supply chain disruptions.

In addition, restrictions on use of fluoropolymers may result in disruption or elimination of some products or technology. Potential adverse impacts from alternative materials or technologies replacing fluoropolymers would also need to be evaluated. Since the discovery of fluoropolymer materials and their high-performance physiochemical properties, these materials have been replacing traditional materials such as metal, glass, and high-performance coatings and composites over a wide range of applications and enabled the miniaturization and advancement of many technologies. Assessing the cost of alternative materials and production technologies depends on relative performance characteristics, material availability, and projected market demand.

This analysis approaches the CBA using a material flow analysis and LCA foundation (discussed in Section 5.1). Market research, environmental reporting and monitoring, chemical company reports, surveys, secondary literature, and prior material flow analysis and LCA research articles were consulted to obtain estimates for the amount and value of fluoropolymers flowing through the U.S. economy in their production, use, and end-of-life phases. This foundation provides the basis from which to qualitatively discuss frameworks for estimating the overall costs and benefits (both direct and indirect) of fluoropolymers for business-as-usual as opposed to phase-out and substitution as two extreme ends of potential policy scenarios for these critical industrial commodities manufactured with non-polymeric PFAS. Estimates from market research indicate that North America's share of global demand for fluoropolymers is about one-quarter that of the globe by volume and market share, where North America's share accounts for approximately 92 kt and $1.4B in 2019, respectively.[47]

5.2.2 Benefits of Fluoropolymer Use and Potential Costs of Substitution

The use of alternative technologies in favor of fluoropolymers could result in several economic implications, including production and performance efficiency losses, increased capital and maintenance costs, and regression of current technologies (Wood, 2020). Alternative technologies used in favor of fluoropolymers could also pose indirect economic implications, including potential higher safety risks, increases in emissions, and impacts to technical advancement (Wood, 2020).

The following provides a summary of critical fluoropolymer applications, and fluoropolymer substitutes of those applications that may have high replacement costs, which considers material properties, manufacturing processes, and performance characteristics.

Aerospace – PTFE and FEP are used for insulation of electrical and data transmission cables that are subject to extreme conditions. Commercial airplanes can use as much as 500 km of wire, where fluoropolymers are used as coatings to maintain reliability in variable temperature conditions and prevent potential electrical arc fires.

Few alternatives in the aerospace industry could meet the critical properties provided by fluoropolymers. For example, at extreme temperatures or conditions, cables may turn rigid causing a breakdown or a system failure, thus compromising aircraft safety.

Automotive – PTFE is used in automotive lambda sensor cables due to its resistance to high temperatures and chemicals, dielectric strength, flexibility, and electrical insulator properties. Lambda sensors adjust the fuel amount that is sent to engine cylinders by optimizing the air and fuel mixture, which reduces carbon monoxide emissions.

[47] Estimates based on PLS080B, 2021, *Fluoropolymer Materials: Technologies and Global Markets*, BCC Publishing; 2019 data and projections for 2020 and 2025.

Silicon, ethylene propylene rubber (EPR), and EPDM rubber could be considered alternatives, but these materials do not work at the required operating temperature of approximately 250 °C, which is frequently encountered in car engines where lambda sensors are installed. Additionally, alternatives do not meet the mechanical properties (e.g., elongation) required by the automotive sector for these lambda sensors.

Batteries – PTFE and PVDF are commonly used as electrode binders and separator coatings in lithium-ion batteries, wherein the materials provide interconnectivity within each electrode. This facilitates electronic and ionic conductivity, increasing the cell manufacturing productivity and overall cell safety. Due to their cohesive and adhesive properties under high voltage, fluoropolymers enable closely packed cathode active materials for high-density electrodes, which improves the energy efficiency of a single unit and helps reduce overall size.

Polyethylene or PET could be used as substitutes for PTFE and PVDF in lithium-ion batteries; however, these materials would not offer the combined set of properties that fluoropolymers provide, particularly for both fire retardancy and battery efficiency. Lead-acid batteries could also be alternatives to lithium-ion batteries; however, lead-acid batteries offer reduced energy efficiency performance because of a lower proportion of energy stored within the batteries. In addition, lead-acid batteries are heavier resulting in reduced functionality and increased energy consumption compared to lithium-ion batteries.

Building construction – Fluoropolymers are critical components in heating, ventilation, air conditioning, and refrigeration equipment because such machinery is subject to continued changes in temperature and pressure and potentially harsh chemicals (e.g., refrigerants). Materials such as PEI, PBI, polyamideimide (PAI), or phenolic resins have been proposed as potential alternatives, but these materials have not been fully tested as replacements for fluoropolymers in this application and may offer lower levels of chemical resistance.

Chemical processing – Fluoropolymers are extensively used in the chemical processing industry. In stringent conditions (e.g., applications with highly corrosive chemicals, high temperature operations, and conditions requiring inert materials to achieve high purity), PTFE, PFA, and ETFE are typically used in pipes, expansion joints, vessels, and fittings to ensure system reliability. Failure of those systems could potentially result in high-risk situations for people or the environment due to leakage, spills, or releases of corrosive and/or high-temperature substances.

When there is no need to protect equipment or chemical products from corrosion, metal or metallic alloy (e.g., black steel, stainless steel, galvanized steel, copper, brass) piping and fitting systems could be used by the chemical processing industry. However, these metals and metallic alloys would be limited to the following situations:

- Chemicals that are non-corrosive (or less corrosive) to steel.
- Processes in which short system lifetime is acceptable.
- Metallic ion impurities in the streams handled in the relevant processes do not raise concerns, from either a quality or safety perspective.

PFA and PTFE are also used for lining pumps in the chemical processing industry, with the aim to avoid corrosion under specific conditions of chemical attack. In addition, fluoropolymer-based seals (e.g., O-rings) are used in those processes to prevent leaks and releases of hazardous materials. Chrome/nickel alloys are usually considered as possible alternatives for these applications. While used for lining in pumps to operate certain chemical processes, and still in use today, these materials are not able to meet specific anti-corrosion requirements.

Infrastructure – A study was also conducted to compare economic impacts of painting a bridge with a fluoropolymer-based paint (i.e., FEVE) versus painting a bridge with polyurethane paint. The cost was determined to be approximately 26% more with the fluoropolymer-based coating compared to polyurethane; however, the polyurethane coating degrades faster and needs to be recoated frequently, and after 30 years, the total cost for such recoating would be 16% more (in total) than the fluoropolymer-based coating (Ghorbanpoor et al., 2013).

PVDF is used in pipe fittings and manifolds for plumbing systems in buildings due to its ease of installation, resistance to chemicals and corrosion, resistance to high temperature, high compatibility with many chemical substances, stability, inertness, and flame retardant and UV resistance properties. Multiple metals (e.g., brass, copper, black steel) are potential alternatives for plumbing applications but are heavier material and offers less resistance to corrosion where PVDF is used. Polyphenylsulfone (PPSU) is an alternative that can be used in plumbing applications; however, PPSU in plumbing is more fragile and less resistant to heat. In addition, PPSU is not compatible with many of the glue compositions frequently used by plumbers during installation.

Hydrogen production and use – Fluoropolymers are used in numerous renewable hydrogen applications, including electrolyzer and fuel cell manufacturing, alkaline water electrolysis, and a variety of critical hydrogen infrastructure and end-use applications (e.g., PTFE used in sealants, valves, fittings, membranes). The European renewable hydrogen industry has indicated that a ban of PFAS (polymeric and non-polymeric) would have significant detrimental effects on polymer electrolyte membrane (PEM) fuel cell and PEM electrolysis technologies. Hydrogen Europe (2023) estimated that over a 10-year timeframe, a complete PFAS ban would put at risk a total investment value in the European hydrogen energy sector of €26–36B (~$27.6B–$38.2B[48]) and would put 147,000–203,000 direct jobs and an extra 263,000–282,000 indirect jobs at risk.

Semiconductors – Like chemical processing applications, PTFE and PFA are used in vessels, pipes, and fitting systems (e.g., diaphragms in valves) for the semiconductor industry due to their high levels of chemical resistance, temperature resistance, and flexibility. These fluoropolymers are used with the aim to protect equipment under very aggressive media while achieving a high purity of the materials involved in the process. For example, PTFE or high purity PFA-lined columns and tanks are used to produce high purity sulfuric acid for etching silicon wafers to manufacture electronic chips. This technology allows for larger wafers and a more efficient microchip production process.

To maintain the current state of the semiconductor industry, no option is currently available to replace the use in fluid systems made from fluoropolymers. A shift towards metal-based materials would potentially preclude the semiconductor manufacturing industry from reaching the standards of efficiency and sophistication that are needed by downstream user sectors (e.g., telecommunications, electronics).

Solar panels – Lorenz et al. (2014) modeled the potential earnings of different commercially available anti-soiling solar panel systems and found that an average of 3.2% yearly gain in profitability could be made by using an anti-soiling coating and an optimized cleaning strategy compared to using uncoated glass. Based on their study, the European plastics industry has estimated that European Union photovoltaics manufacturing with ETFE in favor of glass could yield savings of €43.2M (~$46.8M) (Plastics Europe, 2017).

Fluoropolymers are widely used in the solar industry as backsheets to decrease failure rates. Prior to the integration of fluoropolymers into solar backsheets, Plastics Europe indicated that failure rates were approximately 45%, whereas with fluoropolymer film backsheets, the failure rates are as low as 0.1% (Plastics Europe, 2023b).

[48] Based on October 8, 2023 conversion rate.

5.2.3 Necessary Data for Quantitative Cost-Benefit Analysis

A range of necessary data points and/or information is needed to perform a complete CBA. This report describes several impacts that may result from the removal of fluoropolymers from the U.S. supply chain; however, most of the limited available information was qualitative and does not support an intensive CBA that addresses all required elements. To provide a comprehensive understanding of the costs and benefits of each type of the most widely used fluoropolymers would require detailed analysis of at least hundreds of specific uses across many product sectors. Thus, this CBA is necessarily limited to focused case studies. To perform a more well-rounded CBA with multiple case study analyses, the following information would need to be available.

Benefits

- **Production impacts** – Economic production benefits that may be realized through alternative fluoropolymer technologies or non-fluoropolymer alternative materials, including factors such as raw material expenses, manufacturing efficiency, energy consumption, atmospheric emissions, wastewater discharges and solid waste production, and potential scalability, to determine their potential cost-saving advantages over traditional fluoropolymers
- **Local and regional benefits** – Economic benefits for specific localities and regions that may be realized through alternative fluoropolymer technologies or non-fluoropolymer alternative materials, which consider regional supply chain dynamics, workforce availability, infrastructure readiness, and the potential for job creation and economic growth
- **End use and application benefits** – Potential benefits associated with transition away from fluoropolymers, including opportunities for enhanced performance, safety, or quality in specific industries or applications, and the assessment of any potential advancements or innovations in product development within these sectors.

Costs

- **Raw materials/precursors** – Economic costs of raw materials/precursors for fluoropolymer substitutes, which include analyzing supply chain disruptions, demand shifts, and potential regulatory changes that may affect their costs
- **Prohibitive costs** – Any potential prohibitive economic costs associated with fluoropolymer replacement technologies, which include analyzing factors such as initial investment, production expenses, market availability, regulatory compliance, and long-term economic impacts on industries relying on fluoropolymers
- **End use and application costs** – Costs of transitioning away from fluoropolymers to specific industries and applications, including potential disruptions, changes in product performance, product safety, and the development or adoption of alternative technologies or materials in these sectors.

Overall, carrying out an exhaustive CBA of removing fluoropolymers from the U.S. supply chain and replacing them with alternative materials presents several practical limitations. Fluoropolymers are used in thousands of end-use applications, and potential trade-offs would need to be considered for an enormous number of those applications. In many instances, those data are not publicly available.

Removing fluoropolymers generally or from specific uses could also lead to increased costs, not only in terms of raw material and manufacturing but also from equipment modifications and maintenance and compliance with or revision of industry standards. A transition to fluoropolymer alternatives may necessitate expensive retrofitting of existing infrastructure and machinery. The CBA should consider transition expenses and the potential economic repercussions of reduced efficiency and performance in extreme conditions without fluoropolymers.

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Appendix A. Questions Included in Industry Survey

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Industry Survey

II. Instructions

Please complete the questions in the electronic survey.

This survey is divided into the following sections:

Company Information
Fluoropolymer Manufacturing and Production
Life Cycle Assessment
Use and Competing Technologies
Cost-Benefit Assessment
Conclusion

Note that the questionnaire has branching logic and question numbering may not appear in sequential order, depending on your responses.

Additionally, some responses will be collected via the attached excel file below. Please download the file and complete your responses there.

At appropriate points in the survey, you will be asked if your response contains confidential information.

Once completed, submit the questionnaire. A completion notification will be sent to you along with a pdf of your responses.

If you need more than one session to complete the questionnaire, choose the save and return later option. An email notification will be sent to you with a link to return.

Upon final submission, you will recieve an email confirmation with a pdf of all responses.

III. Company Information

Company Name	
Contact Person Name	
Title	
Telephone Number	
Email Address	
Industry Sector(s)*	
*See Industries at a Glance: NAICS Code Index : U.S. Bureau of Labor Statistics (bls.gov) for more information	

1. What is your company's position in the supply chain? Check all that apply.
   - □ Manufacturer of fluoropolymers
   - □ Importer of fluoropolymers
   - □ Formulator of fluoropolymers
   - □ User of fluoropolymers in manufacturing or products
   - □ Other: _____

2. Who are the primary end users of your products? Check all that apply.
   - □ Component or end product manufacturer
   - □ Formulators
   - □ Consumers
   - □ Government agency
   - □ Other: _____

3. What fluoropolymers and precursors do you manufacture, import, or utilize; what is their physical form (e.g., sheeting, coatings, surfactants), and quantities in 2020 - 2022? [Table 1]

Fluoropolymers	Abbreviation	CAS No.	Physical Forms (e.g., Solid, liquid, suspension/ solution)	Quantity (tons/ yr)		
				2020	2021	2022
copolymer of ethylene and chlorotrifluoroethylene	ECTFE	25101-45-5				
ethylene tetrafluoroethylene	ETFE	25038-71-5 / 68258-85-5				
fluorinated ethylene propylene	FEP	25067-11-2				
perfluoroalkoxy polymer	PFA	26655-00-5 / 31784-04-0				
Polytetrafluoroethylene	PTFE	9002-84-0				
polyvinylidene fluoride	PVDF	24937-79-9				
terpolymer of tetrafluoroethylene, hexafluoropropylene & vinylidene fluoride	THV	25190-89-0				
Other(s)						
Precursors						
Perfluorooctanoic acid	PFOA	335-67-1				
Perfluorooctane sulfonic acid	PFOS	1763-23-1				
Perfluorononanoic acid	PFNA	375-95-1				
Hexafluoropropylene oxide dimer acid (commonly known as GenX Chemicals)	HFPO-DA	13252-13-6				
Perfluorohexane sulfonic acid	PFH	355-46-4				
Perfluorobutane sulfonic acid	PFBS	375-73-5				
perfluoroisobutylene	PFIB	382-21-8				
ammonium perfluorooctanoate	APFO	3825-26-1				
perfluorobutyl ethylene	PFBE	19430-93-4				
Other(s)						

4. Please indicate your products' primary sector of use. Check all that apply.

- □ **Aerospace** (Transportation Equipment Manufacturing NAICS 336, Air Transportation NAICS 481)
- □ **Automotive** (Transportation Equipment Manufacturing NAICS 336, Truck Transportation NAICS 484, Transit and Ground Passenger Transportation NAICS 485)
- □ **Battery** (Electrical Equipment, Appliance, and Component Manufacturing NAICS 335, Battery Manufacturing NAICS 33591)
- □ **Building Construction** (Construction NAICS 23, Construction of Buildings NAICS 236, Heavy and Civil Engineering Construction NAICS 237)
- □ **Chemicals and Chemical Processing** (Basic Chemical Manufacturing NAICS 3251, Resin, Synthetic Rubber, and Artificial and Synthetic Fibers and Filaments Manufacturing NAICS 3252, Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing NAICS 3253)
- □ **Electronics** (Computer and Electronic Product Manufacturing NAICS 334)
- □ **Infrastructure**
- □ **Semiconductor/microprocessor** (Semiconductor and Related Device Manufacturing NAICS 334413)

- □ **Solar Energies** (Solar Electric Power Generation NAICS 221114)
- □ **Wind Energies** (Wind Electric Power Generation NAICS 221115)
- □ **Other Power** (Electric Power Generation, Transmission and Distribution NAICS 221100)

The following codes and associated sectors are included because they may represent a significant fraction of a producer's, importer's or manufacturer's use of fluoropolymers. However, analysis of the use of fluoropolymers in these industries is beyond the scope of the requested reports, and therefore these codes are provided only for completeness.

- □ **Cookware** (Metal Kitchen Cookware, Utensil, Cutlery, and Flatware (except Precious) Manufacturing NAICS 332215)
- □ **Food** (Food Manufacturing NAICS 311)
- □ **Pharmaceuticals** (Pharmaceutical and Medicine Manufacturing NAICS 32541)
- □ **Medical Equipment** (Medical Equipment and Supplies Manufacturing NAICS 339100)
- □ **Textile** (Textile Mills NAICS 313, Textile Product Mills NAICS 314)
- □ Other: _____

IV. Fluoropolymer Manufacturing and Production

5. Please indicate the approximate percentage of fluoropolymers and precursors sold or used in each application or sector of use by your company. Use "Other" rows and columns (add new rows and/or columns, if necessary) for sectors added in Question 4. Please complete Table 2 in Excel workbook. (M, I, F, O)

Sector of use (SU)à ---------- **Fluoro-polymer ↓**	Aerospace	Automotive	Battery	Building Construction	Chemical Processing	Electronics	Infrastructure	Semiconductor	Solar Panel	Wind energy	Other Power	Cookware	Food	Pharma	Medical applications	Textile	**Other**
ECTFE																	
ETFE																	
FEP																	
PFA																	
PTFE																	
PVDF																	
THV																	
Other																	
Precursor↓																	
PFOA																	
PFOS																	
PFNA																	
HFPO-DA																	
PFH																	
PFBS																	
PFIB																	
APFO																	
PFBE																	
Other																	

Fluoropolymers Manufacturing Process (M, I, F, O)

6. What type of polymerization process are you using for the manufacturing of fluoropolymers (suspension, emulsion, etc.)?

7. What fluoropolymers and precursors (fluorinated compounds) and approximate percentages of use (value or range) are your company using as polymerization aids during the manufacturing process? [Table 3]

Fluoropolymers	Abbreviation	CAS No.	Percentage of use (value or range) used as polymerization aids	Comment
copolymer of ethylene and chlorotrifluoroethylene	ECTFE	25101-45-5		
ethylene tetrafluoroethylene	ETFE	25038-71-5 /68258-85-5		
fluorinated ethylene propylene	FEP	25067-11-2		
perfluoroalkoxy polymer	PFA	26655-00-5 /31784-04-0		
Polytetrafluoroethylene	PTFE	9002-84-0		
polyvinylidene fluoride	PVDF	24937-79-9		
terpolymer of tetrafluoroethylene, hexafluoropropylene & vinylidene fluoride	THV	25190-89-0		
Other (add rows as needed)				

8. Which fluorinated polymerization aids could be removed from the manufacturing process without significant detrimental or deleterious impact on the manufacturing process?
9. List which fluorinated polymerization aids could be replaced by available alternatives (non-fluorinated substitutes) and identify the alternative?
10. For each fluoropolymer that you manufacture or process: [Table 4] **CBI**
    a. Which monomers are used in your production process?
    b. What are the molecular weight ranges of fluoropolymers produced?
    c. Which fluoropolymers are produced from recycled feedstocks?

Fluoropolymer (FP)	a) List Monomers used in Production	b) Molecular weight ranges	c) Produced from Recycled Feedstocks	Comment
copolymer of ethylene and chlorotrifluoroethylene (ECTFE)				
ethylene tetrafluoroethylene (ETFE)				
fluorinated ethylene propylene (FEP)				
perfluoroalkoxy polymer (PFA)				
Polytetrafluoroethylene (PTFE)				
polyvinylidene fluoride (PVDF)				
terpolymer of tetrafluoroethylene, hexafluoropropylene & vinylidene fluoride (THV)				
Other (add rows as needed)				

11. Formulation as copolymers:
    a. Which polymers are formulated as copolymers?
    b. What are the types and ratios of monomers used in the production of copolymers?
12. What physical/chemical properties are most critical for the fluoropolymers you manufacture?
13. What additives and/or polymer processing aids do you use in your fluoropolymer manufacturing process? **CBI**
    a. Which low molecular weight additives and/or polymer processing aids are used in fluoropolymer manufacturing?
    b. Which high molecular weight additives and/or polymer processing aids are used in fluoropolymer manufacturing?
    c. At which points in the manufacturing aids are additives and/or polymer processing aids used?
    d. Which polymers and polymer production methods are associated with which specific additives and/or polymer processing aids?
    e. What processes are used to remove excess additives and/or polymer processing aids from produced fluoropolymers before products are complete?
    f. What is the fate of excess or waste additives and/or polymer processing aids in your fluoropolymer manufacturing process?
14. What physical forms are your fluoropolymers formulated in?
    a. What types and fractions of fluoropolymers are extrudable thermoplastics?
    b. Which fluoropolymers are formulated as thermosets?
    c. Which fluoropolymers do you produce through emulsion polymerization?
    d. Physical form during storage
    e. Stability of the physical form
15. Please list the raw materials used in the manufacturing/production of fluoropolymers and their quantities.
    a. How is waste material disposed?
16. Please provide any publicly available information regarding the degradation mechanisms and conditions, and degradation products for each FP produced.

Use of Fluoropolymers in Manufacturing of Products (U, O)

17. Characteristics of fluoropolymers you need for your applications? [Table 5]
    a. Physical characteristics
    b. Chemical characteristics
    c. Stability and durability requirements

Fluoropolymer (FP)	a) Physical characteristics	b) Chemical characteristics	c) Stability and durability requirements	Comment
copolymer of ethylene and chlorotrifluoroethylene (ECTFE)				
ethylene tetrafluoroethylene (ETFE)				
fluorinated ethylene propylene (FEP)				
perfluoroalkoxy polymer (PFA)				
Polytetrafluoroethylene (PTFE)				
polyvinylidene fluoride (PVDF)				
terpolymer of tetrafluoroethylene, hexafluoropropylene & vinylidene fluoride (THV)				
Other (add rows as needed)				

18. What are alternative materials (non-fluoropolymers) with similar physical, chemical and durability characteristics that can be used as replacements for fluoropolymers in your manufacturing process?
19. Please describe the primary advantages to your industry of using specific FP
20. Recycling and Disposal of unused/excess fluoropolymers
    a. What fraction of unused/excess FP are recycled into your processes?
    b. What fraction of unused/excess FP are recycled to the FP manufacturer?
    c. What fraction of unused/excess FP are disposed?
    d. What disposal methods are used for unused/excess FP disposal? Long answer

V. Life Cycle Assessment Questions (for fluoropolymer manufacturers only) (M, I, F, O)

21. Please provide the zip codes for all of the company's manufacturing locations in the United States
    a. Please provide the city, country for companies manufacturing locations outside the United States.
22. Is there a life cycle assessment for the fluoropolymer chemicals the company produces publicly available? (Y/N) If yes, then please provide an electronic copy.
23. Does the company produce fluoropolymers for sale or does the company produce fluoropolymers for internal utilization in downstream products? Y/N What are the specific products?

24. Are there any byproducts or coproducts generated during the production of fluoropolymers? Y/N Can you list their names, yields (ton of byproduct/ton of fluoropolymer) and usage sector? [Table 6]

Fluoropolymer (FP)	Sector of use	List byproducts or coproducts	Yields (ton of byproduct or coproduct/ton of FP)	Comment
copolymer of ethylene and chlorotrifluoroethylene (ECTFE)				
ethylene tetrafluoroethylene (ETFE)				
fluorinated ethylene propylene (FEP)				
perfluoroalkoxy polymer (PFA)				
Polytetrafluoroethylene (PTFE)				
polyvinylidene fluoride (PVDF)				
terpolymer of tetrafluoroethylene, hexafluoropropylene & vinylidene fluoride (THV)				
Other (add rows as needed)				

25. For each fluoropolymer raw material and precursors purchased, please specify the annual quantity used (tons), percentage imported and the country from which it was imported. [Table 7]

Fluoropolymer (FP)	Raw materials and precursors purchased	Annual quantity used (tons)	Percentage imported	Country from which imported	Comment
copolymer of ethylene and chlorotrifluoroethylene (ECTFE)					
ethylene tetrafluoroethylene (ETFE)					
fluorinated ethylene propylene (FEP)					
perfluoroalkoxy polymer (PFA)					
Polytetrafluoroethylene (PTFE)					
polyvinylidene fluoride (PVDF)					
terpolymer of tetrafluoroethylene, hexafluoropropylene & vinylidene fluoride (THV)					
Other (add rows as needed)					

26. If the company producing fluoropolymers also produces the required precursors: what are the mass flows (annual usage) of key materials to produce the precursors? [Table 8]

Fluoropolymer (FP)	Required precursor(s)	Key materials to produce precursor(s)	Annual usage / mass flow (tons) of key materials	Comment
copolymer of ethylene and chlorotrifluoroethylene (ECTFE)				
ethylene tetrafluoroethylene (ETFE)				
fluorinated ethylene propylene (FEP)				
perfluoroalkoxy polymer (PFA)				
Polytetrafluoroethylene (PTFE)				
polyvinylidene fluoride (PVDF)				

terpolymer of tetrafluoroethylene, hexafluoropropylene & vinylidene fluoride (THV)				
Other (add rows as needed)				

27. How are raw materials/precursors transported to the production facility?
28. Please describe any supply chain issues related to fluoropolymer production and raw materials/precursors used (e.g., insufficient supply of raw materials, limitations on domestic or international transportation, import constraints).
29. What is the annual energy consumption of fluoropolymer production?
    a. What is the energy consumption and the fraction of energy from each source onsite (e.g., natural gas, fuel oil/diesel, renewable (solar, wind), others),
    b. What is the energy consumption and the fraction of energy from offsite electricity produced using, coal, natural gas, nuclear, solar, wind, other, etc.
    c. What is the energy consumption and the fraction of energy from offsite thermal energy produced using coal, natural gas, nuclear, electricity, solar, wind, other?
30. What annual amounts of greenhouse gas emissions are generated during the production processes (onsite, offsite) **in metric tons of carbon dioxide equivalent per year)?**?
31. What additional air emissions are generated during the production processes (onsite)?
32. What solid and liquid wastes are generated during fluoropolymer production? What are the quantities (ton of wastes/ton of fluoropolymer production)? How are solid and liquid wastes managed or treated (e.g., landfill, incineration, municipal solid waste, wastewater treatment plant)? [Table 9]

Fluoropolymer (FP)	Wastes (e.g., solid, liquid, solvent)	Quantities (ton of wastes/ton of FP production)	Management/treatment method (e.g., wastewater, landfill)	Comment
copolymer of ethylene and chlorotrifluoroethylene (ECTFE)				
ethylene tetrafluoroethylene (ETFE)				
fluorinated ethylene propylene (FEP)				
perfluoroalkoxy polymer (PFA)				
Polytetrafluoroethylene (PTFE)				
polyvinylidene fluoride (PVDF)				
terpolymer of tetrafluoroethylene, hexafluoropropylene & vinylidene fluoride (THV)				
Other (add rows as needed)				

VI. Use and competing technologies

33. Does your company produce any alternative materials or products as potential replacements for FP products? (All)

34. Please indicate how you evaluate potential alternatives to the FPs in your industry. If possible, please, add a rough estimate of the cost related to the replacement of FPs by each alternative. **(U, O)**
    a. Evaluate technical and economic feasibility, and fitness for use (e.g., same function & level of performance; if not the same, explain the difference).
    b. Specify the type of use for each alternative if the FP has different uses.
    c. What are the potential challenges or limitations associated with using these alternative materials?
    d. Are there any specific performance parameters, specifications, or safety concerns that need to be considered when selecting and using these alternative materials?
    e. If no replacements are available, what are the concerns and considerations for fluoropolymer replacement?

35. Are there specific industries or applications that have alternative materials or technologies showing promising results? **(U, O)**

36. What are the expected lifespan and durability requirements of the products or components using fluoropolymers versus the alternative materials? **(U, O)**

VII. Cost-Benefit Assessment: (U, O)

37. Please indicate the evaluation criteria for potential alternatives to the fluoropolymers for your company in the table below. If possible, please, add a rough estimate of the cost related to the replacement of fluoropolymers by each alternative.

    a. Evaluate technical and economic feasibility, and fitness for use (e.g., same function & level of performance; if not the same, explain the difference).
    b. Specify the type of use for each alternative if the FP has different uses.
    d. What is the timeline of the possible implementation of the alternative(s)? How are you considering replacing fluoropolymers in your product lines (e.g.: stop production, phase in, etc.)?

Fluoropolymer Application	Alternative technology	Cost Estimate of alternative (e.g., QC testing, waste management, recycling, disposal)	Timeline and method of substitution	Primary limitation (e.g., retooling, equipment modification, process change)	Primary Benefit (e.g., cost savings, environmental, waste reduction)	Replacement/ Longevity Concerns

38. With respect to the fluoropolymers that your company produces and/or uses, has your company prepared any benefit-cost analysis in comparison to alternatives? If so, could you share them?
39. With respect to fluoropolymers generally, rank the order of your company's priorities when considering replacing fluoropolymers in your products?
    - lower costs.
    - lower carbon footprint
    - customer concerns
    - less use of natural resources
    - concerns about the persistence of fluoropolymers and degradation products in the environment.
    - concerns about consumer health and safety.
    - concerns about waste management.
    - regulatory pressures.
    - liability risks.
    - other _____
40. With respect to the fluoropolymers that you produce and/or use, what are their most important benefits (compared to the next best alternative) that should be considered in a benefit-cost analysis?
    - lower cost to the producer, the intermediate processor and/or final user;
    - superior performance;
    - low toxicity;
    - small carbon footprint;
    - less use of natural resources
    - superior environmental profile;
    - safety for the consumer;
    - easy of managing as a waste;
    - comparative advantage of production in the US;
    - other.
41. Are there additional comments that you would like to provide to the study team?
42. Are there additional documents or links that you would like to provide to the study team?
43. Would you be available for a follow-on discussion with the team?
44. Would you be available to answer additional questions from the team, if needed?
45. Are there additional POC that you feel would be beneficial to the study team?

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Appendix B. Polytetrafluoroethylene Stoichiometry and Polytetrafluoroethylene-Lined Pipe Screening Life Cycle Assessment

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Polytetrafluoroethylene Stoichiometry and Polytetrafluoroethylene-Lined Pipe Screening Life Cycle Assessment

This appendix provides the calculations for the screening-level comparative life cycle assessment (LCA) between polytetrafluoroethylene (PTFE)-lined pipe and stainless-steel pipe, as discussed in Section 5.1 of this report. The first part of this appendix estimates the material inputs for tetrafluoroethylene (TFE), which is polymerized to create PTFE. Then, greenhouse gas emissions are summarized as 100-year global warming potentials (GWP) are applied to each of the inputs to provide a low-end estimate for PTFE production (Table B-1). This estimate does not attempt to account for yields of some of the precursors, like chloroform, for PTFE production. The estimate also does not account for energy inputs for TFE, PTFE, or the precursors outside of what is provided in some of the cradle-to-gate inventories.

This estimate of GWP for PTFE production is then used in the second part of this appendix in a scenario comparing 1 m of PTFE-lined pipe to 1 m of stainless-steel pipe. This comparative screening-level LCA is used to provide a sense of how the GWPs would compare for these two alternatives in a notional chemical processing facility.

Tetrafluoroethylene Reactions from Chloroform (Siegemund et al., 2016)

$$CHCl_3 + 2HF = CHClF_2 + 2\,HCl$$
$$2\,CHClF_2 = C_2F_4 + 2\,HCl$$

Summarily,

$$2\,CHCl_3 + 4HF = C_2F_4 + 6HCl$$
$$2\,CHCl_3 \cdot 119.38\frac{kg}{kmol} + 4HF \cdot 20\frac{kg}{kmol} = C_2F_4 \cdot 100.02\frac{kg}{kmol} + 6\,HCl \cdot 36.46\frac{kg}{kmol}$$
$$238.76\,kg\,CHCl_3 + 80\,kg\,HF = 100.02\,kg\,C_2F_4 + 218.76\,kg\,Cl$$

Or for just the inputs:

$$2.39\,\frac{kg\,CHCl_3}{kg\,C_2F_4}$$
$$0.79\frac{kg\,HF}{kg\,C_2F_4}$$

Chloroform (Rossberg et al., 2006)

$$CH_4 + Cl_2 = CH_3Cl + HCl$$
$$CH_3Cl + Cl_2 = CH_2Cl_2 + HCl$$
$$CH_2Cl_2 + Cl_2 = CHCl_3 + HCl$$

Summarily,

$$CH_4 + 3\,Cl_2 = CHCl_3 + 3HCl$$
$$CH_4 \cdot 16\frac{kg}{kmol} + 3\,Cl_2 \cdot 70.9\frac{kg}{kmol} = CHCl_3 \cdot 119.38\frac{kg}{kmol} + 3HCl \cdot 36.46\frac{kg}{kmol}$$
$$16\,kg\,CH_4 + 212.7\,kg\,Cl_2 = 119.38\,kg\,CHCl_3 + 109.38\,kg\,HCl$$

Or for just the inputs and then scaled to the TFE functional unit:

$$0.13\frac{kg\,CH_4}{kg\,CHCl_3} \cdot 2.39\frac{kg\,CHCl_3}{kg\,C_2F_4} = 0.32\frac{kg\,CH_4}{kg\,C_2F_4}$$
$$1.78\frac{kg\,Cl_2}{kg\,CHCl_3} \cdot 2.39\frac{kg\,CHCl_3}{kg\,C_2F_4} = 4.25\frac{kg\,Cl_2}{kg\,C_2F_4}$$

Hydrogen Fluoride (Aigueperse et al., 2000)

$$CaF_2 + H_2SO_4 = 2HF + CaSO_4$$

$$CaF_2 \cdot 78.07\frac{kg}{kmol} + H_2SO_4 \cdot 98.08\frac{kg}{kmol} = 2HF \cdot 20\frac{kg}{kmol} + CaSO_4 \cdot 136.14\frac{kg}{kmol}$$

$$78.07\ kg\ CaF_2 + 98.08\ kg\ H_2SO_4 = 40\ kg\ HF + 136.14\ kg\ CaSO_4$$

Or for just the inputs and then scaled to the TFE functional unit:

$$1.95\frac{kg\ CaF_2}{kg\ HF} \cdot 0.79\frac{kg\ HF}{kg\ C_2F_4} = 1.56\frac{kg\ CaF_2}{kg\ C_2F_4}$$

$$2.45\frac{kg\ H_2SO_4}{kg\ HF} \cdot 0.79\frac{kg\ HF}{kg\ C_2F_4} = 1.96\frac{kg\ H_2SO_4}{kg\ C_2F_4}$$

Table B-1. Screening Cradle-to-Gate Life Cycle Inputs per kilogram of Tetrafluoroethylene

Input	Amount per kg TFE	100-year GWP	GWP per kg TFE	Data Source[a]
Natural gas (as proxy for methane)	0.32 kg	0.806 kg CO_2e	0.258 kg CO_2e	Rai et al., 2021
Chlorine	4.25 kg	2.23 kg CO_2e	9.48 kg CO_2e	NREL, 2021a
Sulfuric acid	1.96 kg	0.348 kg CO_2e	0.682 kg CO_2e	NREL, 2021d
Calcium fluoride	1.56 kg	0.174 kg CO_2e	0.272 kg CO_2e	Lai et al., 2021
		Total	**10.7 kg CO_2e[b]**	

[a] Full references are provided at the end of this appendix.
[b] This estimate is based on mass of inputs and cradle-to-gate global warming potentials and does not consider transport of those inputs nor the energy required to actually manufacture the TFE, chloroform, or hydrogen fluoride.

GWP = global warming potential. TFE = tetrafluoroethylene.

Pipe Calculations

PTFE stainless-steel pipe and liner dimensions are summarized in Table B-2 and Table B-3, respectively. Dimensions for 2-in. nominal pipe were derived from Mersen (2021, p 15).

Table B-2. Polytetrafluoroethylene Steel Pipe Dimensions

Outer diameter	60.3	mm
Thickness	3.9	mm
Inner diameter	52.5	mm
Steel pipe area	691.0	mm^2
Length	1,000	mm
Steel pipe volume	691,025	mm^3
	0.000691	m^3
Steel density	7750	kg/m^3
Steel mass	5.36	kg/m

Table B-3. Polytetrafluoroethylene Liner Dimensions

Outer diameter PTFE	52.5	52.5	mm
Thickness	1	5	mm
Inner PTFE	50.5	42.5	mm
PTFE area	162	746	mm^2
Length	1,000		mm
PTFE volume	161,792	746,128	mm^3
	162	746	cm^3
PTFE density	2.16		g/cm^3
PTFE mass	0.35	1.61	kg

PTFE = polytetrafluoroethylene.

The total mass of PTFE-lined pipe is summarized in Table B-4. The 1 m pipe LCA comparison is provided in Table B-5.

Table B-4. Total Mass of Polytetrafluoroethylene-Lined Pipe

Steel mass		5.36	kg/m
PTFE mass	0.35	1.61	kg/m
Total mass	5.7	6.97	kg/m

Note that Mersen (2021, p 16) shows the weight to be 7 kg/m, so the 5 mm thickness of PTFE is assumed for the final product.
PTFE = polytetrafluoroethylene.

Table B-5. One Meter Pipe Life Cycle Comparison

Component	Mass	GWP	GWP per m	Data Source[a]
Steel	5.36 kg	2.3 kg CO_2e/kg	12.3 kg CO_2e	NREL, 2021b
PTFE	1.61 kg	10.7 kg CO_2e/kg	17.2 kg CO_2e	This appendix
		Total	**29.5[b] kg CO_2e**	
304 stainless steel	5.36 kg	7.72 kg CO_2e/kg	41.3 kg CO_2e	NREL, 2021c

[a] Full references are provided at the end of this appendix.
[b] This estimate does not consider transportation of those inputs nor the energy required to manufacture the PTFE, chloroform, or hydrogen fluoride.

GWP = global warming potential. PTFE = polytetrafluoroethylene.

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Appendix C. Biographical Sketches of the Fluoropolymer Review Team

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Biographical Sketches of Fluoropolymer Review Team

Project Management Team

Stephanie Jacobs, PhD, is a Biological Scientist at Savannah River National Laboratory (SRNL) and the Director of the Regulatory Center of Excellence. SRNL's Regulatory Center of Excellence provides technical, regulatory, and communications assistance to facilitate resolution of complex or difficult regulatory, policy, and stakeholder challenges. She has a BS degree in Chemistry from the University of South Carolina Aiken and a PhD in Biomedical Sciences from Augusta University. Her graduate research focused on molecular mechanisms of learning and memory. Prior to joining SRNL, she was at the South Carolina Department of Health and Environmental Control working in environmental sampling, analysis, and compliance assistance.

Dr. Jacobs has participated on teams looking at soil and groundwater remediation and regulatory considerations across the U.S. Department of Energy (DOE) complex, consent-based consolidated interim storage communications, and deactivation and decommissioning regulatory challenges. Her research has included molecular mechanisms of learning and memory, effects of substances on learning, biological breakdown of per- and polyfluoroalkyl substances (PFAS), and monitoring of microbial corrosion.

David S. Kosson, PhD, is the Gass Family Chair in Energy and the Environment, and Distinguished Professor of Civil and Environmental Engineering at Vanderbilt University, where he also has appointments as Professor of Chemical Engineering and Professor of Earth and Environmental Sciences, and is the Director of the Environmental Engineering Laboratory. Professor Kosson is the principal investigator for the multi-university Consortium for Risk Evaluation with Stakeholder Participation (CRESP) supported by DOE to improve the risk-informed basis for remediation and management of nuclear waste from former defense materials production and nuclear energy. Professor Kosson's research focuses on management of nuclear and chemical wastes, including leaching assessment, process development, and contaminant mass transfer applied to groundwater, soil, sediment, and waste systems.

Professor Kosson's research on waste management and environmental remediation allows new understanding of the fundamental behavior of chemical and radionuclide contaminants in wastes, engineered systems, and the environment to impact major decisions and policy. For example, work by his research group in collaboration with other faculty and international partners has resulted in establishment of the U.S. Environmental Protection Agency (EPA) Leaching Environmental Assessment Framework (LEAF), which is now being used for national policy decisions and regulations on waste management in the U.S. and other countries.

Professor Kosson has participated in or led many external technical reviews on nuclear waste processing and environmental remediation for DOE, including for tank wastes and a range of technology approaches at the Hanford Site, Savannah River Site (SRS), Waste Isolation Pilot Plant, and Idaho National Laboratory. For two decades, he has provided expertise and leadership for the National Academies, and as advisory to the U.S. Department of Defense (DOD), on demilitarization of chemical weapons in the U.S. and abroad. He has authored more than 200 peer-reviewed professional journal articles, books and book chapters, and other archival publications. Professor Kosson received a PhD in Chemical and Biochemical Engineering from Rutgers University, where he subsequently was Professor of Chemical and Biochemical Engineering. He also served as the Department Chairman for Civil and Environmental Engineering at Vanderbilt University from 2000–2012.

Connie Herman is the Associate Laboratory Director of the Environmental and Legacy Management Directorate at SRNL. The organization provides technical strategies and technologies for nuclear material processing, radioactive waste processing and stabilization, soil and groundwater remediation, risk assessment, and deactivation and decommissioning for the DOE Office of Environmental Management (EM) and Office of Legacy Management. The directorate shepherds competencies in materials science and engineering and biological sciences for national security programs and alternative energy applications.

Ms. Herman has been at SRS since 1990 where she has been primarily engaged in the development and deployment of technologies and processes for stabilization of nuclear waste and has managed research and development programs across the full spectrum of DOE-EM activities from inception to deployment. This program support included start-up and operations of the SRS Defense Waste Processing Facility. Ms. Herman has worked at other DOE sites where she provided technical leadership for development of the flowsheet and equipment for the plutonium disposition program at Lawrence Livermore National Laboratory and directly supported the Office of River Protection at Hanford on technical issue resolution for the Waste Treatment and Immobilization Plant. She has also participated as a subject matter expert and led independent technical assessments for several DOE-EM flowsheets and facilities, including at Hanford and Idaho.

Brady Lee, PhD is the Director of the Earth, Biological and Quantitative Systems Science Division at SRNL. He is classically trained in microbiology and has over 30 years of experience in applying biological and hybrid biological/chemical processes for environmental, bioenergy, and national security purposes. He spent the first 24 years of his career at the Idaho National Laboratory where he served as a researcher, principal investigator, and program manager. In these roles, he specialized in biogeochemistry, environmental microbiology, extremophilic microbiology, and molecular biology. Prior to joining SRNL in 2020, Dr. Lee spent 7 years at the Pacific Northwest National Laboratory (PNNL), where he led the microbiology program for the Deep Vadose Zone Program at the laboratory. He also developed a PNNL capability overview related to analysis and remediation of perfluorinated organic compounds associated with DOD activities. He currently has management oversight of a DOE-EM project looking at PFAS bioavailability. Through the years, Dr. Lee has managed projects that span from basic science at the bench-scale to full-scale remediation operations. From this research, he has written numerous technical reports, approximately 50 peer-reviewed journal articles, has received 15 patents, and has given hundreds of technical presentations at national and international meetings.

John D. Graham, PhD, is Professor of Risk and Policy Analysis at the Paul H. O'Neill School of Public and Environmental Affairs at Indiana University. He has been recognized for lifetime contributions by the Society for Risk Analysis and the Society for Benefit-Cost Analysis. From 2001 to 2006, Professor Graham served in the George W. Bush administration as Senate-confirmed Administrator, Office of Information and Regulatory Affairs, U.S. Office of Management and Budget.

Robert Seifert is the Director of the Office of Subsurface Closure and has served in this DOE-EM program for nearly 29 years. Starting in 1993 at the Paducah Gaseous Diffusion Plant, Mr. Seifert has held a number of technical and management positions as both a contractor and DOE federal employee. He joined the DOE Headquarter team in 2014. Mr. Seifert has a BS degree in Chemistry and Biology from Murray State University.

Michael (Josh) Silverman, PhD, leads the DOE Office of Environmental Protection and ES&H Reporting within the Office of Environment, Health, Safety and Security (EHSS). His innovative organization focuses on reducing DOE's environmental footprint, minimizing safety risks, and improving organizational performance, with a diverse portfolio covering environmental compliance, sustainable operations, natural and cultural resource protection, public and environmental radiation protection, organizational and safety culture, and ES&H reporting and analysis.

Dr. Silverman is designated as the Department's Federal Preservation Officer, pursuant to the National Historic Preservation Act. He is also designated as the Department's lead for PFAS, a chemical of increasing health and regulatory concern. His efforts to help DOE reduce releases of sulfur hexafluoride (SF_6), the world's most potent greenhouse gas, was recognized by the Partnership for Public Service "Service to America Medals" program.

Dr. Silverman joined DOE in 2000 after receiving his PhD in History and Policy at Carnegie Mellon University. His dissertation, "No Immediate Risk: Environmental Safety in American Nuclear Weapons Production," examines DOE management of environment, safety, and health risks from World War II through the end of the Cold War.

Alyssa Wingard is a Chemist and an Environmental Protection Specialist with the DOE-EHSS Office of Sustainable Environmental Stewardship (EHSS-21). In her position, Ms. Wingard leads the technical management of the DOE Consolidated Audit Program – Accreditation Program (DOECAP-AP) portion of the Analytical Services Program, bringing over 30 years of analytical testing experience. She also co-chairs the PFAS working group, the DOECAP data validation working group, and the newly formed PFAS Supply Chain working group for the Department. Ms. Wingard has a BS degree in Chemistry from Virginia Tech. Prior to joining DOE, she served as a Senior Chemist for over 16 years with the DOD providing management to compliance programs, including the Overseas Drinking Water Program and the DOD Environmental Laboratory Accreditation Program.

April Kluever, PhD, is a board-certified toxicologist with a science policy background working at the US Food and Drug Administration, Executive Office of the President, and Department of Energy. She is an interagency leader in White House Per- and Poly-Fluoroalkyl Substance (PFAS) technical and policy working groups, helping to coordinate federal efforts to address PFAS. Dr. Kluever received her Ph.D. in Environmental Health Sciences from Johns Hopkins University Bloomberg School of Public Health with a specialization in Neurotoxicology and certification in Risk Sciences and Public Policy.

Julie James is the Assistant Director of CRESP III in the Department of Civil and Environmental Engineering at Vanderbilt University. She interacts with CRESP university consortium members, departments, divisions, and principal investigators regarding administrative, budgetary, and compliance requirements. Ms. James reviews budget proposals annually for accuracy and completeness, ensures compliance with DOE federal policies and regulations, and organizes/triages proposals and reporting requirements in conjunction with the CRESP research team. She also oversees the execution and maintenance of the CRESP Knowledge Management system to establish a record for the DOE CRESP III cooperative agreement to effectively communicate with DOE, primary DOE sites, key government agencies, and other designated stakeholders.

Project Support Team

Artha Petermann is a Technical Communications Specialist, with over 40 years of experience working on technical and cost proposals and licensing applications for various clients primarily for work on DOE-EM/National Nuclear Security Administration (NNSA), DOD, and U.S. Nuclear Regulatory Commission (NRC) projects. She also supports special projects in the areas of nuclear waste management/cleanup, transportation systems, medical isotopes production, and computer systems development. Areas of expertise include proposal development, document development to industry standards/requirements, technical writing and editing, graphics design and editing, promotional materials design and production, and computer systems development and implementation. Her skill set in technical communications encompasses all aspects of document creation and publication, including layout and design, templates, style guides, editing, formatting, proofreading, and production. Ms. Petermann has a BS degree in Management Science (Information Technology) and Marketing/Business Administration from Central Washington University.

Richard Stringer-Hye has served as the CRESP Research Librarian in the Department of Civil and Environmental Engineering at Vanderbilt University since 2020. Prior to that he was a Science and Engineering Librarian in the Science and Engineering Library at Vanderbilt since 1995. Mr. Stringer-Hye provides research support, document retrieval, and organization for the CRESP research team. He

graduated with a Master's in Library and Information Science (MLIS) from the University of Rhode Island and a BA degree in Geology from the University of Colorado.

Subject Matter Expert Team

Kevin G. Brown, PhD, BCEEM is a Research Associate Professor in the Civil and Environmental Engineering Department at Vanderbilt University and Management Board Member of CRESP. While at the Savannah River Laboratory (1986–2002), Dr. Brown was recognized as a DOE complex-wide authority in process and product control for high-level waste vitrification. Dr. Brown spent 2002–2003 at the International Institute for Applied Systems Analysis (IIASA) in Laxenburg, Austria where he estimated potential transboundary radiation doses resulting from hypothetical accidents at Russian Pacific Fleet sites – the first such studies known in the West. Dr. Brown's current research, supported by CRESP, focuses on life-cycle risk evaluation, model integration, and waste management issues related to proposed advanced nuclear fuel cycles and cementitious materials and barriers for nuclear applications.

In 2009, Dr. Brown participated in the External Technical Review chartered by DOE-EM to evaluate system-level modeling and simulation tools in support of SRS and DOE Office of River Protection liquid waste processing. In 2010 and 2011, Dr. Brown participated on the Tank Waste Subcommittee of the DOE Environmental Management Advisory Board (EMAB) chartered to provide independent technical reviews of liquid waste capital and operations projects related to the DOE-EM tank waste cleanup program at major DOE sites.

Dr. Brown has participated as a subject matter expert on:

- DOE construction project and peer reviews for the Hanford Tank Waste Treatment and Immobilization Plant, low-activity waste pretreatment system, and SRS Salt Waste Processing Facility (2011–2019)
- Congressionally mandated (Section 3125 of the 2021 National Defense Authorization Act) Federally Funded Research and Development Center (FFRDC) team to study supplemental treatment of Hanford low-activity waste
- DOE-directed Network of National Laboratories for Environmental Management and Stewardship (NNLEMS) evaluation of the Hanford tank waste cleanup mission and development of a research and development roadmap in support of the DOE-EM budget request to Congress.

Dr. Brown holds a BE degree in Chemical Engineering, an MS degree in Environmental and Water Resources Engineering, and a PhD in Environmental Engineering from Vanderbilt University.

Ashley Cutshaw, PhD, earned her BS degree in Biosystems and Agricultural Engineering (BAE) from the University of Kentucky and completed her PhD in BAE with a dual degree in Environmental Science and Policy at Michigan State University. Her dissertation provided a comprehensive evaluation of co-located microalgal cultivation and biorefineries using life cycle and techno-economic assessment frameworks. Dr. Cutshaw is currently a Senior Engineer at KeyLogic where she serves as a support contractor for the DOE National Energy Technology Laboratory (NETL). At NETL, she works within the life cycle analysis competency of the Strategic Systems Engineering Analysis directorate. Since joining in June 2022, she has contributed to several publicly available reports, tools, and resources.

Justin Conrad, PhD, is the Gary K. Bertsch Director of the Center for International Trade and Security (CITS) and a professor in the School of Public and International Affairs at the University of Georgia. He is also a Joint Appointee at SRNL and a member of SRNL's Regulatory Center of Excellence.
Dr. Conrad's current work focuses on nuclear energy and waste policy, energy security, and regulatory policy. He has published many articles in leading academic journals and is the author of two books. He is a former U.S. Navy officer and previously worked in the public affairs industry.

Rebe Feraldi is an experienced life cycle assessment (LCA) and Biomimicry Scientist involved in setting up and managing LCAs and science-based sustainability research and projects for target setting, reporting metrics, and innovation. Ms. Feraldi, a life-long student, uses a biomimicry lens to identify opportunities for innovation at the form, process, and system levels. She is proficient in establishing and maintaining LCA projects, life cycle inventory databases, training users in data collection, modeling, quality control, analyzing, data visualization, reporting, and supporting out-of-the box thinking and pivotal process improvements to sustainability, innovation, and LCA analyses and analysis systems. She has 14 years of experience offering LCA consulting to public and private clients at local, national, and international scales. She is well-versed in environmental labeling practices and relevant government policies.

Lee Ferguson, PhD, is an Associate Professor of Environmental Science and Engineering at Duke University in Durham, North Carolina. He received BS degrees from the University of South Carolina in Chemistry and Marine Science, before earning a PhD in Coastal Oceanography at State University of New York – Stony Brook. His postdoctoral research was conducted in the area of proteomics at PNNL in Richland, Washington. Before joining Duke, Dr. Ferguson was an Assistant and Associate Professor of Chemistry at the University of South Carolina.

Jennifer Guelfo, PhD, is an Assistant Professor and an Edward and Linda Faculty Fellow in Civil, Environmental, and Construction Engineering at Texas Tech University. She joined Texas Tech University in 2018 following a postdoctoral appointment in the Brown University School of Engineering. Dr. Guelfo has a BA degree in Geology from the College of Charleston, and an MS degree in Environmental Science & Engineering and a PhD in Hydrologic Science and Engineering, both from the Colorado School of Mines. For the past 13 years, her research has focused primarily on occurrence, fate, transport, and remediation of PFAS. In addition to academia, Dr. Guelfo has a combination of consulting and industry experience, and she uses this background to engage in activities that can inform policy and bridge gaps between research and practice.

Troy Hawkins, PhD, is a Senior Scientist and leads the Fuels and Products Group of the Systems Assessment Center at Argonne National Laboratory. His research focus is on improving the environmental performance of energy and product systems, with particular focus on decarbonization, where he applies LCA and other quantitative systems analysis approaches to provide actionable insights. He has evaluated the energy and environmental impacts of conventional and alternative transportation energy systems, electricity and biopower, plastics and chemicals, and industrial processes, and has developed new methods for LCA and environmentally extended input-output analysis. He contributes to the development of Argonne's GREET (Greenhouse Gases, Regulated Emissions, and Energy Use in Technologies) model for life cycle analysis of energy systems, products, and technologies. Prior to joining Argonne, he worked as a consultant providing environmental and economic assessment for clients in the private and government sectors, led LCA research for the EPA, and worked as a researcher in the Industrial Ecology Programme at Norwegian University of Science and Technology. He holds a PhD from Carnegie Mellon University and has a BS degree in Physics from the University of Michigan.

Matt Jamieson serves as a Senior Life Cycle Analyst at NETL, as part of the life cycle analysis competency within the Strategic Systems Engineering Analysis directorate. He has been performing life cycle analyses of complex energy systems at the laboratory for 10 years and has contributed to a number of publicly available tools, reports, and peer-reviewed articles. Mr. Jamieson has a BS degree in Mechanical Engineering from the University of Minnesota – Duluth.

Alex Kugler, PhD, is an Earth Scientist on the Subsurface Signatures Discovery team at PNNL, where he develops remediation technologies and analytical methodologies to assist with regulatory compliance. He received his PhD in Geology from Miami University, where he specialized in aqueous geochemistry and geomicrobiology. He has worked on the degradation and fate and transport of PFAS, along with other environmental contaminants such as dioxin, petroleum, heavy metals, trichloroethylene (TCE), and radionuclides.

Radha Kishan Motkuri, PhD, is a Senior Principal Scientist/Chemical Engineer and Team Lead for the Applied Chemistry and Engineering team in the Earth System Science Directorate at PNNL. He serves as principal investigator, co-principal investigator, and project manager on a diverse range of materials chemistry and chemical/nuclear security projects. Dr. Motkuri has over 26 years of experience in inorganic, materials chemistry, and security (approximately 7 years). Materials chemistry emphasizes nanoporous materials, specifically focused on materials that include metal-organic frameworks, zeolites, covalent organic frameworks, hierarchical porous carbons, and mesoporous silica, for potential applications.

Joshua Torgeson is an Earth Scientist on the Signatures research team in the Earth System Science Division at PNNL. He received an MS degree in Geology from the University of Minnesota; his thesis work, "Hydrobiogeochemical interactions in the hyporheic zone of a sulfate-impacted, freshwater stream and riparian wetland ecosystem," was published in *Environmental Science: Processes & Impacts*. At PNNL, his research experience has included geochemical characterization using X-ray absorption spectroscopy (XAS), development of cost-effective sensors, radioisotope detection, and spectral-induced polarization (SIP). His XAS experience has included both extended X-ray absorption fine-structure (EXAFS) and X-ray absorption near edge structure (XANES) to investigate biogeochemical cycling in environmental systems impacted by anthropogenic activity and to assess pyrogenic organic matter dynamics. Sensor development has included ratiometric planar optodes for high-throughput monitoring of organic matter respiration and in situ monitoring of PFAS using electrical impedance spectroscopy.

Additionally, Mr. Torgeson has used his expertise in 3D modeling and additive manufacturing to optimize commercially available sensors for environmental monitoring, including drone-based nuclear decommissioning. His expertise in geochemical characterization and electrochemistry experience has proven invaluable for development of SIP as a tool for monitoring complex subsurface environments, supporting the Induced Spectral Interrogation Technology for the Environment (INSITE) project.

Scott Unger, PhD, is a Sustainability Engineer at PNNL. His research and expertise focuses on development of sustainability metrics through LCA, techno-economic analysis, and cost-benefit analysis. Previous research projects include generation of life cycle inventories for proprietary industrial chemicals, development of environmental metrics to quantify RCRA and CERCLA remediation actions, and development of environmental product declarations for multinational manufacturers of consumer and industrial products (e.g., disinfectants, vitamin supplements). He has also calculated and characterized ecotoxic impacts from national-scale increased biofuel production, developed climate action plans for municipalities in the greater Phoenix area, and calculated cradle-to-grave impacts from renewable vs. non-renewable energy systems.

Jingyi Zhang, PhD, is an Energy Systems Analyst in the System Assessment Center at Argonne National Laboratory. Her research primarily revolves around mitigating environmental impacts in diverse systems, such as algal systems, lithium-ion batteries, solar energy, wastewater treatment, and saline water desalination, by using life cycle analysis. Prior to joining Argonne, Ms. Zhang served as a postdoctoral researcher at Northwestern University. She obtained her PhD in Mechanical Engineering from Case Western Reserve University.

Appendix III

Coalition of Manufacturers of Complex Products

March 1, 2024

Katrina Kessler, Commissioner
Minnesota Pollution Control Agency
520 Lafayette Rd. N.
St. Paul, MN 55155-4194

Via eComment at https://minnesotaoah.granicusideas.com/

Re: Planned New Rules in Minnesota Governing Currently Unavoidable Use Determinations About Products Containing Per- and Polyfluoroalkyl Substances, Revisor's ID No. R-4837

Dear Commissioner Kessler:

The Coalition of Manufacturers of Complex Products (Coalition) appreciates the opportunity to respond to the Minnesota Pollution Control Agency's (MPCA) request for comments regarding the planned new rules for the MPCA's determination of currently unavoidable uses (CUU) of per- and polyfluoroalkyl substances (PFAS) in products. Additionally, the Coalition submits requests a CUU determination for complex consumer and durable goods, their components and replacement parts, as part of this rulemaking.

Coalition members manufacture equipment and products by assembling tens to hundreds or thousands of parts, components, and raw materials to provide, in many cases, critical services to society. These include commercial and consumer products such as appliances, vehicles, vessels, motors, heating, ventilation, air conditioning, refrigeration, and water heating equipment (HVACR- WH), electronics, and their replacement parts. Coalition members serve and support nearly every major sector in the nation, providing critical products and services for government agencies, the military, law enforcement, first responders, and public safety, food and agriculture (including commercial fishing and sea farming), energy, transportation and logistics (including for commuting and for island residents), public works and infrastructure support services, critical manufacturing, the defense industrial base, conservation, and life-saving climate control and ventilation in homes, hospitals, schools, and eldercare facilities, or food preservation and processing and for critical health and life sciences. Services dependent on refrigeration include everything from the prevention of dangerous food spoilage to life-giving medicines, vaccines, proteomics, therapeutics, blood plasma, and other temperature-dependent elements in the life sciences and pharmaceutical sectors. Collectively these products and services constitute a vital part of the economy, at all levels, including for public safety..

A ban on the use of complex consumer and durable goods in Minnesota would significantly disrupt the safety, health, and functioning of society in Minnesota, national security, and critical infrastructure. The Coalition is pleased to provide additional input below, in response to MPCA's questions listed in the request for comments. In addition to our responses, the Coalition is including comments submitted on establishing currently unavoidable use exemptions in Maine (Attachment 1). Please note that the information there was developed with both Maine and Minnesota's programs in mind.

1. **Should criteria be defined for "essential for health, safety, or the functioning of society"? If so, what should those criteria be?**

In Section 1 of Attachment 1, the Coalition provides the definition for "complex consumer and durable goods." In Section 2 of Attachment 1, the Coalition explains the criteria by which complex consumer and durable goods are essential to the safety and functioning of critical domestic infrastructures such as national defense, transportation, communications, and construction, and are used in security systems, safety lighting, and life-saving medical devices.

2. **Should costs of PFAS alternatives be considered in the definition of "reasonably available"? What is a "reasonable" cost threshold?**

The Coalition submits that MPCA should not only consider the costs of PFAS alternatives, but all associated costs, such as the costs that companies incur over the time it takes to implement alternatives across the complex supply chains for these products. In Section 4 of Attachment 1 the Coalition describes the length of time it takes to identify and implement alternatives across complex supply chains.

3. **Should unique considerations be made for small businesses with regards to economic feasibility?**

The Coalition supports taking small business considerations into account in providing exemptions from reporting and the law's product ban.

4. **What criteria should be used to determine the safety of potential PFAS alternatives?**

In determining the safety of potential PFAS alternatives, the Coalition supports a risk-based approach, as described in Section 3 of Attachment 1.

5. **How long should PFAS currently unavoidable use determinations be good for? How should the length of the currently unavoidable use determination be decided. Should significant changes in available information about alternatives trigger a re-evaluation?**

The Coalition supports CUU determinations that are not time limited. As described in Section 4 of Attachment 1, identification of and transition to safer feasible alternatives for PFAS in complex consumer and durable goods takes many years. The variety of ways in which PFAS components are used and the myriad of products does not align with a single transition period.

6. **How should stakeholders request to have a PFAS use be considered for currently unavoidable use determination by the MPCA? Conversely, could stakeholders request a PFAS use not be determined to be currently unavoidable? What information should be submitted in support of such requests?**

The Coalition supports exemptions by product category. The Coalition does not support redirecting limited state resources to requests for not unavoidable determinations. Product manufacturers are in the best position to know their products and whether alternatives are feasible. The Coalition supports having the same criteria that Maine requires for CUU exemptions.[1]

7. **In order to get a sense of what type of and how many products may seek a currently unavoidable uses determination, please share what uses and products you may**

[1] Maine Department of Environmental Protection, *PFAS in Products: Currently Unavoidable Uses* (Last visited February 29, 2024).

submit a request for in the future and briefly why. There will be a future opportunity to present your full argument and supporting information for a possible currently unavoidable uses determination.

The Coalition respectfully requests that MPCA grant an exemption for the product category of complex consumer and durable goods, as defined in Section 1 of Attachment 1. The Coalition believes that this product category fulfills all of the requirements for a CUU determination.

8. **Should MPCA make some initial currently unavoidable use determinations as part of this rulemaking using the proposed criteria?**

Yes. Due to the essential nature of and the additional time needed to find alternatives, CUU determinations should be part of the proposed rule. We ask that complex consumer and durable goods be included. To avoid uncertainty around the extremely negative socio-economic consequences of a ban on complex consumer and durable goods, CUU determinations should be made as soon as possible. The proposed rule should include a process for requesting additional exemptions.

9. **Other questions or comments relating to defining currently unavoidable use criteria and the process MPCA uses to make currently unavoidable use determination.**

The Coalition believes that a CUU exemption should apply to the 2032 ban and the reporting requirement, set to become effective in Minnesota as of January 1, 2026.

* * *

The Coalition would welcome an opportunity to discuss these comments with you and answer any questions. The Coalition respectfully requests that MPCA grant our request to provide a currently unavoidable use exemption in proposed and final regulations for complex consumer and durable goods, their components and replacement parts. For further information about these comments, please do not hesitate to contact Martha Marrapese, Partner at Wiley Rein LLP, at (202) 719-7156 or mmarrapese@wiley.law.

Enclosure

Coalition of Manufacturers of Complex Products

March 1, 2024

Melanie Loyzim, Commissioner
Maine Department of Environmental Protection
17 State House Station
Augusta, Maine 04333-0017
PFASProducts@maine.gov

Re: Request to Maine for a Currently Unavoidable Use Exemption for Complex Consumer and Durable Goods, their Components and Replacement Parts

Dear Commissioner Loyzim:

The Coalition of Manufacturers of Complex Products (Coalition) appreciates the opportunity to submit to the Maine Department of Environmental Protection (MDEP) this request for a currently unavoidable use (CUU) exemption pursuant to 38 M.R.S. §1614 for "complex consumer and durable goods, their components and replacement parts."

Coalition members manufacture equipment and products by assembling tens to hundreds or thousands of parts, components, and raw materials to provide, in many cases, critical services to society. These include commercial and consumer products such as appliances, vehicles, vessels, motors, heating, ventilation, air conditioning, refrigeration, and water heating equipment (HVACR-WH), electronics, and their replacement parts. Coalition members serve and support nearly every major sector in the nation, providing critical products and services for government agencies, the military, law enforcement, first responders, and public safety, food and agriculture (including commercial fishing and sea farming), energy, transportation and logistics (including for commuting and for island residents), public works and infrastructure support services, critical manufacturing, the defense industrial base, conservation, and life-saving climate control and ventilation in homes, hospitals, schools, and eldercare facilities, for food preservation and processing and for critical health and life sciences. Services dependent on refrigeration include everything from the prevention of dangerous food spoilage to life-giving medicines, vaccines, proteomics, therapeutics, blood plasma, and other temperature-dependent elements in the life sciences and pharmaceutical sectors. Collectively these products and services constitute a vital part of the economy, at all levels, including for public safety.

As explained below, in response to the criteria specified by MDEP for requesting a CUU exemption, Coalition members produce complex consumer and durable goods with internal components that may contain substances in the class of substances defined broadly as per- and polyfluoroalkyl substances (PFAS) at 38 M.R.S. §1614(1)(F). The use of PFAS in these applications warrants an exemption from both Maine's reporting program and 2030 ban. There is an exceptionally low or no likelihood of exposure to PFAS from using these products, and the process of identifying where PFAS are present, researching feasible alternatives, and implementing changes throughout these large and complex supply chains will take many years beyond January 1, 2030.

1. Description of Individual Product Category.

Maine's law is entitled "SALE OF CONSUMER PRODUCTS AFFECTING THE ENVIRONMENT". As written, the requirements of this law apply the more general concept of a "product," defined in 38 M.R.S. § 1614(1)(G) as:

> "an item manufactured, assembled, packaged or otherwise prepared for sale to consumers, including its product components, sold or distributed for personal, residential, commercial or industrial use, including for use in making other products."[1]

The inclusion in the definition above of items that are sold and distributed *for commercial and industrial use* extends well beyond items that are sold to individuals and households.[2]

Given its scope, the Coalition is extremely grateful that Maine's law offers a rational approach to product identification, and specifically allows manufacturers to supply information for categories of products, rather than for each individual product or product type.[3] According to 38 M.R.S. §1614(5)(C), the Department may "identify products by category or use that may not be sold" (emphasis added) and "prioritize the prohibition of the sale of product categories" (emphasis added). According to 38 M.R.S. §1614(5)(D), MDEP may "specify specific products or product categories in which it has determined the use of PFAS is a currently unavoidable use" (emphasis added).[4] Maine's website specifies that a separate proposal must be submitted for each individual product category. In these comments we explain how "complex consumer and durable goods" is an individual product category.

To make the expansive scope of this law rational and targeted so that it addresses Maine's concerns, and do so in an efficient manner, the Coalition respectfully urges Maine to think broadly in establishing exempt product categories. The definition of a CUU in the law offers support for

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[1] Under subparagraph H, a "product component" is defined as an identifiable component of a product, regardless of whether the manufacturer of the product is the manufacturer of the component.

[2] The expansive scope is echoed in the Frequently Asked Questions (FAQs) prepared by MDEP. In response to the question "What products must be reported? "DEP responds:

> "38 M.R.S. §1614 (1)(G) defines a product as "an item manufactured, assembled, packaged or otherwise prepared for sale to consumers, including its product components, sold or distributed for personal, residential, commercial or industrial use, including for use in making other products." The statute defines "product component" as "an identifiable component of a product, regardless of whether the manufacturer of the product is the manufacturer of the component."
>
> All products and product components sold in Maine for personal, residential, commercial, or industrial use are subject to this program. If a product is offered for sale in Maine for one of those purposes, the Manufacturer of the product must report the amount of PFAS in their product."

In response to the question "Are products that are sold for industrial or commercial use treated differently than those meant for personal or residential use?" MDEP responds:

> "No, under the law all products, regardless of whether they are sold for personal, residential, commercial, or industrial use are treated the same.

The law also requires reporting for components of the final product and products that are sold to be incorporated into another product. (38 M.R.S. §1614(1)(G))."

[3] 38 M.S.C. 1614(2)(B).

[4] MDEP, *PFAS in Products: Currently Unavoidable Uses* (Last visited February 29, 2024).

this approach, speaking in terms of "a use of PFAS" absence of a reference to a "product", "individual product category" or the term "industrial sector." It states:

> "a use of PFAS that the department has determined by rule under this section to be essential for health, safety or the functioning of society and for which alternatives are not reasonably available."[5]

Examples of the uses we ask to be exempt include, but are not limited to, HVACR-WH equipment, boats, marine vessels, automobiles, off-highway vehicles, farm equipment, personal assistive mobility devices, household appliances, consumer electronics, furniture, tools, industrial, commercial and consumer lighting installation equipment, sports equipment, and medical equipment. These items, when categorized as complex consumer and durable goods, qualify as a "product category" under the Maine law because the use of PFAS in all of these products is essential for the health, safety, or functioning of society.

Accordingly, the Coalition asks MDEP for a CUU determination for use in complex consumer and durable goods, their components and replacement parts. Complex consumer and durable goods are manufactured items that are sold and distributed for personal, residential, commercial, or industrial use. It is appropriate to treat them as a product category because of the high degree of complexity associated with identifying and requesting an exemption for each and every affected component.

A. <u>Proposed Language for this Exemption</u>.

We request that the term "complex consumer and durable goods" be defined similar to the language found in the Toxic Substances Control Act (TSCA) § 6(c)(2)(D) to mean:[6]

> "electronic devices, mechanical devices, and manufactured goods composed of multiple components, with an intended useful life of 3 or more years, where the product is intended for consumer, commercial, or industrial use and is typically not consumed, destroyed, or discarded after a single use, and for which the components would be impracticable to redesign or replace."

Pursuant to 38 M.R.S. §1614(1)(B), we offer the following language to describe the exemption:

> "Complex consumer and durable goods, their components, and replacement parts, including but not limited to:
>
> a. Cooling, heating, ventilation, air conditioning, water heating and refrigeration equipment.
> b. Vehicles, including watercraft and marine vessels, automobiles, off-highway vehicles, farm equipment, personal assistive mobility devices, e-scooters, and e-bikes.
> c. Solid state and LED industrial, commercial and consumer lighting and system installations and smart home systems.
> d. Consumer electronics and communication devices.
> e. Medical devices.

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5 38 M.R.S. §1614(1)(B).

6 15 U.S.C. § 2605(6)(c)(2)(D).

The Coalition does not think Maine's law requires the use of brick codes or HTS codes to implement CUU exemptions. We do not support requiring their use as a condition for qualifying for a CUU exemption.

The Coalition's proposed approach is the kind of pragmatic thinking Maine needs to address such a critical issue. Instead of having to review and sign off on hundreds or more individual product exemptions, MDEP can address all of them under the sole product category of complex consumer and durable goods. This idea has been adopted by the federal government under TSCA.[7]

If MDEP chooses another approach, then the Coalition supports all requests in that regard for the products listed above as well as others. Additionally, the Coalition suggests that a product category can be a group of chemicals, such as fluoropolymers or refrigerants. For manufacturers of these chemicals, the fluoropolymers and refrigerants are their products. They are manufactured from other chemical components and packaged and sold for commercial and industrial use to manufacture other products and components, including complex consumer and durable goods. If MDEP permits an exemption for a product, product category, or use based on a request by a single manufacturer (or a group of manufacturers), the Coalition urges Maine to ensure that the exemption applies to all manufacturers of those products or uses.[8] Ultimately, the Coalition believes that the number of requests that Maine may receive to exempt various kinds of complex consumer and durable goods will highlight the need for a complex consumer and durable goods category as the most effective way to ensure that Maine will not be deprived of essential goods when the 2030 ban becomes effective.

2. Use Information In Complex Consumer And Durable Goods That Are Essential For The Health, Safety, And Functioning Of Society.

Complex consumer and durable goods are essential to the safety and functioning of critical domestic infrastructures such as defense, aerospace, communications, indoor climate control, cooling systems, transportation, communications, and construction. These products are used in security systems, lighting, life-saving medical devices, military equipment, and for transitioning to a clean energy-based economy. Coalition members serve and support nearly every major sector in the nation, providing critical products and services for government agencies, the military, law enforcement, first responders, and public safety, food and agriculture (including commercial fishing and sea farming), energy, transportation and logistics (including for commuting and for island residents), public works and infrastructure support services, critical manufacturing, the defense industrial base, conservation, and life-saving climate control and ventilation in homes, hospitals, schools, and eldercare facilities, for food preservation and processing and for critical health and life sciences. Services dependent on refrigeration include everything from the prevention of dangerous food spoilage to life-giving medicines, vaccines, proteomics, therapeutics, blood plasma, and other temperature-dependent elements in the life sciences and pharmaceutical sectors. Collectively, these products and services constitute a vital part of the economy, at all

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[7] For example, EPA is proposing to exempt wire harnesses and semiconductors from the PIP 3:1 product ban. Decabromodiphenyl Ether and Phenol, Isopropylated Phosphate (3:1); Revision to the Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 82287 (Nov. 24, 2023).

[8] The Coalition does not support granting CUU determinations that exclude other market participants. Such a determination would be contrary to 38 M.R.S. §1614(5)(C) and (D) which refer to products by category or use, not by manufacturer or groups of manufacturers.

levels, including for public safety. Put in the context of MDEP's proposed definition of "essential for health, safety or the functioning of society,"[9] a ban on complex consumer and durable goods could disrupt normal societal functions and jeopardize the health and safety of Maine citizens.

PFAS chemicals are on the minds of every lawmaker at the local, state, federal and international level. Exposure to these PFAS must be addressed with expediency and pragmaticism. Unfortunately, getting caught up in the Maine law meant to regulate PFAS are many products that we rely on every day that present low or no potential for exposure. These products could be outright banned by 2030 if Maine's current approach does not shift toward a more inclusive and pragmatic version. Right now, any manufacturer who sells a product in Maine will be required by 2025 to report to the state if the product contains one of nearly 8,000 chemicals designated as PFAS. By 2030, the PFAS needs to be out of the product, or they must stop selling them in the state.

Complex consumer and durable goods are necessary to maintain current lifestyles. We all have systems in our house that have PFAS enclosed in them. Thermal insulation, heating, wiring, and lighting systems are examples. Think about your refrigerator, microwave, car, computer, and most starkly, heat pumps. Heat pumps are designated as energy efficient to cool and heat homes, and Maine goes so far as to give rebates to its citizens for putting them in their homes. Under the current law, they will be banned by 2030 because the refrigerants in them contain PFAS. The refrigerants are in a closed system, and these are the kind of products that maintain their integrity.

Another example is commercial and recreational boats. The supply chain for these complex products is fragmented, with around 3000 boat builders in the US. All electrical components, tubing, speakers, electronics, fuel systems, vents, dispensers, nozzles, all ordered from a catalogue and there is a lot of customization. A typical boat has over 1000 components and each item has in turn several parts. There are parts (*e.g.* coolers, ignition box) assembled into the boat that are separate complex consumer or durable goods themselves.

Banning PFAS in all complex consumer and durable goods six years from now would have unprecedented national security consequences. The U.S. Department of Defense (DOD) issued a Report in August 2023 to explain these consequences. DOD classifies the use of PFAS as critical for several, common complex consumer and durable goods.[10] This report shows how complex consumer and durable goods are central to the functioning of all fundamental infrastructures that are essential to the functioning of society. Again, these include our defense capabilities, public safety, food and agriculture, energy, education, medical care, transportation, and logistics.

As the Maine Legislature stated in the preamble to Public Law 2021 c. 477, the purpose of Maine's law is "to phase out the sale of certain nonessential products containing PFAS."[11] The Coalition submits that there are no complex consumer or durable goods that are nonessential, and the failure to exempt complex consumer or durable goods as a category will inevitably result in spending more resources on CUU determinations, not to mention depriving the state of products that are essential to safety and health and functioning of society.

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9 MDEP, *PFAS in Products: Currently Unavoidable Uses* (Last visited February 21, 2024).

10 Department of Defense, *Report on Critical Per- and Polyfluoroalkyl Substance Uses, Pursuant to Section 347 of the James M. Inhofe National Defense Authorization Act for Fiscal Year 2023 (Public Law 117-263)* (August 2023).

11 Public Law 2021, c. 477, An Act To Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution (LD 1503, 130th Legislature).

3. The Specific Use of PFAS Essential for Products to Function. If this use of PFAS is required by federal or state law or regulation, provide citations.

The Coalition supports a risk-based approach to regulation of the broad category of PFAS chemicals. Such an approach aligns with the directive in 38 M.R.S. §1614(5)(C) for MDEP to "prioritize the prohibition of the sale of product categories that, in the department's judgment, are most likely to cause contamination of the State's land or water resources if they contain intentionally added PFAS." The components containing PFAS are bound or encased within complex consumer and durable goods. Therefore, there is little to no likelihood of human exposure or release to the environment during the useful life of the product.[12] Many types of PFAS that can be found in complex consumer and durable goods have not yet been sufficiently studied to confirm whether they exhibit the persistent, bioaccumulative and toxic characteristics found in the most common PFAS that were studied. Less than 1% of known PFAS are currently monitored by targeted analysis.[13] Yet, Maine's sweeping definition that captures around 8,000 PFAS would ban them indiscriminately in spite of the significant differences in characteristics among the substances that fall into that category.

In some cases, the use of PFAS in complex consumer and durable goods can be essential due to their unique properties under extreme conditions (*e.g.*, elevated or freezing temperatures, high pressure, and exposure to aggressive chemicals) and electrical and thermal insulation. They are used as neat chemicals as regulated refrigerant gases, foam blowing agents, specialty fluids, aerosol propellants, and heat transfer fluids. In cases where substitutes can be identified, the replacement process for complex consumer and durable goods often takes many years.

A. <u>Applicable Federal Laws and Regulations</u>.

38 M.R.S. §1614 subsection 4A states that "[a] product for which federal law governs the presence of PFAS in the product in a manner that preempts state authority" is out of the scope of the law. There are numerous examples of federal laws that govern complex consumer and durable goods. For instance, the list below provides examples of some of the federal laws already governing HVACR-WH products:

- EPA's Significant New Alternatives Program (SNAP) under the Clean Air Act;
- EPA's new chemicals and significant new uses program under Section 5 of TSCA;
- EPA's American Innovation and Manufacturing (AIM) Act Technology Transitions Final Rule for the Phase down of HFC's;
- Drugs, medical devices, biologics, and diagnostics and equipment authorized under the Food and Drug Act (FFDCA); and
- Devices subject to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (i.e. air purifiers).

[12] The Coalition would like to continue to see Maine regulate the disposal of PFAS-containing products through the state's waste management laws, rather than through a law instituting a PFAS ban.

[13] Nicolas Humez, Prevention of PFAS pollution & Monitoring of PFAS environmental releases, OECD Webinar (Dec. 10, 2023).

4. **Whether There Are Alternatives For This Specific Use Of PFAS Which Are Reasonably Available.**

Maine's law mandates that the manufacturers report on PFAS and remove PFAS by 2030, but in most cases the manufacturers of complex consumer and durable goods are not the origin of the PFAS ingredient. For example, the components of a heat pump are made by multiple suppliers for assembly by the manufacturer of the heat pump. The component suppliers are not normally required to provide detailed information on the ingredients they use. Due to the sheer number of parts and suppliers, it is extremely difficult to find out if and where PFAS is used.

Determining the presence of PFAS in complex international supply chains, finding potential suitable alternatives, and performing rigorous testing, reformulation, and other steps involved in implementation can easily take twenty years or more. The process begins with a preliminary screen for possible alternatives, evolves to a more in-depth analysis on performance and economic feasibility of suitable candidates, and finally results in the need for adequate performance testing to ensure safety, reliability, performance, and quality control parameters are met. Moreover, due to the myriad and diverse products which qualify as complex consumer and durable goods, there is no single time limit that would be suitable for an exemption for these products. MDEP can and should avoid the need to spend more resources to re-engage with industry and undertake additional rulemakings to extend specific product exemptions.

5. **Contact Information For The Submission.**

The Coalition thanks MDEP for consideration of this request for CUU. For more information on this request, please contact:

Martha Marrapese, Partner
Wiley Rein LLP
2050 M Street, N.W.
Washington, D.C. 20036
(202) 719-7156
mmarrapese@wiley.law

SYENSQO
ADVANCING HUMANITY

Public Comments In the Matter of Proposed New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS), Revisor's ID Number R-4828
May 21, 2025

Dear Administrative Law Judge Jim Mortenson,

On behalf of Solvay Specialty Polymers USA, LLC, member of the Syensqo Group ("Syensqo"), we appreciate the opportunity to submit public comments regarding the matter of proposed new rules governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS)

Syensqo is a global leader in advanced materials and specialty chemicals. Our tailor-made range of products and constantly evolving research offers everyday sustainable market-based solutions for next-generation transportation, resource efficiency, consumer goods, healthcare, and industrial production to accommodate U.S. consumers' needs. Syensqo, through its predecessors, has been connecting people and scientific minds for 160 years. Innovation is at our core and part of our DNA. In the United States, Syensqo employs over 4,800 people working in over 35 sites across 25 states. Our U.S. footprint includes our composite materials manufacturing site in Winona, Minnesota where we have over 200 employees. This site is critical to the American aerospace and defense industrial base and provides irreplaceable materials for military and civilian applications.

We are supportive of finding ways to address the more common and higher-risk routes of potential environmental and human health exposure associated with problematic PFAS. As a global leader in fluoropolymer manufacturing, Syensqo hopes to have an open dialogue with the state to craft meaningful policy that will address environmental risk while balancing American competitiveness and national security.

Syensqo's Partnership with the U.S. Department of Energy

We are a science company with a remarkable past, aiming to reinvent the future with our technologies, particularly in the emerging clean energy markets. In that vein, in October 2022, Syensqo was awarded a $178M grant from the Department of Energy (DOE) as part of an Infrastructure Investment and Jobs Act battery material funding program to produce a PVDF fluoropolymer production facility in Augusta, GA.[1] This facility has the potential to provide enough PVDF fluoropolymer to supply more than 5 million EV batteries per year at full capacity, and the project is expected to create more than 500 local construction jobs and 100 highly-skilled jobs. Once fully operational, our project is an

[1] *See https://www.energy.gov/sites/default/files/2022-10/DOE%20BIL%20Battery%20FOA-2678%20Selectee%20Fact%20Sheets%20-%201_2.pdf*

American investment that will fill a significant domestic supply gap with all major feedstocks, including fluorspar (a designated critical mineral), coming from North America. Our PVDF also finds its way into stationary energy storage applications, and are key to ensuring low cost and reliable storage are available to developers. Both of these applications are necessary for Minnesota to achieve the state's statutory goal of net-zero GHG emissions by 2050.

Our project is an American investment that will fill a significant domestic supply gap with all major feedstocks, including fluorspar (a designated critical mineral), coming from North America. As noted in the Biden Administration's June 2021 report on Executive Order 14017 "Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad Based Growth,"[2] PVDF is indispensable in the production of batteries as a cathode binder and separator coating material. The report further states that PVDF is a necessary component to the U.S. battery supply chain and a priority for increased investment.

Fluoropolymer Exemption

Syensqo actively promotes the continued responsible and safe manufacture, use and placement of products which are essential to U.S. industry and to the decarbonization of the global economy. We take the subject of PFAS very seriously,[3] and health and safety are Syensqo's top priorities.

We request that the MPCA exclude fluoropolymers from the scope of the regulation. This step would recognize the distinct differences in PFAS chemistries, particularly with respect to fluoropolymers which present low hazards to human health and the environment. These chemistries are vital to the critical industries that are the foundation of our sustainable future, including hydrogen-based energy, semiconductor manufacturing, EV batteries, and aerospace and defense applications. Some of the most important uses of fluoropolymers that Syensqo provides include:

- Critical solutions in electronic and hydraulic systems, exterior coatings and o-rings and gaskets for aerospace and defense applications.
- Cathode binders and separators in high-capacity lithium-ion batteries for electric vehicle applications. All lithium-ion batteries need PVDF in order to operate safely and effectively.
- Solar panels, hydrogen membranes, wind turbines and semiconductors, all of which rely on these products' specific properties.

Specifically, fluoropolymers are molecules that are inert, relatively large and have "documented safety profiles; are thermally, biologically, and chemically stable, negligibly

[2] http://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf
[3] For example, see Syensqo's recent settlement with the NJ Department of Environmental Protection, https://www.solvay.com/en/press-release/solvay-reaches-settlement-new-jersey-department-environmental-protection-pfas.

soluble in water, nonmobile, nonbioavailable, nonbioaccumulative, and nontoxic."[4] Moreover, 96% of the commercially available fluoropolymer market meets the Organisation for Economic Co-operation and Development (OECD) definition of polymer of low concern (PLC).[5]

One of the biggest threats to Syensqo's ability to advance US competitiveness is regulatory uncertainty on PFAS. The U.S. Department of Defense recently highlighted this in their recent report on, "Report on Critical Per- and Polyfluoroalkyl Substance Uses."

> "PFAS are critical to DoD mission success and readiness and to many national sectors of critical infrastructure, including information technology, critical manufacturing, health care, renewable energy, and transportation…
>
> Emerging environmental regulations focused on PFAS are broad, unpredictable, lack the specificity of individual PFAS risk relative to their use, and in certain cases will have unintended impacts on market dynamics and the supply chain, resulting in the loss of access to mission critical uses of PFAS. These market responses will impact many sectors of U.S. critical infrastructure , including but not limited to the defense industrial base. Collectively, international and U.S. regulatory actions to manage PFAS' environmental impacts and identify and eliminate PFAS from the market, and the resulting market changes, pose risks to DoD operations and the defense industrial base supply chain. In addition, impacts to the global PFAS supply chain will present risks to the DoD Foreign Military Sales program and to North Atlantic Treaty Organization interoperability."[6]

The MPCA has an opportunity to recognize the fundamental differences in PFAS compounds, fluoropolymers' importance to critical product supply chains, and new innovations with fluoropolymer production technology. This will allow space to refocus on the potential threats that certain PFAS pose to human health, and how best to curtail the higher-risk routes that more problematic PFAS get into the environment.

Syensqo Comments on Manufacturer Reporting

Confidential Business Information (CBI)

Syensqo relies on strong confidentiality protections for our proprietary business information to maintain our competitiveness globally. As a fluoropolymer producer, our materials are found in a number of products critical to national security and in key supply chains for batteries, semiconductors, hydrogen fuel cells, and more. In many cases, the addition of one of Syensqo's materials is a key differentiating factor between competing

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[4] *See Korzeniowski, S.H.; Buck, R.C.; Newkold, R.M.; El Kassmi, A.; Laganis, E.; Matsuoka, Y.; Dinelli, B.; Beauchet, S.; Adamsky, F.; Weilandt, K.; et al. A Critical Review of the Application of Polymer of Low Concern Regulatory Criteria to Fluoropolymers II: Fluoroplastics and Fluoroelastomers. Integr. Environ. Assess. Manag. 2023, 19, 326–354.*

[5] *Ibid.*

[6] *See https://www.acq.osd.mil/eie/eer/ecc/pfas/docs/reports/Report-on-Critical-PFAS-Substance-Uses.pdf*

articles in the marketplace. As such, our customers seek protections to ensure that this information is safeguarded not only from competitors, but also geopolitical adversaries.

It is vitally important that the MPCA develops a robust system to protect manufacturers' intellectual property as part of the implementation of this statute. Minnesota law recognizes the economic value of "trade secrets" as defined in the Minnesota Uniform Trade Secrets Act (§ 325C.01), and further requires that this information be treated as "nonpublic data" per the Minnesota Government Data Practices Act (§ 13.37).

Syensqo encourages the MPCA to allow respondents to claim that the information submitted as part of this reporting requirement are "trade secrets" and therefore considered non-public or confidential information. The process for which these claims are asserted and the appropriate steps for respondents to take should be thoroughly detailed in the final rulemaking. On the federal level, the EPA's management of CBI as required by the Toxic Substances Control Act provides an instructive model for the MPCA to consider (see: 40 CFR 711.30)

As the MPCA works to establish CBI protections for respondents, Syensqo recommends the following for consideration or to be included in a final rulemaking:

Duplicative State and Federal Reporting:

MPCA should be aware of the potential for the information which it will be requesting may be duplicative to the U.S. Environmental Protection Agency's TSCA Section 8(a)(7) reporting rule as modified by the 2020 National Defense Authorization Act. Currently, the EPA is conducting a major reporting exercise to gather data on all PFAS materials – and articles that contain PFAS – that were imported or manufactured since 2011. At the conclusion of this data-gathering it is understood that the information will have a level of public accessibility.

Section 7036.0090 (A) of the proposed rule states that products for which federal law governs the presence of PFAS in the product in a manner that preempts state authority are exempt from reporting, but Syensqo believes that this exemption should be extended for all instances of federal reporting for PFAS.

Syensqo requests clarity on this exemption and encourages the MPCA to take steps to ensure that respondents are not required to duplicate efforts to report on a state and federal level by allowing information required by the EPA to be used for fulfilling reporting requirements. Should the MPCA require more information than what is being required by the EPA, this rulemaking should be crafted to address that information gap.

Data Protection:

Syensqo requests that the MPCA refrain from sharing the data gathered through this rulemaking with any other states or third-party organizations without the proper

measures to maintain trade secrets protections. If MPCA wishes to engage in a data sharing agreement, the details of such agreement should be subject to public review and a comment period for an appropriate period of time.

Moreover, the MPCA should establish within the rulemaking the system by which a respondent is able to be notified of a disclosure of their submission which contains a trade secret both within and outside the state. This would be consistent with current Minnesota law (§ 115.A.06), "when data is classified private or nonpublic pursuant to this subdivision the commissioner may: (1) use the data to compile and publish analyses or summaries and to carry out the commissioner's statutory responsibilities in a manner which does not identify the subject of the data; or (2) disclose the data when the commissioner is obligated to disclose it to comply with federal law or regulation but only to the extent required by the federal law or regulation. (b) The subject of data classified as private or nonpublic pursuant to this subdivision may authorize the disclosure of some or all of that data by the commissioner."

Joint Submission Option:

MPCA should consider implementing a "joint reporting" system to aid manufacturers and chemical suppliers be compliant while addressing CBI needs and the lack of information at certain points in the supply chain. Specifically, the process as described by the EPA in their recently released final rulemaking for TSCA 8(a)(7) would be a favorable model to emulate.[7] This system would enable respondents to submit all pertinent information to extent it is known or reasonably ascertainable to them while sending a request to their suppliers to provide confidential information directly to supplement as a "secondary submitter." This system does not force suppliers to disclose confidential information to their customers, therefore maintaining CBI protections between both parties.

Thank you for the opportunity to provide comments. If you have any questions, please do not hesitate to contact me.

Very truly yours,

David A. Cetola
Vice President, Global Government Affairs
Syensqo Group
dave.cetola@syensqo.com

[7] See *https://www.federalregister.gov/documents/2023/10/11/2023-22094/toxic-substances-control-act-reporting-and-recordkeeping-requirements-for-perfluoroalkyl-and#:~:text=116%E2%80%9392%2C%20section%207351),to%20report%20information%20described%20in*

RECEIVED
By: OAH on 5/21/2025

Elizabeth Nugent Morrow Attachment

Beveridge & Diamond

1900 N Street, NW, Suite 100
Washington, DC 20036

May 21, 2025

Submitted via the Minnesota Office of Administrative Hearings eComments Website

Minnesota Pollution Control Agency
520 Lafayette Road North
St. Paul, Minnesota 55155-4194

Re: Response to Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees, Revisor's ID Number R-4828

On behalf of a client who is a specialty chemicals company, thank you for the opportunity to comment on the Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees. Our client supports the State of Minnesota's commitment to the environment and transparency, and respectfully makes the following recommendations for the final rulemaking to ensure effective and accurate compliance by manufacturers:

- Extend the January 1, 2026 reporting deadline. Our client respectfully requests a one-year extension of the current January 1, 2026 reporting deadline. The current timeline presents significant challenges for manufacturers as the reporting deadline is less than seven months away. Manufacturers often produce a wide range of products, with some companies selling thousands of SKUs. Requesting and gathering data on potential PFAS contained in products and their components requires significant time and resources, including coordination with numerous suppliers who may not have the information readily available. Additionally, manufacturers require sufficient lead time to establish internal protocols to collect, verify, and report PFAS data based on final rules. Given that Minnesota's regulations will not be finalized until late 2025, it is reasonable to extend the reporting deadline. Our client recommends at minimum an extension until January 1, 2027, which would align with the recently enacted New Mexico House Bill 212. Consistency in compliance deadlines would help to reduce the compliance burden. Our client believes an extension of the reporting deadline to January 1, 2027 would provide manufacturers with the necessary time to comply fully and accurately, ensuring the integrity of data submitted to the Minnesota Pollution Control Agency ("MPCA").

- Adopt a "known to or reasonably ascertainable by" ("KRA") due diligence standard. Our client urges MCPA to adopt a "known to or reasonably ascertainable by"

reporting standard into the final rule. The term "known to or reasonably ascertainable by" is defined in 40 C.F.R. § 705.3, to mean all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know. This approach would be consistent with the Environmental Protection Agency's TSCA Section 8(a)(7) PFAS Reporting Rule (40 C.F.R. Part 705) due diligence standard, as well as Maine's recently amended PFAS in Products law (38 MRSA §1614). Alignment of reporting standards across jurisdictions reduces confusion and complexity for manufacturers and promotes compliance. Furthermore, the KRA standard is a well-understood threshold for manufacturers to determine what information must be reported. Manufacturers with complex, global supply chains may be unable to obtain complete PFAS data from upstream suppliers, therefore Minnesota's currently proposed due diligence requirement may not be feasible. The KRA standard would allow companies to conduct reasonable due diligence without being held liable for data they could not access despite best efforts.

Our client is committed to environmental stewardship and protection of human health and supports the MPCA's efforts to regulate PFAS in products in Minnesota. Our client believes that the recommendations made in this letter will facilitate compliance and enhance effectiveness of the reporting program. We appreciate your consideration of these comments.

May 21, 2025

Submitted via email to: https://minnesotaoah.granicusideas.com/

The Honorable Jim Mortenson
Office of Administrative Hearings
600 North Robert Street, P.O. Box 64620
St. Paul, Minnesota 55164-0620

Re: Comments on PFAS in Products – Reporting and Fees

Dear Honorable Judge Mortenson:

The Motorcycle Industry Council (MIC), the Specialty Vehicle Institute of America (SVIA), and the Recreational Off-Highway Vehicle Association (ROHVA) represent several hundred manufacturers of motorcycles, all-terrain vehicles (ATVs), recreational off-highway vehicles (ROVs which are also commonly referred to as side-by-sides or UTVs), and aftermarket parts and accessories. We submit the following regarding MPCA's request for comments related to the rulemaking on PFAS reporting and fees.

MIC, SVIA, and ROHVA appreciate MPCA's willingness to consider our previously submitted comments as well as the calls and meetings you have granted to our associations and our representatives in Minnesota. We understand the need for clear and well-thought-out reporting requirements. The assessment of fees associated with reporting reinforces the need for MPCA to ensure that reporting is as efficient and effective as possible to minimize the amount of reporting manufacturers will be subject to, while providing MPCA with the required information for the program. The wide variety of products manufactured by our members and the remaining regulated parties also call for a degree of flexibility in reporting. We have the following comments based on these crucial factors:

1. The requirement to report all PFAS January 1, 2026, is exceedingly difficult if not impossible for most manufacturers to meet and we request a 36-month extension (rather than the proposed 90-day extension period) to ensure adequate time for testing, supply chain certification, and reporting.
2. Under the law[1] the MPCA is provided authority to grant information requirement waivers[2] and we request that they provide waivers for our powersports vehicles, replacement parts and fluids/refrigerants.
3. Manufacturers must be able to group sufficiently comparable products together in reporting which we believe is allowed under the law.
4. The payment process must be flexible and allow purchase orders, invoices, electronic funds transfer, credit cards, checks and other means to ensure that large and small

[1] Minn. Stat. § 116.943
[2] Minn. Stat. § 116.943, Subdivision 3(a)

businesses are able to track administrative costs without being overly burdened by limited payment options.

5. Fee amounts must be minimized and should be reasonable without requiring manufacturers to pay fees for their supplier parts and components that are part of our finished product vehicles.
6. Recertification should be extended from the proposed annual reporting to a timeframe of every 3-5 years. This would help to reduce the impact on our member companies doing business in Minnesota and on the MPCA staff, while still providing the State with ample information and revenue.

Background Information:

MIC represents a diverse group of members ranging from small woman-owned powersports clothing suppliers, to large distributors of powersports gear and replacement parts, to manufacturers of complex powersports vehicles who are facing a massive task in determining which of the hundreds of component parts may contain PFAS and securing certification from hundreds of suppliers across the global supply chain to ensure accurate reporting. We are having to do this on scores of product vehicles and compile reporting for a patchwork quilt of laws and regulations across states. As has been indicated to the MPCA staff through many conversations, meetings, and written comments, this requires significant effort and time to accomplish in order to fully comply with the law and proposed regulations. MPCA's rulemaking will obviously add to this already daunting workload as we work in parallel to find alternatives for products in a short time.

Powersport global supply chains are complex and multi-layered. PFAS may be intentionally or unintentionally added at various points in the manufacturing processes. Companies may not be aware of the exact amounts of intentionally or unintentionally added PFAS constituents or concentrations. It may be many years before the ability to identify and determine the quantity of intentionally or unintentionally added PFAS becomes available to manufacturers. We are concerned that the January 1, 2026, deadline is largely unattainable, particularly for vehicle manufacturers with hundreds of parts and the diverse supply chain noted above. This overly aggressive timeline will cause manufacturers to discontinue sales or operations in MN while consumers in the state will go to neighboring states to purchase products that are then imported into Minnesota. We request MPCA provide more flexibility and time for reporting requirements of complex products such as powersports vehicles by extending the reporting deadline by 36 months.

Manufacturers often have products with variations unrelated to chemical composition or potentially the content of PFAS. Manufacturers must be allowed to take advantage of instances of sufficient similarity in the content of PFAS in products to reduce unnecessary waste in producing multiple reports containing similar PFAS content information. Multiple reports containing similar information will also unnecessarily drive up the cost of reporting for manufacturers and negatively impact business.

Manufacturers utilize many different payment methods. Large manufacturers may have access to payment methods that are not available for smaller manufacturers. Payment methods that make sense for smaller manufacturers may not work for larger manufacturers having more complex

tracking needs. In order to meet the reasonableness standard MPCA must ensure the payment process is as flexible as possible for large and small manufacturers. Without sufficient flexibility, manufacturers may find themselves unable to make payments or have payments delayed.

Finally, the cost of this law, including costs of testing to identify PFAS, testing to determine the suitability of alternatives, redesigning and developing products, and removing and managing product already in the market is already overwhelming for manufacturers. Fees assessed for reporting and the frequency of reporting must be reasonable and minimized to avoid unnecessary additional burden.

For these reasons, we request MPCA work with manufacturers to develop the most flexible reporting timing and process with reasonable and minimal cost. Should you have any questions, please do not hesitate to contact me at sschloegel@MIC.org or 703-446-0444 x 3202.

Sincerely,

Scott P. Schloegel
Senior Vice President, Government Relations

RECEIVED
By: OAH on 5/21/2025
Maureen Hardwick Attachment

21 May 2025

SUBMISSION TO:
Minnesota Pollution Control Agency (MPCA)
Via Minnesota Office of Administrative Hearings eComments Website

Comments Regarding the Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees, Chapter 7026, Revisor ID No. RD-4828

The undersigned appreciates the opportunity to share comments regarding Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees, including considerations regarding the impact on hydrofluorocarbons (HFCs) used in pressurized metered dose inhalers (MDIs). We share below our comments highlighting the key considerations relevant to MDIs as Minnesota moves forward in its deliberations.

1) *FDA-Regulated Products, Including MDIs, Should Be Exempt from the Need to Report Intentionally Added PFAS to the State of Minnesota*

Three medical propellants used in MDIs - HFC-134a, HFC-227ea, and HFO-1234ze - are considered PFAS under Minnesota's definition. Rapid removal of these propellants from the supply chain and the market – especially with no alternatives immediately ready to take their place – is not technically or economically feasible and would risk the health of patients in Minnesota and around the world. For example, prematurely banning these products could lead to drug shortages of essential, life-saving medicines. The Minnesota legislature recognized the risk of prohibiting PFAS in life-saving applications and exempted drugs and medical devices from the PFAS testing requirements and PFAS prohibition under the enacting statute. Minn. Stat. 116.943 Subdiv. 8.

Given these legislative exemptions, it is unclear why manufacturers of these FDA-regulated products should be included in the scope of required reporting under the proposed permanent rules. Since Minnesota is not testing or prohibiting intentionally added PFAS in these products, MPCA should specify that drugs and medical devices approved by the U.S. Food and Drug Administration (FDA) are exempt under proposed rule section 7026.0090(A). The contents of a drug or medical device are well-known to FDA, and the agency will not

approve one of these products if the product does not pass the Agency's benefit-risk assessment related to human health, including evaluation of toxicity.

In short, the Minnesota legislature already exempted FDA-regulated products from the primary requirements of the statute and MPCA should follow this example by clearly articulating that FDA-regulated products are exempt from reporting requirements. At minimum, MPCA should articulate why manufacturers of drugs and medical devices are required to report intentionally added PFAS in FDA-approved products and explain how MPCA plans to use such PFAS data given the clear exemptions in the enacting legislation.

2) *Manufacturers Lack Clarity Regarding the Logistics of Reporting and Sufficient Time to Gather Data and Submit Required Reports*

While the proposed rules purport to address the substance of the required reporting, the rules do not clearly address the logistics of conveying the required information to MPCA. For example, MPCA's Statement of Need and Reasonableness indicates that it plans to use the Interstate Chemicals Clearinghouse (IC2) High Priority Chemicals Data System as the reporting portal. However, the platform is unlikely to be accessible before late 2025, giving companies very little time to familiarize themselves with the platform, the specifics of the required information, and the logistics of the submission.

The lack of clarity regarding the logistics of reporting makes the January 2026 deadline highly burdensome to manufacturers. It is atypical for environmental reporting to be mandated without clear indication of what and how information should be conveyed to an agency. Instead, agencies typically open reporting platforms many months in advance of a reporting deadline to give companies sufficient time to become familiar with the specifics and technicalities of the submission process. For example, the U.S. Environmental Protection Agency anticipates opening its CDX platform for required reporting under the Toxic Substances Control Act Section 8(a)(7) in April 2026 in preparation for an October 2026 reporting deadline under the federal PFAS Reporting Rule. Conversely, in Minnesota, companies may only have a matter of weeks to understand the platform before reports are due in January 2026. Simply, this is not enough time. The state of Minnesota needs to clearly articulate how information must be submitted to MPCA under these proposed permanent rules and should understand that its failure to articulate any such information to date is exacerbating the administrative and regulatory burdens of these proposed rules. Additionally, it is unclear how confidential submissions may be executed via the platform and what steps IC2 and MPCA will take to ensure the protection of confidential information through the platform.

Accordingly, MPCA should extend the deadline for reporting by at least one year.

3) *Reporting of PFAS by Concentrations in Product Lacks Methodological Clarity and Is Inconsistent with Efforts to Identify the Volume of a Chemical with Potential for Environmental Release*

The enacting statute, Minn. Stat. 116.943 Subdiv. 2(2), prescribes that manufacturers of products containing intentionally added PFAS must submit information that includes "the amount of each PFAS, identified by its chemical abstracts service registry number, in the product, reported as an exact quantity determined using commercially available analytical methods or as falling within a range approved for reporting purposes by the commissioner." The proposed rules are based on the final clause of this statutory provision and require manufacturers to report concentrations of PFAS within prescribed ranges, or by Total Organic Fluorine, if the amount of PFAS is not known within applicable due diligence standards. This approach is flawed.

Identifying the concentration of a specific PFAS chemical in a given product does not identify that product's potential risk to human health or the environment. Traditionally, reporting of environmentally sensitive substances requires companies to tell an environmental agency the volume of the chemical manufactured, imported, or used in the jurisdiction. Doing so allows the agency to evaluate the potential environmental impact from the amount of the substance in the jurisdiction and account for volume potentially released to the environment. Additionally, volume-based reporting is consistent with both existing Canadian PFAS reporting obligations[1] and forthcoming federal PFAS reporting obligations. Conversely, Minnesota's proposed concentration-based reporting is untethered to traditional scientific principles of chemical reporting and risk assessment. For example, the concentration of a specific PFAS in a specific product does not indicate whether that PFAS or product poses a risk to human health or the environment. Additionally, the proposed rules do not clearly set forth what method(s) a manufacturer may use to calculate the reported concentration in the product. Lastly, as discussed above, the amount of PFAS used in a particular application may provide a benefit relative to the risk of the disease or condition treated by a medical product containing PFAS.

MPCA should clarify the definitions of product, component, and homogeneous materials. For example, the current definition of "component" under the proposed rules means "a distinct and identifiable element or constituent of a product." This definition does not sufficiently articulate whether dyes, colorings, and coatings are themselves "components" or whether the definition of a "component" applies only to the product element to which that dye, coloring, or coating is applied.

[1] See: Canada Gazette, Part 1, Volume 158, Number 30: SUPPLEMENT.

Finally, the concentration of Total Organic Fluorine does not identify the concentration of PFAS. MPCA should remove Total Organic Fluorine as a reporting standard for a rule intended to evaluate intentionally added PFAS content.

About IPAC

IPAC was formed in 1989 in response to the mandates of the Montreal Protocol and fully supported a timely and effective transition away from chlorofluorocarbons (CFCs) under the Montreal Protocol that balanced patient health and environmental concerns. IPAC's mission is to ensure that environmental policies relevant to inhaled therapies are patient-centric and appropriately balance both patient care and sustainability objectives. IPAC's members: AstraZeneca, Bespak, Boehringer Ingelheim, Chiesi, Cipla, GSK, Kindeva, and Teva. Further information is available at www.ipacinhaler.org.

IPAC thanks MPCA for its consideration of the above comments.

RECEIVED
By: OAH on 5/21/2025

PERFORMANCE FLUOROPOLYMER PARTNERSHIP

May 21, 2025

Office of Administrative Hearings
Attn: Mr. William Moore
600 North Robert Street
St. Paul, Minnesota 55164-0620

Submitted electronically to the Office of Administrative Hearings Rulemaking eComments website at https://minnesotaoah.granicusideas.com

Re: Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees. Revisor ID: R-4828. Minnesota Rules: Chapter 7026

The American Chemistry Council's Performance Fluoropolymer Partnership appreciates the opportunity to submit comments to the Minnesota Pollution Control Agency (hereafter "MPCA") on the Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees (hereafter "proposed rule") and the accompanying Statement of Need and Reasonableness (hereafter "Statement"). The Partnership's members are some of the world's leading manufacturers, processors, and users of fluoropolymers, including fluoroelastomers and perfluoropolyethers.[1] The Partnership's mission is to promote the responsible production, use, and management of fluoropolymers, while also advocating for a sound science- and risk-based approach to their regulation.

As an initial matter, the fact that the reporting and fee rules are just now being proposed, with barely seven months remaining before reports are due, and the fact that the planned reporting platform has not been released for evaluation and testing puts all stakeholders, particularly industry stakeholders who may have a reporting obligation, at a significant disadvantage with respect to providing comments informed by having a view of the full context of MPCA's planned implementation of Minnesota Statutes §116.943. Significantly more time and clarity are needed to apply for and await decisions on trade secret data protection requests and to allow the supply chain to consider, codify, and execute supply chain reporting agreements. It is unreasonable to expect that manufacturers (or any member of the public) can provide adequate and thorough comments on the current proposed rule with no understanding of the reporting platform and whether, from the perspective of manufacturers with reporting obligations, it is being designed in a way that does not frustrate compliance. The regulated community needs regulatory certainty to appropriately provide the required information to MPCA.

In our view, studying the current Interstate Chemical Clearinghouse (IC2) database is an inadequate surrogate and therefore an unreasonable surrogate. The reporting requirements in this proposed rule are significantly more complex than what we see in the current IC2 database.

[1] https://fluoropolymerpartnership.com

At this time, manufacturers do not understand whether they will be responsible for submitting a single report covering all products requiring reporting, or if multiple, separate reports for each product (or similar products made of homogeneous materials) will be required. We strongly recommend that reporting should not be required until 12 months after MPCA has accounted for feedback on a test version of the reporting system and verified that the reporting system is ready to receive reports from manufacturers. This is especially important in light of the large number of manufacturers that will likely be reporting under the proposed rule, over a compressed reporting period.[2]

The legislature has given the Commissioner authority to grant extensions to manufacturers, and we strongly recommend that the Commissioner do so until the reporting system is tested and ready to receive reports from manufacturers.[3]

Our remaining comments are organized below according to the appearance of text in the proposed rule.

7026.0010 DEFINITIONS

Brief description of the product. We are unable to provide a meaningful comment on the proposed definition because MPCA has not provided a description of the size and nature of the character-limited description.

Chemical identifying number. We support the flexibility afforded in the proposed definition; however, as discussed under 7026.0030, submitters should be permitted to use any acceptable chemical identifying number in their reports, regardless of whether a CAS number exists for a substance.

Chemical name. We do not agree that a specific IUCPAC chemical name is necessary if a chemical identifying number is provided. It is also reasonable to anticipate that manufacturers of proprietary chemicals with confidential chemical identities will not risk the potential revelation of such confidential chemical identity information by manufacturers situated far down a complex global supply chain. Once such information is revealed, it affects and may nullify a manufacturer's ability to protect its proprietary information globally. Submitters should be

[2] As MPCA notes at page 40 of the Statement of Need and Reasonableness for this proposed rule, US EPA estimates that there are approximately 131,157 importers of articles potentially containing PFAS and, using its professional judgment, EPA assumes that roughly 10% of those importers will submit reports under EPA's PFAS reporting regulations at 40 CFR Part 705. MPCA asserts that it expects ***fewer*** manufacturers to report under the proposed rule due to differences between the MPCA and US EPA rules, however this expectation defies logic since: (i) the definition of "PFAS" used by EPA is ***narrower*** than the definition used by MPCA (so more substances will be subject to reporting under the MPCA proposed rule); and (ii) the EPA regulation only applies to ***importers*** of PFAS-containing articles, while the MPCA proposed rule applies to domestic manufacturers of PFAS containing products ***as well as*** importers of such products. Therefore, it is reasonable to anticipate that the number of manufacturers reporting for the MPCA rule will exceed the number of article importers reporting for the EPA regulation.

[3] Minn. Stat. §116.943 Subd3(d). *"The commissioner may extend the deadline for submission by a manufacturer of the information required under subdivision 2 if the commissioner determines that more time is needed by the manufacturer to comply with the submission requirement."* We note that the legislature has not prescribed a specific length of an extension and therefore it is in the commissioner's discretion to grant extensions based on the completion of important milestones.

permitted to provide commercial or trade names as an alternative to specific IUPAC names. Therefore, we urge MPCA to modify the definition of "chemical name" to include the IUPAC name for the substance, the trade name for the substance, or the name associated with the substance's chemical identifying number. We suggest adding the following sentence to the end of the currently proposed definition of "Chemical name":

> Where the IUPAC name is proprietary or unavailable, the trade or commercial name or the non-confidential chemical name associated with the United States Environmental Protection Agency Toxic Substance Control Act (TSCA) accession number or other chemical identifying number.

Component. The proposed definition of component would cover packaging "only when the packaging is inseparable or integral to the final product's containment, dispensing, or preservation." This element of the proposed definition goes far beyond MPCA's statutory authority, which is unreasonable. The statute does not contain the world "packaging", much less contemplate oversight and reporting of packaging as a product component in the highly generic way articulated in the proposed definition. MPCA's statutory authority is limited to product and product components that contain intentionally added PFAS, which is not reflected in the proposed definition, and MPCA appears to acknowledge that fact in the Statement.[4] We therefore suggest the following clarifying language:

> "Component" means a distinct and identifiable element or constituent of a product. Component incudes packaging only when the packaging contains intentionally added PFAS, ~~and~~ is inseparable or integral to the final product's intended function or use ~~containment, dispensing, or preservation~~, and when the packaging is the product.

Still, even with our proposed modification, the proposed definition is difficult to square with real world examples of how products are shipped in commerce. For example, Company A produces a substance that it delivers to its customer, Company B, in sealable bins manufactured by Company C. The sealable bins are used to contain the product during transit and preserve its purity by protecting it from dust, moisture, or other sources of contamination. When Company B receives the product, it dumps the product into a hopper or other holding equipment, and Company A takes the sealable bins back for reuse. If the sealable bins contain a gasket or other component that contains intentionally added PFAS, would MPCA consider the gasket a "component" of the product that was contained in (and subsequently removed from) the sealable bin? Under what circumstances would MPCA see any of the companies having a reporting obligation? If the sealable bins were themselves sold as a product in Minnesota, we could see that Company C (or the first seller or distributor of Company C's sealable bins in Minnesota) could have a reporting obligation, but we cannot deduce from the proposed definition how MPCA would see potential obligations for Company A or B. It is unreasonable that assignation of responsibility and, therefore, an understanding of a company's potential compliance obligations are so unclear this close to the reporting deadline.

[4] Page 25: "Similarly, the statute does not define packaging and, where packaging is considered an integral "component" and/or that packaging is the sole component of a product containing intentionally added PFAS, then the responsible manufacturer must report on that product."

Distribute for sale. We suggest the following modification to more clearly and accurately reflect the scope of the law:

> "Distribute for sale" means to ship or otherwise transport a product with the intent or understanding that the product will be sold or offered for sale in Minnesota by a receiving party after the product is delivered."

Function. The proposed definition appears to deviate significantly from the statutory definition of "intentionally added". The statutory definition is clear: "Intentionally added" means PFAS deliberately added during the manufacture of a product where the continued presence of PFAS is desired in the final product or one of the product's components to perform a specific function. The proposed definition of "function" seems to go well beyond the legislative intent by requesting information on "PFAS when intentionally incorporated in any stage in the process of preparing a product or its constituent components . . ." The language could be interpreted to cover any PFAS used in any aspect of the manufacturing process (e.g., in a lubricant that helps keep machinery running reliably), which goes far beyond the statute. We offer the following language to better align the definition of "function" with the statute:

> "Function" means the explicit purpose or role ~~served by~~ of intentionally added PFAS ~~when intentionally incorporated at any stage~~ in ~~the process of preparing~~ a product or ~~its constituent~~ product component~~s for sale, offer for sale, or distribution for sale~~.

We support the proposed use of the TSCA functions list with which some, but certainly not all, manufacturers will be familiar. We understand MPCA's desire to reduce free-text entries to the extent possible. However, without a view into the reporting system, we cannot comment on the adequacy of the approach described in the Statement (p. 25).

Manufacturer. The proposed definition of "manufacturer" does not provide necessary clarity to identify the entity ("manufacturer") who has primary compliance responsibility. As noted in previous comments to MPCA, we predict significant confusion and a high likelihood of duplicative or otherwise inaccurate reporting emerging from the current definition of manufacturer, which includes companies whose brand is attached to a product in addition to an actual producer of a good.[5] We are concerned that duplicative reporting will likely result in a meaningful overestimation of the amount of PFAS in products in Minnesota and any conclusions about human or environmental exposure based on such estimates. MPCA's lack of a risk-based approach by grouping all PFAS together with no regard to their diverse chemical, physical, and toxicological properties compounds such concerns.

For example, consider a scenario in which Company A contracts Company B to manufacture a private label product carrying Company A's brand name and logo. Based on the proposed regulatory definition, both Company A (the brand owner) and Company B (the

[5] Performance Fluoropolymer Partnership. November 2, 2023. Comments in response to *Planned New Rules Governing Reporting by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS), Revisor's ID Number R-4828*.

producer of the product) would be “manufacturers” with reporting obligations for the same product. Company A will likely be unable to submit the report described at 7026.0030 because, in the case of brand licensing, the licensor typically has no visibility or oversight of its licensees’ supply chains. Company A is unlikely to know the components that go into Company B’s product and whether Company B uses intentionally added PFAS, much less the specific type or concentration (among other things). It is unreasonable to lay the compliance burden on Company A.

The sale of products by independent distributors presents a different and perhaps more difficult challenge. For example, consider a scenario in which a manufacturer (Company A) manufactures a product bearing Company A’s brand name and logo and sells that product to an independent distributor located outside of Minnesota. Company A does not sell its product to purchasers in Minnesota, but, unbeknownst to Company A, the out-of-state distributor sells Company A’s product to a Minnesota purchaser. In this scenario, Company A would appear to bear sole responsibility for reporting its product to the Agency, based on the proposed definition, even though Company A has no idea that its product is being sold in the State. This is not an uncommon scenario. Again, it is unreasonable to lay the compliance burden on Company A.

As these examples illustrate, the proposed definition creates confusion and uncertainty about the entity that is required to report a product and, in many instances, would place the burden of reporting on an entity that has no visibility on whether its product is being sold in Minnesota. To address this concern, the regulation must provide greater clarity concerning the entities that will be responsible for reporting. In particular, we urge the Agency to specify in the regulations that primary responsibility for reporting a product containing intentionally added PFAS falls on the entity that first sells the product or offers the product for sale in the State of Minnesota. Only these entities will know with certainty which products are sold in the State, and placing responsibility squarely on these entities will help reduce the possible double counting of products sold or offered for sale.

We strongly recommend that, in an attempt to add clarity, MPCA consider the following changes to the proposed definition:

> "Manufacturer" means the person that creates or produces a product, that has a product created or produced, or whose brand name is legally affixed to the product, <u>whichever is first to sell, offer for sale, or distribute for sale the product in the state</u>. In the case of a product that is imported into the United States when the person that created or produced the product or whose brand name is affixed to the product does not have a presence in the United States, manufacturer means either the importer or ~~the first~~ domestic distributor of the product, whichever is first to sell, offer for sale, or distribute for sale the product in the state.

Numeric product code. We appreciate MPCA’s acknowledgement that “[n]ot all products have the same code system assigned to them.”[6] However, without access to the

[6] Statement, page 26.

reporting system, we cannot adequately comment on how MPCA plans to implement what it proposes, which is an unreasonable situation given the narrow window until the reporting deadline. That said, we strongly recommend that MPCA provides flexibility in the use of codes to be able to group products under one product code when doing so makes sense. For example, MPCA should be clear that it will allow flexible use of the multi-layered Harmonized Tariff Schedule (HTS) codes (e.g., 6-, 8-, or 10-digit codes) for categorizing groups of products. More specifically, a manufacturer should be permitted to use the broadest applicable product code to describe a group of products for which all of the criteria in 7026.0030, subpart 1(A)(1)(a) can be satisfied.

Significant change. MPCA could provide better legal clarity by specifying "intentionally added" PFAS and offer the following text:

> "Significant change" means a change in the composition of a product that results in the addition of a specific intentionally added PFAS not previously reported in a product or component or a measurable change in the amount of a specific intentionally added PFAS from the ~~initial~~ amount reported previously that would move the product into a different concentration range listed under part 7026.0030, subpart 1, item C.

We suggest not using the word "initial" as it causes confusion. See our comments below concerning Section 7026.0100.

Used product. The explanation in the Statement does not address the phrase "or that is otherwise offered for resale" in the proposed statute.[7] It speaks only to sales by retailers. We interpret the word "otherwise" in that phrase to mean "not by a retailer" and suggest offsetting the phrase "or that is otherwise offered for resale" with commas to emphasize that difference.

7026.0020 PARTIES RESPONSIBLE FOR REPORTING

The late issuance of MPCA's proposed permanent rules likely makes the formation of supply chain agreements contemplated in the section impossible within the few months remaining before the current deadline for product reporting. There is insufficient time to identify all the relevant manufacturers in the supply chain, negotiate responsibilities, put legal agreements and protections in place, collect and aggregate data, and other actions that a reporting agreement would necessitate. We strongly recommend that the commissioner use the discretion provided in the statute to grant an extension to manufacturers who wish to explore and potentially report as a group.

Subpart 1. This subpart states that a manufacturer (or group of manufacturers) "must submit a report for each product," which could be interpreted to mean that a separate report must be submitted for each product or product component. Elsewhere in the proposed rule and Statement, MPCA makes clear that multiple products can be included in a single report. MPCA

[7] Statement, page 27.

should modify the language of Subpart 1 to clarify that multiple products and components may be included in a single report.

Subpart. 2.C. We cannot comment on the appropriateness and reasonableness of "format specified by the commissioner" as a concept.

Subpart. 2.D. In our reading, the subpart does not contemplate the scenario in which a group of manufacturers covered by an agreement is represented by an authorized representative who would pay a fee on behalf of all members of the agreement. The use of "all manufacturers" suggests that MPCA anticipates separate payments from each member of an agreement and, moreover, that failure of one manufacturer to submit a fee could invalidate the report with respect to all manufacturers covered by the report. We think this outcome would be unreasonable. We strongly recommend that MPCA clarify that a group of manufacturers can elect to make a single payment through their authorized representative and, importantly, that such an arrangement will be accommodated in whatever payment mechanism is to be used.

7026.0030 REPORT; REQUIRED INFORMATION

Subpart 1. We suggest the following clarification to the first sentence:

> A manufacturer or group of manufacturers of a product that is sold, offered for sale, or distributed <u>for sale</u> in the state and that contains intentionally added PFAS must submit a report to the commissioner on or before January 1, 2026.

We realize that the sentence in the proposed rule is verbatim that in the statute; however, we also note that the legislature appropriately clarifies the extent of "distributed" in Subdivision 5(b) of the statute, which says:

> The commissioner may by rule identify additional products by category or use that may not be sold, offered for sale, or **distributed for sale in this state** if they contain intentionally added PFAS and designate effective dates. (Emphasis added.)

Similarly, in Subdivision 2(d) the legislature specified that:

> A person may not sell, offer for sale, or **distribute for sale in the state** a product containing intentionally added PFAS if the manufacturer has failed to provide the information required under this subdivision and the person has received notification under subdivision 4." (Emphasis added.)

We strongly recommend that the purpose of distribution (for sale in the state) as clarified in Subdivisions 2 and 5 be operationalized throughout the rule to prevent misinterpretation that movement through the state, but not for the purpose of sale in the state, could be an action that triggers a compliance obligation.

Also, although the legislation does not specify a practicable reporting standard (e.g., known to or reasonably ascertainable), it is impractical and unreasonable not to include such a reporting standard in the implementing regulations. The final rule must contain a reporting standard that acknowledges the realities of information flow up and down complex, multi-layered, global supply chains for the massive number of products and components subject to reporting." The State of Maine made the same error in its initial PFAS in product law and subsequently adopted the known or reasonably ascertainable standard in amendments to the initial law.[8]

In reality, many manufacturers will be unable to provide all of the information elements that they "must include" in the report detailed in this section. They will also be unable to get the information necessary to evaluate whether products meet the criteria for grouping at A(1)(a)(i-iv).

This highlights the unanswered question of whether information gaps in a report, despite reasonable efforts to fill those gaps, will be considered non-compliance by MPCA. The proposed rule is not at all clear on this point, which creates unreasonable uncertainty about when a manufacturer will be in or out of compliance. We strongly recommend that MPCA reconsider this section and section 7026.0080 (Due Diligence) such that a manufacturer's inability to provide some of the required information because, as an example, entities in its supply chain are unresponsive or affirmatively refuse to provide requested information, is not considered out of compliance if the manufacturer can provide documentation of its good faith information collection efforts.

Subpart 1.A(1)(a)(i-iii) and 1.A(b)(i-iii). We offer the following suggestions to enhance consistency with the statute and legal clarity:

i. the intentionally added PFAS chemical composition in the products are the same;
ii. the intentionally added PFAS chemicals in the products fall into the same reporting concentration ranges;
iii. the intentionally added PFAS chemicals in the products provide the same function in each product; and

Subpart 1.A(2)(a). Many manufacturers organize their products by HTS codes. Therefore, we recommend that the option of using HTS codes be made available for all products, not just imported products.

Subpart 1.B. For clarity, add the phrase "Intentionally added" before "PFAS chemicals".

Subpart 1.B(1). As discussed earlier, submitters should be permitted to provide an alternative to the specific IUPAC name for a substance, since upstream suppliers can be expected to withhold specific IUPAC names for proprietary chemicals. Therefore, we reiterate

[8] 38 M.R.S. § 1614(1)(D-2). "Known to or reasonably ascertainable by" means, with respect to a person, all information in the person's possession or control as well as all information that a reasonable person similarly situated might be expected to possess, control or know.

our request that MPCA modify the definition of "chemical name" in 7026.0010 to include the IUPAC name for the substance, the trade name for the substance, or the name associated with the substance's chemical identifying number, or an otherwise structurally descriptive generic name.

Subpart 1.B(2). Chemicals may have proprietary identities, and it is unreasonable to expect that a manufacturer of a proprietary chemical would share its Chemical Abstracts Service Registry number (CASRN) with entities several layers down the supply chain. Should those entities not adequately protect the proprietary information, that information would lose its protection globally. Therefore, we strongly recommend allowing the use of any of the types of chemical identifying numbers listed at 7206.0010 Subpart 5.

Subpart 1.C(1)(a-h). We recommend that MCPA adopt the same concentration ranges for reporting the maximum concentration of PFAS by weight in an imported article in U.S. EPA's Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances.[9] Those ranges are:

- Less than 0.1% by weight
- At least 0.1% but less than 1% by weight
- At least 1% but less than 10% by weight
- At least 10% but less than 30% by weight
- At least 30% by weight

Many manufacturers are likely to have classified their products according to these ranges to the extent that the concentrations are known or reasonably ascertainable, and it is unclear that a different regulatory group of ranges is needed. We strongly encourage MPCA to retain proposed Subpart 1.C(1)(i).

Finally, in the context of "significant change" and trade secret protection, we recommend that MPCA give manufacturers the option to combine the two lower ranges for product grouping purposes. The precision associated with these very low concentrations is more likely to be competitively sensitive. Also, analytical variability for testing articles could easily fluctuate above and below 1000 ppm, triggering a potential range change, which would be deemed a "significant change".

Subpart 1.C(2). We do not support the use of total organic fluorine (TOF) measurements as a proxy or surrogate for the amount of PFAS in a product or product component, and TOF data should not be used to make conclusive statements about the type, source, or concentration of any specific PFAS or group of PFAS substances. TOF should only be used as a screening method, as it is prone to identifying inorganic fluorides or other organofluorine substances that do not meet Minnesota's definition of PFAS. In fact, U.S. EPA, in its most recent updated draft guidance on PFAS disposal and destruction offers the following caution:

[9] 88 Fed Reg 70516, See Table 1 to Paragraph (a)(3)(viii), page 70556.

> *TOF analysis is an ongoing research area: data users must recognize the benefits of receiving general screening data for a wide array of potentially present PFAS, while also recognizing the limitations and uncertainties inherent in not knowing which PFAS or class of PFAS is present in the sample, including uncertainties associated with potential health risk. In addition, to minimize the risk of PFAS false positives, techniques within a validated method or methods must be developed that demonstrate effective separation and removal of inorganic fluorine from organic fluorine (Koch et al., 2020). TOF is not specific to PFAS, and any fluorine-containing compounds (e.g., pesticides, pharmaceuticals) that are retained during extraction would be included in the organic fluorine measurement.*[10]

MPCA should also review TOF protocols used by manufacturers for the extraction and accounting for inorganic fluorine according to standardized, validated protocols.

Also, MPCA does not define the phrase "commercially available analytical methods" To create an even playing field and to help ensure that data on which future regulatory decisions may be based are sound, MPCA must elaborate its intention regarding baseline criteria or performance standards for "commercially available analytical methods" and the laboratories generating such data. "Commercially available" describes the analytical method, not the entity running the method, and therefore MPCA should not restrict the ability to run analysis to only those labs that sell their analytical services. MPCA should also allow for an appropriately qualified in-house laboratory to provide any needed analytical support, especially given the uncertainties around commercial laboratory capability and capacity. We suggest the following language:

> <u>"Commercially available analytical method" means any test methodology used by a laboratory that performs analyses or tests for third parties to determine the concentration of intentionally added PFAS in a product, or an in-house laboratory running such method. Commercially available analytical methods must have been independently validated and must include quality control parameters and performance criteria that satisfy method objectives and assure data quality. A laboratory used by a manufacturer to determine the concentration of intentionally added PFAS in a product must be certified to the most current version of ISO/IEC 17025, the U.S. Environmental Protection Agency's Good Laboratory Practice Standards, or the Organization for Economic Cooperation and Development's Principles of Good Laboratory Practice.</u>

ISO/IEC 17025 is an international standard that sets a minimum threshold for the competence, impartiality, and consistency of laboratories, and therefore the accuracy and

[10] U.S. Environmental Protection Agency. Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances—Version 2 (2024). April 8, 2024. Page 58. https://www.epa.gov/system/files/documents/2024-04/2024-interim-guidance-on-pfas-destruction-and-disposal.pdf.

reliability of their testing.[11] It is recognized globally as the core requirement for laboratory competency. The U.S. EPA's Good Laboratory Practice Standards "prescribes good laboratory practices for conducting studies relating to health effects, environmental effects, and chemical fate testing."[12] The Organization for Economic Cooperation and Development's Principles of Good Laboratory Practice (GLP) "is a quality system concerned with the organisational [*sic*] process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported."[13]

Also, we highlight the very practical concern that, depending on the number of manufacturers testing for reporting, there is likely insufficient third-party laboratory capacity to handle all the testing that the program described in the proposed rule would require. Therefore, manufacturers acting in good faith should not be precluded from using documented in-house methods or penalized for otherwise being delayed in their reporting due to third-party laboratory capacity constraints. The Department must make accommodation for such circumstances. Not doing so would be unreasonable.

Subpart 1.D. It is reasonable to expect that product assemblers may not know the function of an intentionally added PFAS in a product or product component. For example, a company that assembles an electronic product from many components may know, but only if informed by a supplier, that PFAS are intentionally added to the coating on a circuit board but not know the function. MPCA needs to make accommodation for this very real scenario.

Subpart 3. See our comments at Subpart 1 of the section regarding the impracticality of the report requirements and due diligence standard.

7026.0040 REPORTING UPDATES

We request that MPCA clarify whether a manufacturer will be able to use the reporting system to submit the types of updates described in this section and whether other means will also be available. Also, it is our interpretation that, if a manufacturer removes all intentionally added PFAS from a notified product, that manufacturer would no longer have any reporting obligations, including required updates or annual recertification, since the manufacturer would no longer be a "manufacturer" as defined in the statute. In addition, we ask MPCA to clarify whether the product will be removed from the IC2 database once all intentionally added PFAS has been removed from the product.

Subpart 1. In our reading, the proposed language here is overly broad. The phrase "new product information" at (2) should be clarified as information other than a significant change directly relevant to the reporting requirements at 7026.0030, and (3) should be clear that it

[11] ISO/IEC 17025. General requirements for the competence of testing and calibration laboratories. (2017; reaffirmed 2023).
[12] 40 CFR Part 792.
[13] Organization for Cooperation and Development. 2005. Good Laboratory Practice: OECD principles and guidance for compliance monitoring. OECD Publishing, Paris, https://doi.org/10.1787/9789264012837-en.

applies to new products containing intentionally added PFAS. We suggest the following changes:

(1) a significant change was made to a product;
(2) new product information that is not information about a significant change but is otherwise directly relevant to the information required under part 7026.0030 was provided to a manufacturer or group of manufacturers in a supply chain agreement as described in section 7026.0020; or
(3) a new product containing intentionally added PFAS was sold, offered for sale, or distributed in or into the state if the new product is not already represented by a previously reported product group as provided at 7026.0030 Subpart 1.A(1)(a).

Subpart 2. The proposed regulation uses the word "recertification", but "certification" is used in neither the statute nor elsewhere in the proposed rule. We offer the following language for clarity:

Annual ~~re~~certification. If an update is not required under subpart 1, a manufacturer or group of manufacturers must ~~re~~certify the existing report submitted under part 7026.0030 by February 1 each year.

The change from "recertify" to "certify" should carry over to the discussion of fees.

7026.0050 WAIVERS

Subpart 4. This section does not address the question of whether a manufacturer is out of compliance if the commissioner fails to decide on a waiver request after the established reporting due date. In our reading of the language at B, MPCA has contemplated that scenario. It is unreasonable to leave such a critical compliance question unanswered. It is also unreasonable to deem a manufacturer that acted in good faith and is awaiting a decision from the commissioner out of compliance. We suggest the addition of the following in Subpart 4:

C. A manufacturer or group of manufacturers that has submitted a waiver request in compliance with this section but has not received a decision from the commissioner prior to the established reporting due date will not be considered out of compliance.

Subpart 4.A. MPCA proposes that manufactures must submit their waiver request "at least 30 days before the applicable reporting due date." It is our interpretation that manufacturers can submit a waiver request well before the reporting due date to give MPCA sufficient time to consider the request.

7026.0060 EXTENSIONS

Subpart 3. As with section 7026.005, the proposed rule does not address the question of whether a manufacturer is out of compliance if the commissioner fails to decide on an extension request by the established reporting due date. It is unreasonable to leave such a

critical compliance question unanswered. It is also unreasonable to deem a manufacturer that acted in good faith and is awaiting a decision from the commissioner out of compliance. We suggest the addition of the following:

> D. A manufacturer or group of manufacturers that has submitted an extension request in compliance with this section but has not received a decision from the commissioner prior to the established reporting due date will not be considered out of compliance.

Subpart 3.A. MPCA is proposing that manufactures must submit their extension request "at least 30 days before the reporting due date established in part 7026.0030." It is our interpretation that manufacturers could submit an extension request well before the reporting due date to give MPCA sufficient time to consider the request.

Subpart 3.B. We anticipate that, in many cases, a 90-day extension may not be sufficient to seek, receive, and synthesize information described in section 7026.0030. Therefore, we recommend that MPCA give the option for a 180-day extension and, importantly, include language clarifying that manufacturers can seek additional extensions if the manufacturer, acting in good faith, is unable to acquire the information as described in the plan for completion (Subpart 2D). It should also be made clear in the final rule that a manufacturer acting in good faith who is unable to provide all the information described in section 7026.0030 should not be considered delinquent in reporting. MPCA should also clarify that a manufacturer granted an extension request or awaiting a determination on an extension request can still sell, offer for sale, or distribute for sale the product(s) subject to the extension request.

7026.0070 TRADE SECRET DATA REQUEST

Subpart 1. The procedure for trade secret protection described in part 7000.1300 requires the Commissioner's review and approval of a trade secret request. Manufacturers must initiate the request process prior to reporting to determine whether the Commissioner will grant the request and how to proceed based on the response (remove trade secret protection or cease sale, offer for sale, or distribution for sale in Minnesota). The Commissioner is not held to a specific response time to respond to trade secret data requests, which could result in noncompliance if for any reason the Commissioner fails to respond in a timely manner.

In the absence of a final rule that clearly and unambiguously describes reporting requirements and any insight into the reporting platform, the time frame for manufacturers acting in good faith to *also* have to await a trade secret determination to plan their compliance approach is unreasonable. MPCA should include an exception to the reporting obligation at 7026.0030 that allows a manufacturer to exclude or withdraw data it has identified in good faith as trade secret and where the determination is pending or MPCA has denied the trade secret request until clarification and resolution with MPCA of a reasonable alternative for reporting that does not disclose trade secrets.

We appreciate that the proposed rule contemplates chemical name, chemical identifying number, and specific supply chain information identified in part 7026.0080, subpart 2, as eligible

for trade secret protection. However, concentration and function information can also be commercially sensitive, and we think it is reasonable to include those information elements as eligible for trade secret protection as well.

7026.0080 DUE DILIGENCE

As currently written, the due diligence standard is unreasonable and virtually ensures broad non-compliance. We disagree with the statement "This thorough approach . . . helps mitigate the risk of non-compliance, ensuring that no stage of the production process is overlooked and that the ultimate responsibility for accurate reporting is fulfilled."[14] That sentence appears to be premised on the assumption that all entities in the supply chain of a manufacturer or group of manufacturers with a reporting obligation will supply information "until all required information is known."[15] There will be gaps, and it would be unreasonable for MPCA to deem noncompliant manufacturers or a group of manufacturers acting in good faith should their requests for information go unanswered.

Subpart 2. The expectation of "until all required information is known" is unreasonable and ignores the realities of supply chains. Suppliers will not provide their trade secret information in response to a customer inquiry unless they have confidence that the customer will continue to protect it as carefully as the supplier, which cannot be guaranteed, even with the use of legal tools like non-disclosure agreements, especially if that information is destined to be shared across multiple levels of a supply chain or multiple supply chains, or reported to an agency with no assurance that trade secret status will be granted. We offer the following language to make the expectation here more reasonable:

> A manufacturer or group of manufacturers must request detailed disclosure of information required in part 7026.0030 from their supply chain necessary to obtain ~~until~~ all required information ~~is known~~ and take reasonable steps to obtain responses.

Again, MPCA must clarify that a manufacturer will not be deemed non-compliant if the manufacturer can demonstrate reasonable diligence in its requests of supply chain vendors and good faith reliance on the information received (or not received) from those vendors.

Subpart 3.A. The proposed rule contemplates that a "manufacturer or group of manufacturers must maintain documentation of all communication with other manufacturers, including emails, letters, and responses regarding PFAS reporting compliance and reporting responsibility agreements as provided in part 7026.0020, subpart 2." We interpret the language to apply only to manufacturers who participate in an agreement with other manufacturers. Also, the scope of this provision is overly broad. The requirement to maintain "all" records is an unreasonable burden, particularly if the intent of the requirement is to assure retention of records necessary to document compliance with the rule. We offer the following less burdensome language:

[14] Statement, page 37.
[15] Proposed Rule, page 13 line 13.15.

A manufacturer or group of manufacturers must maintain documentation of ~~all~~ communication with other manufacturers~~, including emails, letters, and responses~~ regarding intentionally added PFAS reporting compliance and reporting responsibility agreements as provided in part 7026.0020, subpart 2, sufficient to demonstrate compliance with this rule.

7026.90 REPORTING EXEMPTIONS

We support the exemptions listed in this section. With respect to classified information, our understanding of the proposed rule is that a product or product component is exempt from reporting requirements if information regarding that product or product component constitutes classified information under federal law. However, if the same product or product component is used in non-classified applications, it would be subject to reporting requirements only in those non-classified applications. If that interpretation is correct, it should be made explicit in the final rule. Another critical compliance question is whether a product or product component used in a classified application would be subject to the currently unavoidable use test and potentially banned in 2032. Without a comprehensive picture of the full PFAS in products program, a more complete understanding of compliance obligations is impossible.

7026.0100 FEES

Subpart 2. MPCA makes it clear in the Statement that MPCA is proposing a per-manufacturer approach and not a per-product report.[16] Although unclear in either the proposed rule or the Statement, it is our interpretation that MPCA is also not proposing a per-report fee. For example, Company A may choose to submit a report with other manufacturers for some, but not all, of its products. Company A also chooses to report alone, not as part of a group, for the remainder of its products (a possible reason could be to protect information claimed as a trade secret). In such a case, Company A would only have to pay the proposed, per-manufacturer $1,000 fee to MPCA to cover all of its products. A single manufacturer fee would cover both reports. We therefore offer the following clarifying language:

> ~~**Initial r**~~**Report.** A manufacturer must pay a $1,000 fee to submit ~~the initial report~~ under part 7026.0030, subpart 1. If a group of manufacturers is reporting or a manufacturer is reporting on behalf of multiple manufacturers as allowed under part 7026.0020, subpart 2, each individual manufacturer must pay a $1,000 fee. In no case will an individual manufacturer be required to submit more than $1,000, regardless of whether for some products or product components it chooses to submit alone or as a group of manufacturers.

[16] Statement, page 40. “The Agency did not want to impose a per-product fee that would deter manufacturers from reporting to avoid excessive costs or to avoid manufacturers potentially grouping products beyond what was allowed for in rule. It was ultimately determined that a flat fee was the most reasonable approach and should be used on a per-manufacturer basis.”

Generally, speaking we believe the adjective “initial” could be eliminated to avoid confusion. We therefore recommend that “initial” be deleted at 7026.0030 Subpart 3. Voluntary updates.

Subpart 5. We oppose the proposed imposition of a fee for submission of an extension request. In most instances, extension requests will be prompted by factors beyond the control of the manufacturer. These factors may include MPCA inaction or delayed action, such as delayed issuance of reporting guidance, delayed rollout of the reporting database, or delayed promulgation of final reporting regulations. A manufacturer should not be burdened with fees to request an extension, when the extension is, in all likelihood, necessitated by factors beyond the manufacturer’s control.

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Thank you for the opportunity to provide these comments. We would welcome the opportunity to discuss them with you and answer any questions you may have.

Jay West
Executive Director
Performance Fluoropolymer Partnership

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Carlos Gutierrez Attachment

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May 21, 2025

Minnesota Office of Administrative Hearings
Judge James Mortenson
600 North Robert Street
St. Paul, MN 55164-0620

RE: Proposed New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS), Revisor's ID Number R-4828, OAH docket number 5-9003-40410.

Judge James Mortenson,

On behalf of the Consumer Healthcare Products Association (CHPA), the national trade association representing the leading manufacturers of over-the-counter (OTC) medicines, dietary supplements, and OTC medical devices, I am writing to provide comments on the proposed PFAS reporting requirements outlined in proposed rule parts 7026.0020 to 7026.0100. My comments specifically address part 7026.0090 (Reporting Exemptions) of the proposed rule.

CHPA respectfully opposes the current language of part 7026.0090 as it fails to include a clear, necessary exemption for Food and Drug Administration (FDA) regulated consumer healthcare products. Specifically, over-the-counter medications and medical devices were explicitly exempted from the original PFAS ban in Minnesota law, yet they appear to be subject to these new reporting requirements. While exemptions 1 and 5 in part 7026.0090 may potentially apply to these products, the current language creates significant uncertainty that should be addressed through a specific amendment to the proposed rule.

Alignment with Existing Exemption Categories

The proposed rule already exempts "products where federal law governs PFAS presence in a manner that preempts state authority" (exemption category 1) and "information regarding PFAS-containing products provided to federal government agencies that is classified information" (exemption category 5). FDA-regulated consumer healthcare products logically fall within the spirit of these exemptions, as they are comprehensively regulated by federal law and manufacturers often share detailed compositional information with federal agencies. However, the current language creates unnecessary ambiguity about whether these products qualify for these exemptions.

Background and Legislative Intent

The Minnesota legislature made a clear policy decision when it explicitly exempted consumer healthcare products from PFAS restrictions in the original law. Specifically, Minnesota Statutes, Section 116.943, Subdivision 8(b) states:

"Subdivisions 4 and 5 do not apply to a prosthetic or orthotic device or to any product that is a medical device or drug or that is otherwise used in a medical setting or in medical applications regulated by the United States Food and Drug Administration."

This exemption from PFAS prohibitions for FDA-regulated products was not accidental, but rather reflected a deliberate legislative determination that these products should be treated differently due to their importance to public health and the existing comprehensive federal regulatory oversight they already face. However, while these products are exempt from the prohibitions in Subdivisions 4 and 5, they currently appear to be subject to the reporting requirements in Subdivision 2.

This creates an inconsistency - products deemed important enough to exempt from the actual PFAS restrictions are nonetheless subject to burdensome reporting requirements. The reporting requirements, as currently written, appear to contradict this legislative intent by potentially requiring reporting for products that were intentionally exempted from the underlying restrictions.

Regulatory Redundancy Concerns

FDA-regulated consumer healthcare products are subject to extensive federal oversight regarding their composition, safety, and efficacy. The FDA's rigorous approval and monitoring processes already ensure these products meet stringent safety standards. Adding state-level reporting requirements creates an unnecessary regulatory burden without corresponding public health benefits. Manufacturers already comply with comprehensive federal requirements, and adding another layer of state reporting specifically for PFAS represents duplicative regulation that increases costs without enhancing consumer protection.

Federal Preemption and Applicability of Exemption Category 1

While part 7026.0090 (A) exempts "a product for which federal law governs the presence of PFAS in the product in a manner that preempts state authority," this language creates significant uncertainty for manufacturers of FDA-regulated products. The FDA has comprehensive authority over drugs , medical devices , and dietary supplements under the Federal Food, Drug, and Cosmetic Act (FDCA). This includes authority over the ingredients and composition of these products, which extends to PFAS content.

The FDA's regulatory framework for these products includes:

- **Pre-market approval processes** for drugs and certain medical devices, which require detailed information about product composition and materials.
- **OTC drug monograph system** that establishes conditions under which certain active ingredients are generally recognized as safe and effective for specific indications without requiring individual product applications.
- **Current Good Manufacturing Practice (cGMP) requirements** that ensure the identity, purity, quality, strength, and composition of products.
- **Labeling regulations** that require disclosure of ingredients.
- **Safety reporting requirements** for adverse events.

- **Material and component standards** for medical devices.

For medical devices specifically, the FDA reviews material composition as part of the 510(k) premarket notification process. Changes in "design, material, chemical composition, energy source, manufacturing process, or indications for use" require new submissions. The FDA also evaluates biocompatibility and the safety of device materials.

These comprehensive federal regulations may indeed preempt state authority regarding PFAS in these products, but the current rule language places the burden on manufacturers to make this determination on a case-by-case basis. This creates regulatory uncertainty, potential for inconsistent application, and unnecessary compliance costs. A clear exemption would eliminate this uncertainty while still honoring the intent of exemption category 1.

Federal Reporting Requirements and Applicability of Exemption Category 5

FDA-regulated products are subject to extensive reporting requirements to federal agencies. Manufacturers must submit detailed information about product composition to the FDA through:

- **New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs)**: The Federal Food, Drug, and Cosmetic Act requires manufacturers to provide "a full list of the articles used as components of such drug" and "a full statement of the composition of such drug."
- **Medical Device 510(k) Submissions**: Manufacturers must provide detailed information about device materials and composition, particularly when there are changes "related to the design, material, chemical composition, energy source, manufacturing process, or indications for use."
- **Adverse Event Reporting Systems**: Manufacturers must report adverse events that may be related to their products, which often involves disclosure of product composition information.
- **Product Registration Requirements**: Various FDA-regulated products must be registered with the FDA, often requiring disclosure of composition information.

Much of this information may overlap with the PFAS reporting requirements, creating duplicative reporting. While exemption category 5 exempts "information regarding PFAS-containing products provided to federal government agencies that is classified information," this exemption is too narrow as it is currently written.

Supply Chain and Operational Challenges

The due diligence requirements in part 7026.0080 would create substantial operational challenges for healthcare product manufacturers, who typically have complex global supply chains. These manufacturers would need to implement extensive new processes to track, document, and report PFAS presence throughout their supply chains. Given that these products are already exempt from the actual PFAS restrictions, requiring this level of supply chain investigation seems disproportionate and could potentially threaten the availability of

important healthcare products for Minnesota consumers if manufacturers decide the compliance burden is too great.

Proposed Solution

To address these concerns and to maintain consistency with the legislature's intent to exempt FDA-regulated healthcare products from PFAS restrictions, I respectfully request that part 7026.0090 be amended to add the following exemption:

"F. a product regulated as a drug, medical device, or dietary supplement by the U.S. Food and Drug Administration (FDA) *under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 et seq., sec. 3.2(e) of 21 U.S. Code of Federal Regulations"*

This proposed language would:

1. Align the reporting exemptions with the existing PFAS ban exemptions in Minnesota Statutes, Section 116.943, Subdivision 8(b).
2. Clarify the application of exemption category 1 by explicitly recognizing that FDA-regulated products are subject to comprehensive federal regulation that may preempt state authority.
3. Expand upon exemption category 5 by acknowledging that FDA-regulated products are already subject to federal reporting requirements.
4. Provide regulatory certainty to manufacturers of FDA-regulated products.
5. Avoid unnecessary regulatory burden on products already subject to rigorous federal oversight.

Conclusion

I appreciate the agency's efforts to implement comprehensive PFAS reporting requirements. The proposed rule already includes exemptions for federally-regulated products (category 1) and information reported to federal agencies (category 5), but these exemptions as currently written create uncertainty for manufacturers of FDA-regulated consumer healthcare products.

The requested amendment would simply extend the existing statutory exemption for these products from PFAS prohibitions to also include an exemption from PFAS reporting requirements. This approach is entirely consistent with both the existing exemption categories in the proposed rule and the original legislative intent to exempt these products from PFAS restrictions under Minnesota Statutes, Section 116.943, Subdivision 8(b).

This targeted exemption would not undermine the overall goals of the PFAS reporting program while ensuring regulatory consistency and avoiding potential disruptions to healthcare product availability. It represents a logical extension of the existing exemption framework that would provide much-needed clarity to manufacturers.

Thank you for the opportunity to provide these comments. I would be happy to discuss this matter further or provide additional information if needed.

Respectfully submitted,

Carlos I. Gutiérrez
Vice President, State & Local Government Affairs
Consumer Healthcare Products Association
cgutierrez@chpa.org | 202-429-3521

cc: Commissioner Katrina Kessler, Minnesota Pollution Control Agency

RECEIVED
By: OAH on 5/21/2025

AHAM
ASSOCIATION OF HOME APPLIANCE MANUFACTURERS

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May 21, 2025

The Honorable Judge James Mortenson
Office of Administrative Hearings
600 North Robert Street
St. Paul, MN 55164

Re: Proposed New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS); Revisor's ID Number R-4828

Dear Judge Mortenson,

On behalf of the Association of Home Appliance Manufacturers (AHAM), I would like to raise the following points concerning the PFAS in Products Reporting Rule.

AHAM represents manufacturers of major, portable and floor care home appliances, and suppliers to the industry. AHAM's membership includes over 150 companies throughout the world. In Minnesota, the home appliance industry is a significant and critical segment of the economy. The total economic impact of the home appliance industry to Minnesota is $3.6 billion, more than 20,000 direct and indirect jobs, $468.5 million in state tax revenue, and more than $1.2 billion in wages. The home appliance industry, through its products and innovation, is essential to U.S. consumer lifestyle, health, safety, and convenience. Through its technology, employees and productivity, the industry contributes significantly to U.S. jobs and economic security. Home appliances are also a success story in terms of energy efficiency and environmental protection. New appliances often represent the most effective choice a consumer can make to reduce home energy use and costs.

AHAM's members produce hundreds of millions of products each year. They design and build products at the highest levels of quality and safety. As such, they have demonstrated their commitment to strong internal safety design, monitoring, and evaluation/failure analysis systems. AHAM supports the intent to protect consumers against all unreasonable risks, including those associated with the exposure to potentially harmful chemicals. AHAM also adamantly supports the appropriate use of PFAS chemicals in appliances. Together with industry design practices, test requirements, and redundant safety mechanisms, PFAS chemicals play a key role in the safety of household appliances.

Appliance manufacturers employ a complex, global supply chain for thousands of models with hundreds of thousands of components, often involving multi-tiered suppliers located on multiple continents with thousands and thousands of components. This includes an array of manufacturers, from small private firms to multinational corporations, providing chemicals, component parts, and assemblies that come together in a final manufactured article. Given the complexity of modern

supply chains, appliance manufacturers reported that to meet current reporting requirements, they must obtain supplier declarations regarding the content of components. Not only is it challenging to get such a document from the supplier of every component, but it often involves communications in several countries and languages. This rule is unique in the amount of information required at the speed at which to provide it with the complexities and mechanics of the appliance manufacturer supply chain. Knowing what is sold in Minnesota is extremely difficult for many manufacturers because many appliances are sold through national and even US-Canada retailers. In the development of this rule, we have several concerns in the proposed rule that need to be addressed before a final rule is adopted.

I. MPCA's Proposed Timeline Is Unrealistic

In alignment with this statute, the MPCA aims to create rules that offer clarity and adaptability, making compliance as straightforward as possible for manufacturers and other regulated entities. MPCA's current rulemaking schedule anticipates the final adoption of rule by January 1, 2026, which is the same date when manufacturers must report the presence of PFAS in their product. MPCA overly complicates compliance and provides manufacturers with only a few months to comply with these first-of-its-kind reporting obligations. Even with this compressed timeline, January compliance dates are challenging due to the complexities of the holiday season. Manufacturers will have an insufficient amount of time to complete reports by early December. Without additional clarity and further guidance well in advance of the reporting deadline, it will be extremely difficult for appliance manufacturers to provide the necessary data to comply.

There seems to be a significant overlap between Minnesota's reporting requirements and those of the U.S. Environmental Protection Agency (EPA) in terms of substances and product scope. Even at the federal level, EPA has had issues with their PFAS reporting rule portal. Just this week, EPA postponed the TSCA section 8(a)(7) PFAS reporting rule for nine months.[1] EPA also provides additional time for smaller manufacturers reporting exclusively as article importers. We would encourage MPCA to provide additional compliance time for smaller manufacturers who do not have the resources to comply even with the extended timeline AHAM suggests.

MPCA should also recognize the problems facing manufacturers with respect to meeting reporting requirements in other jurisdictions. Companies that distribute products in Europe are subject to the European Union's regulations on chemicals ("REACH") and persistent organic pollutants. In these instances, manufacturers are already having trouble identifying all the PFAS chemicals required to be disclosed under these rules. In addition to tracing materials through the supply chain, manufacturers are having difficulty determining whether trace amounts of PFAS are "intentionally added" or not and often occurs deep into the supply chain before a final complex article is placed onto the market. With the late issuance of MPCA's proposed permanent rules, there is insufficient time to identify all the relevant manufacturers in the supply chain, negotiate responsibilities, put legal agreements and protections in place, collect and aggregate data, and other actions that this reporting agreement would necessitate.

[1] https://www.federalregister.gov/documents/2025/05/13/2025-08168/perfluoroalkyl-and-polyfluoroalkyl-substances-pfas-data-reporting-and-recordkeeping-under-the-toxic

We do appreciate the opportunity to request extensions by December 1, 2025, but the proposed rule does not address if a manufacturer would be out of compliance if the commissioner fails to decide an extension request by the compliance date of January 1. We believe it is unreasonable for a manufacturer who acted in good faith and submitted all the necessary extension requests to be potentially out of compliance. MPCA should consider issuing temporary enforcement discretion for manufacturers that file an extension request to allow MPCA the needed time to review and to ensure that there is necessary time for the requestor to comply after a denial or acceptance. We would also request extending the 90-day extension to at least 180 days to allow the manufacturer to perform their obligated due diligence across their supply chain.

AHAM recommends that the MPCA consider imposing the reporting requirements incrementally. Under this scenario, MPCA would analyze different product categories on a risk-based approach for likelihood to cause contamination of the environment in Minnesota. This would be done by identifying PFAS by CAS number as there are roughly 15,000 PFAS that could potentially be reported. With respect to the home appliance industry, refrigerants or foam blowing agents, or other PFAS materials found in internal components, are inaccessible to consumers and warrant separate assessments. This will allow manufacturers to more effectively identify the chemicals that need to be disclosed. MPCA should prioritize the types of PFAS releases they are seeking to prevent, and subject those to scrutiny before uses that pose far less risk. Once an initial round of reporting has been completed, MPCA can then move to the next group. Such a phased approach will permit both MPCA and the regulated community to adjust the new requirements and address any practical issues that may arise. MPCA can then make any adjustments to reporting requirements if needed.

II. Lack of Reporting Platform Amplifies Delay Necessity

As the January 2026 reporting deadline quickly approaches the reporting platform does not appear to be ready prior to Fall 2025. Manufacturers could already be making thousands of entries, and this delay creates a technical burden for companies that MPCA must resolve well in advance of any reporting requirements. Canadian regulatory agencies carried out significant stakeholder outreach to iron out "bugs" from their PFAS and plastics reporting systems before the mandated deadline for reporting.

Furthermore, manufacturers still do not have a comprehensive understanding of the reporting requirements nor clarity on whether they will be responsible for submitting a single report covering all products, or if multiple, separate reports for each product will be required. Without a clear delineation of the reporting requirement's boundaries, manufacturers will not be able to provide data that MPCA can efficiently analyze for its intended goals.

MPCA should have systems in place that can manage the voluminous data that will be submitted. Manufacturers should have clarity on reporting requirements, format for submission and the necessary time to adjust their submissions to meet the platform's design specifications. MPCA must be forthcoming with those specifications if they are available. If they are not readily available, a delay in the compliance date is entirely appropriate. MPCA must also consider its testing of the system, and the time required to fix any problems.

Accordingly, AHAM requests a minimum ninety-day delay in enforcement once the reporting platform becomes publicly available. MPCA should consider a longer extension, which may be both necessary and appropriate. This will allow for increased accuracy of data submissions and increased utility of the data provided to MPCA. Similarly, we recommend that MPCA seek harmonization with other states implementing similar PFAS reporting programs, including New Mexico[2], which will require PFAS reporting in 2027 and seeking this harmonization will strengthen MPCA's reporting program and compliment the overall effort and goals of the program. Ideally, this system would be set up to harmonize existing benchmarks both nationally and internationally to ensure better compliance and accuracy.

III. Due Diligence Requirements Are Unclear

AHAM advocates for reporting mechanisms that promote flexibility and reflect reality for complex products such as home appliances. The expectation that a manufacturer or group of manufacturers must request detailed disclosure of information from their supply chain "until all required information is known" is unreasonable and ignores said realities concerning complex, global supply chains. There are confidentiality and language barriers that will hinder a true 100% supplier participation. Communicating across the globe and disclosing this communication opens the door to exposing confidential business information (CBI). Products and product components containing PFAS are often purchased without the purchaser knowing the intended function of the PFAS in the product.

With many sub-suppliers located outside of the United States, it may be difficult to obtain requisite information in a timely manner. A manufacturer should not be deemed non-compliant if the manufacturer can document and demonstrate sufficient due diligence into its supply chain vendors and good faith reliance on the information received (or not received) from those vendors.

We request that a manufacturer is only required to report information to the extent such information is "known to or reasonably ascertainable" by that manufacturer. The "known or reasonably ascertainable" standard is used by the EPA in its PFAS TSCA reporting.[3] Application of TSCA's "known to or reasonably ascertainable by" standard would allow notifying entities to rely on supplier declaration and to limit to manageable levels the scope of due diligence that manufacturers would be expected to undertake with upstream suppliers. With this, manufacturers can self-declare or do material analysis themselves if suppliers do not respond. EPA has applied this standard for years in its TSCA Chemical Data Reporting Rule and recently extended its application to the agency's PFAS reporting rule. We would encourage MPCA to model this standard.

IV. Other Concerns That MPCA Should Consider

A. Responsible Party

[2] https://www.nmlegis.gov/Legislation/Legislation?chamber=H&legtype=B&legno=212&year=25

[3] https://www.epa.gov/system/files/documents/2024-02/tsca-8a7-jan-2024-webinar.pdf

The proposed definition of "manufacturer" does not provide clarity on identity who has primary compliance responsibilities. We anticipate significant confusion and a high likelihood of duplicative reporting. For example, many manufacturers are not based in United States and have little knowledge of a product's ultimate destination. Manufacturers rely on importers and regional distributors to supply products to a state, sometimes without their knowledge. Minnesota's regulation unfairly places the burden of reporting on an entity that may have no visibility into whether its products are entering the Minnesota market. We encourage MPCA to further clarify and simplify reporting responsibilities for complicated relationships and supply chains—such as Tier 1, 2, and 3 suppliers, domestic manufacturers, foreign manufacturers, OEMs, private labelers, licensed products, distributors, and retailers. MPCA should clarify this to the greatest extent possible and consider providing illustrative scenarios outlining who is responsible in various situations, as DOE has done to clarify its own certification responsibilities and who qualifies as the "manufacturer." We also recommend that MPCA generate a table that outlines the reporting hierarchy for domestic and international manufacturers and allow third parties to report on behalf of manufacturers.

B. "Intentionally added PFAS"

AHAM requests a more precise definition of "intentionally added PFAS." The definition should consider and determine the number of stages downstream in the supply chain a manufacturer must investigate to decide as to whether or not any PFAS is intentionally added. The proposed definition appears to deviate significantly from the statutory definition[4] of "intentionally added" by requesting information on "PFAS when intentionally incorporated in any stage in the process of preparing a product or its constituent components." This language could be interpreted to cover any aspect of the manufacturing process and would make reporting even more challenging.

C. MPCA Must Limit the Choices for Manufacturers to Designate "Function"

The Agency states that its purpose is to get as many responses into standardized function categories rather than as customized, free-text entry descriptions by individual companies. To avoid a free text option, we would encourage a drop-down menu or similar feature for increased functionality and operability. PFAS function and product/component categories should be given in dropdown and selectable list formats to streamline submissions. Additionally, we request further clarity on how reporting parties can group similar models and parts together to minimize burden—similar to how manufacturers can group sales models as "basic model numbers" for energy testing and certification. This would simplify reporting and help consumers who want to navigate the database. MPCA should examine chemical reporting programs in other jurisdictions to determine the design and approach that is most effective.

[4] 325F.075 (d) "Intentionally added" means PFAS deliberately added during the manufacture of a product where the continued presence of PFAS is desired in the final package or packaging component to perform a specific function.

D. MPCA Must Provide Additional Clarity Concerning Annual Updates

It remains unclear what triggers the requirement for an annual update to the program. For example, a mere aesthetic change in a product should allow for recertification in a manner that avoids a full product update. MPCA must also provide procedures, for instance where a manufacturer removes intentionally added PFAS from a product. A manufacturer that removes intentionally added PFAS should no longer be required to report and the product, beginning with the year in which the substitution is made, should be removed from the reporting system. MPCA must also create reporting procedures for PFAS uses that are exempted under Minnesota's 2032 PFAS prohibition. Finally, MPCA must have procedures in place whereby a manufacturer can make corrections in instances when a report made in good faith and with due diligence needs to be amended or corrected. MPCA should not hold such manufacturers liable in these instances, and MPCA should not hold such reports against manufacturers as evidence of non-compliance.

E. The Fee Structure Is Unclear

Imposing disclosure and fee requirements across the entire supply chain for all PFAS-containing products entering Minnesota creates a burden for manufacturers of complex products. MPCA makes it clear in the Statement of Need and Reasonableness that MPCA does not want to impose unnecessary fees to deter manufacturers from reporting. MPCA should therefore specify that the fees listed are one-time, flat fees that will be charged to each reporting entity and not on a per-product basis. Manufacturers that report should pay the same flat fee regardless of the number of reports they submit.

F. MPCA Does Not Provide Sufficient Protection for Trade Secrets

AHAM appreciates that MPCA allows for protecting trade secrets with respect to chemical names and specific supply chain information. However, these protections are insufficient and may result in other sensitive information being released into the public domain. As mentioned above, under the notification's requirements, manufacturers must disclose the purpose and function for which PFAS are used in the product, including PFAS in any product component. For appliance manufacturers, most parts are purchased from a supplier without disclosure of the purpose and function of specific substance or material. This is often because the formulation and/or function are proprietary to that supplier. A supplier may refuse to disclose the information required by MPCA, to protect its intellectual property. As a result, the reporting entity may not have the information MPCA seeks. Therefore, MPCA should expand its protections for trade secrets, such that suppliers feel comfortable releasing the necessary information to downstream manufacturers.

Thank you for considering our views and we encourage MPCA to consider these implications before moving forward. Please contact me at jkeane@aham.org or 202-872-5955 to discuss in more detail.

Respectfully submitted,

John Keane

John Keane
Manager of Government Relations

American Chemistry Council | Center for the Polyurethanes Industry

Submitted Electronically to: MN OAH Rulemaking eComments Website

May 21, 2025

The Honorable James Mortenson
Administrative Law Judge
Office of Administrative Hearings
600 North Robert Street, P.O. Box 64620
St. Paul, Minnesota 55164-0620

Re: Minnesota Pollution Control Agency (MPCA) Proposed Permanent Rules Relating to PFAS in Products: Reporting and Fees [Docket Number 5-9003-40410]

Dear Judge Mortenson:

The American Chemistry Council's (ACC) Center for the Polyurethanes Industry[1] (CPI) appreciates the opportunity to provide input on the Minnesota Pollution Control Agency's (MPCA) *Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees*.[2] MPCA's proposed rule is intended to implement portions of Minnesota's 2023 law establishing prohibitions and reporting requirements for products containing intentionally added per- and polyfluoroalkyl substances (PFAS)[3] and is supported by a detailed "Statement of Need and Reasonableness" (SONAR),[4] which also informs CPI's comments.

General Statement of Issues

In general, CPI's comments present needed clarifications and improvements to this proposal. MPCA indicates in the SONAR Statement of General Need that this rule "will lead to the unprecedented disclosure of the presence and quantity of intentionally added PFAS in products and their components."[5] The requirements in the proposed rule, however, are exceedingly complicated and do not foster compliance with state law, particularly for manufacturers of complex products such as those in the automobile, appliance, and construction sectors. Providing the unprecedented amount of data that this proposal requires is further challenged by the unreasonable timeline MCPA has created, even considering the limited provisions allowing for an extension.

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[1] The Center for the Polyurethanes Industry (CPI) of the American Chemistry Council (ACC) serves as the voice of the polyurethanes industry in North America, promoting its development and coordinating with polyurethane trade associations across the globe. CPI members are companies that produce and sell the raw materials and additives that are used to make polyurethane products, equipment used in the manufacture of polyurethanes, and companies engaged in end-use applications and the manufacture of polyurethane products. The polyurethane industry supports research and initiatives that serve its communities and customers.

[2] Proposed New Rules Governing PFAS in Products, *Minnesota Rules*, Chapter 7026.

[3] Minn. Stat. § 116.943.

[4] MPCA, *Statement of Need and Reasonableness in the Matter of Proposed Minnesota Rules New Chapter 7026* (Revisor ID No. RD-4828), April 2025.

[5] MPCA, *Statement of Need and Reasonableness in the Matter of Proposed Minnesota Rules New Chapter 7026* (Revisor ID No. RD-4828), April 2025. Page 10.

In addition to the specific areas of the proposal addressed here, CPI supports and incorporates by reference comments submitted separately by ACC. Minnesota's PFAS law is the broadest and most stringent in the nation, and implementing regulations will have sweeping implications for consumer products being sold in the state and, thus, should be informed by the companies that will have responsibilities under the law. Accordingly, CPI submitted comments during previous review periods where MPCA sought information to develop the current proposed rule.[6]

Comment Area: Parties Responsible for Reporting (Section 7026.0020)
MPCA proposes allowing one manufacturer to serve as the reporting entity for the full supply chain with the condition that appropriate documentation be submitted demonstrating one manufacturer is the reporting entity. This provision appears to consider reporting in the context of complex products that could include many individual components produced by different manufacturers, where the final product manufacturer would serve as the reporting entity. The lack of process clarity and requirements for the reporting entity and supply chain manufacturers in the proposal are likely to cause inconsistent and incomplete reporting.

MPCA acknowledges this lack of clarity in the SONAR, indicating that "Detailed guidance on how reporting entities can submit on behalf of multiple manufacturers will be included in the reporting system instructions or in a supplemental guidance document," but that "This information will be available once the reporting system's functional capabilities are fully established, ensuring that entities have clear, practical steps for submission on behalf of multiple manufacturers."[7] No timeline is provided for release of this critical information. CPI has significant concerns about MPCA's reliance on forthcoming, nonbinding guidance to improve the ambiguities of the current proposal, especially without access to additional details and insight about the reporting system capabilities and how these regulatory requirements will be addressed in the reporting system.

Further, manufacturers may purchase products or product components without knowledge of which (or if) PFAS are contained or the intended function of the added PFAS, making it exceptionally difficult to meet the required notification contemplated in the proposal. Finally, manufacturers generally do not disclose suppliers in an effort to maintain confidential business information, such as private label arrangements. As written, the proposed rule would result in the release of sensitive information into the public domain with the potential to create unintended consequences throughout the supply chain.

Comment Areas: Report; Required Information (Section 7026.0030) and Extensions (7026.0060)
The proposed rule stipulates an initial reporting date of January 1, 2026. Considering the timing of this proposal, an incomplete reporting system, and the unprecedented request for PFAS data, MPCA has created an unreasonable timeline for manufacturers. While the proposed rule provides the opportunity for a limited extension, 90 additional days will not be sufficient, and the requirements for requesting an extension are onerous and, ultimately, may not result in more time. CPI previously recommended that the

[6] Notice of Request for Comments (c-pfas-rule1-01) and Notice of Request for Comments (c-pfas-rule2-01).
[7] MPCA, *Statement of Need and Reasonableness in the Matter of Proposed Minnesota Rules New Chapter 7026* (Revisor ID No. RD-4828), April 2025. Page 27.

extension period be one year and we continue to believe that granting up to 12 additional months for reporting will improve compliance plans for submitting data under this program as well as MPCA's ability to collect and interpret manufacturers' reports. Additionally, MPCA should develop a phased reporting schedule or staggered compliance dates, allowing for database piloting and high-level submissions while manufacturers build capacity for full reporting.

In terms of the required information per report per product, MPCA has set forth a structure that is simply unworkable considering the complexities of manufacturing supply chains. MPCA's SONAR recognizes the challenges that other federal and state programs have had in collecting data, including the U.S. Environmental Protection Agency's (EPA) rule under Section 8(a)(7) of the Toxic Substances Control Act (TSCA) that requires comprehensive reporting of manufactured and imported PFAS. MPCA indicates that the current proposal aligns with TSCA regulations but addresses known limitations and "challenges by establishing a robust and efficient reporting system that actively monitors PFAS in products sold within the state."[8] As noted above, the reporting system does not yet exist at the time of reviewing this proposed rule, and MPCA's proposed reporting framework does not adequately address the supply chain complexities that have become evident during the implementation of other PFAS reporting programs that do not require the amount of information that MPCA is seeking with this regulation. As a parallel, U.S. EPA extended the TSCA PFAS reporting period to "allow EPA to further develop and test the software being used to collect the data from manufacturers, thereby providing critical feedback to EPA."[9] Adoption of a similar extension in the final rule would be prudent for MPCA.

MPCA should ensure that reporting requirements are both practical and clearly understandable within the reporting system design and functionality. For example, MPCA should allow manufacturers to group similar models and parts under a single reporting entry, similar to the way U.S. Department of Energy (DOE) permits certification of "basic model numbers" to streamline reporting under the Energy Policy and Conservation Act.[10] The reporting system should also include standardized dropdowns for PFAS functions and product/component categories to facilitate accurate and consistent submissions.

Lastly, further clarification is needed for the Due Diligence provisions (7026.0080) of the proposed rule. As written, these provisions place the responsibility on reporting manufacturers to provide an amount of information that is impractical for complex product and supply chains. MPCA should establish a "known or reasonably ascertainable" threshold that is able to be met by reporting entities.

Comment Area: Reporting Exemptions (Section 7026.0090)
MPCA provides a limited number of product categories that are exempt from the rule requirements, but that do not align with other state and federal regulations that are already being implemented and informed by on-the-ground realities. This is despite MPCA's evaluation of these programs in support of

[8] MPCA, *Statement of Need and Reasonableness in the Matter of Proposed Minnesota Rules New Chapter 7026* (Revisor ID No. RD-4828), April 2025. Page 59.
[9] U.S. EPA, "EPA Extends Reporting Period for PFAS Manufacturers," May 12, 2025. U.S. EPA also notes that it is "considering a separate action to reopen other aspects of this rule for public comment."
[10] U.S. DOE, Implementation, Certification and Enforcement.

the proposed reporting and fees rule in the SONAR. CPI strongly recommends that MPCA expand the exemptions list to include products and chemistries that have been exempted by similar programs, in particular those recognizing acceptable substitutes listed under U.S. EPA's Significant New Alternatives Policy (SNAP) Program.

Established under the federal Clean Air Act, U.S. EPA's SNAP program is designed to "evaluate substitutes for ozone-depleting substances and hydrofluorocarbons (HFCs)" and "helps identify safer alternatives to reduce environmental and health risks."[11] For example, U.S. EPA has determined that some hydrofluoroolefin (HFO) blowing agents that have replaced HFCs in polyurethane foams are "acceptable," meaning that they "reduce overall risk to human health and the environment compared to other substitutes for the particular end-use" and "may be used without restriction in the specified end-uses."[12] Further, HFO foam blowing agents are not considered PFAS by U.S. EPA[13] and they are not classified as persistent, bioaccumulative, or toxic (PBT).[14]

In implementing the nation's first PFAS in Products law, the Maine Board of Environmental Protection (BEP) recently approved a rulemaking by the Department of Environmental Protection (DEP), *Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances*. The final rule exempted products using chemistries "listed as acceptable, acceptable subject to use conditions or acceptable subject to narrowed use limits by the EPA pursuant to the Significant New Alternatives Policy Program at 42 U.S.C. 82(G), as long as the refrigerant, foam, or aerosol propellant is sold, offered for sale or distributed for sale for the use for which it is listed pursuant to that program."[15] This language appropriately scopes Maine's regulation to accommodate U.S. EPA's HFO blowing agents determination under SNAP. Similarly, the State of New Mexico adopted exemptions for SNAP-approved substitutes in legislation passed this year to establish prohibitions on PFAS in consumer products.[16]

The exemption language and categories in the proposal should be updated to recognize differing characteristics within the broad class of fluorinated chemicals, bringing them into better alignment with similar PFAS in products programs.

Comment Area: Fees (Section 7023.0100)
Under the proposal, manufacturers are required to pay a $1,000 fee to submit an initial report on a product, with all individual manufacturers in a group or under a single reporting entity subject to the $1,000 fee. The regulatory language is not clear that this is not a per-product fee, which MPCA states in the SONAR:

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[11] https://www.epa.gov/snap.
[12] See: EPA's Classifications of Decisions on Alternatives.
[13] U.S. EPA, "National PFAS Testing Strategy: Identification of Candidate Per- and Polyfluoroalkyl Substances (PFAS) for Testing," October 2021.
[14] ECHA PBT Assessment List. Available at: https://echa.europa.eu/fi/pbt.
[15] Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances. Section 4(5)(F)(2).
[16] New Mexico House Bill 212, 2025 Regular Session, "Per- & Poly-fluoroalkyl Protection Act," Chapter 102, signed by Governor on April 8, 2025.

> *The Agency did not want to impose a per-product fee that would deter manufacturers from reporting to avoid excessive costs or to avoid manufacturers potentially grouping products beyond what was allowed for in rule. It was ultimately determined that a flat fee was the most reasonable approach and should be used on a per-manufacturer basis.*

CPI recommends that MPCA update the language in the final regulation to better reflect the SONAR justification. Additionally, CPI requests that MPCA remove the annual recertification fee of $500, which is inconsistent with the "excessive cost justification" as the fee would be required even if there are no changes to what was submitted the prior year. The program would still collect a $500 fee as part of a reporting update that would be required if PFAS concentrations in a specific product change.

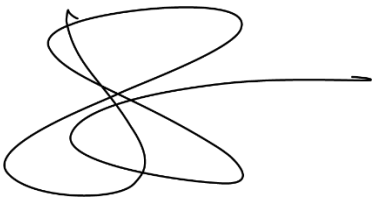
Summary

As designed, MPCA's proposed rule would require manufacturers to report an unprecedented quantity of data on an impracticable timeline, which continues to shorten as this regulation and the associated reporting system are being developed. These improvements – clarified responsibilities, phased compliance, harmonization with other state and federal programs, a refined fee structure, and user-friendly reporting features – are critical to supporting manufacturer compliance and MPCA's implementation goals.

****

CPI appreciates the opportunity to submit comments on MPCA's *Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees*. If you have any questions or need further clarification about the information that has been provided, please feel free to contact me at (202) 249-6105 or Jason_Sloan@americanchemistry.com.

Sincerely,



Jason Sloan
Director, CPI
American Chemistry Council

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By: OAH on 5/21/2025

Tillie Fowler Attachment

EssilorLuxottica

May 21, 2025

The Honorable Jim Mortenson
Minnesota Office of Administrative Hearings
600 North Robert Street
PO Box 64620
St. Paul, Minnesota 55164-0620

Re: Comments on Rules Governing Reporting and Fees Paid by Manufacturers Upon Submission of Proposed Required Information about Products Containing Per- and polyfluoroalkyl substances ("PFAS"), Revisor's ID Number R-4828.

Judge Mortenson,

This letter is in response to the Minnesota Pollution Control Agency's ("MPCA") request for comments on the Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fee Rule being promulgated pursuant to Minnesota Statute Section 116.943. EssilorLuxottica ("EL") appreciates the opportunity to provide comments on the upcoming proposed rule.[1]

EL designs, manufactures, and distributes ophthalmic prescription and nonprescription lenses, frames, sunglasses, and the instruments and chemicals used to manufacture such products. Some of our brands include Ray-Ban® and Oakley® along with lens technology brands Varilux®, Transitions® and Crizal®.

7026.0090 Reporting Exemptions – Exemption for Medical Devices

Ophthalmic devices, including spectacle frames, lenses, sunglasses, and other diagnostic and therapeutic instruments are medical devices governed under the Federal Food and Drug Administration ("FDA")[2] and are preempted from state authority[3]. Therefore, medical devices should fall under the exemptions in the Minnesota Statute Section 116.943, Subdivision 8(a)(1) which exempts "a product for which federal law governs the presence of PFAS in the product in a manner that preempts state authority."

EL requests that MPCA include an express exemption in the rule from all subsections for medical devices regulated by the FDA in the regulations to implement this Section. Manufacturers of medical devices should not be required to comply with section 7026.0030 of the statute because it is preempted by federal law and such a requirement places a substantial burden on manufacturers of medical devices without furthering the purpose of Minnesota Statute Section 116.943. Further, similar exemptions have been incorporated into similar laws and regulations

[1] Comments have been submitted electronically to https://minnesotaoah.granicusideas.com/discussions/40410-minnesota-pollution-control-agency-request-for-comments-on-pfas-in-products-reporting-and-fee-rule.
[2] 21 CFR Part 886 and *Guidance Document for Nonprescription Sunglasses* (10/09/1998.)
[3] 21 CFR Section 808.1.

that have been enacted or proposed in other states, including HF1627, which was introduced in Minnesota earlier this year.

Alternatively, EL requests that MPCA establish a threshold for reporting of medical devices. For example, limit reporting of medical devices to those with intentionally added PFAS at or above a specified threshold based on a specific list of PFAS with CAS numbers. This is similar to the Canadian Environmental Protection Act ("CEPA") PFAS reporting regulations, which imposes minimum thresholds for reporting, depending on the type of manufactured items being reported. This would minimize the burden of reporting on manufacturers of medical devices.

EL's mission is to help people *see more and be more* by helping to correct, protect and frame the eyes, make good vision a basic human right, and eliminate uncorrected poor vision. Eyeglasses and sunglasses are essential to fulfill EL's mission. To ensure eye protection and clear vision, photochromic, antireflective, and scratch resistant coatings are often applied to both prescription and non-prescription eyeglasses and sunglasses, which are medical devices regulated by the FDA. Some of these coatings contain PFAS, the key component to protect lenses from fingerprints, smudges, and scratches. Although EL is actively seeking alternative coatings, a PFAS-free alternative is not currently available.

The proposed rule fails to balance risk and places a substantial burden including significant costs on manufacturers of medical devices without furthering the purpose of Minnesota Statute Section 116.943.

Section 7026.0030 Reporting Information Required

Due to the breadth of the definition of "manufacturer" as set forth by the Proposed Rule, EL may be considered a manufacturer of some products that are not medical devices regulated by the FDA. With respect to those products, EL would like MPCA to consider the following:

Section 7026.0030, Subpart 1 Report Required

This section of the Minnesota statute currently requires manufacturers to submit information to the Commissioner on or before January 1, 2026, regardless of when the rule is finalized. That is less than eight months away and the rule is not yet final. This deadline does not consider the number of products the company manufactures or the size and resources of the company. Since many products are manufactured through a complex global supply chain, companies require sufficient lead time to implement any reporting requirement, especially when the obligation for reporting is very broad in scope and requires detailed information that may not be in the company's possession. Many items are sourced from multiple suppliers, requiring manufacturers to facilitate information requests, create databases to generate necessary reports, educate suppliers to understand the information requests (especially those outside of North America), validate and clarify any information received, and then link all received information to products sold.

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To ensure sufficient time to establish a process and gather and analyze the information for accuracy, MPCA should promulgate rules that would allow an additional 24 months after the final rule is published, which is consistent with other federal laws (OSHA & EPA standards). Although section 7026.0060 provides a process to request an extension, the extension request requires a fee, and the maximum extension granted is only for 90 days. The MPCA can also decline the extension request, in which case, the information must be submitted within 30 days with no other recourse to request further extension.

Additionally, section 7026.0060 requires the submission of supporting documentation, including any relevant documents that substantiate the need for an extension, such as communication records with other manufacturers, evidence of technical challenges or third-party testing delays. Companies need more specific information from MPCA regarding the types of evidence required to adequately satisfy this documentation requirement. EL has over 2000 vendors to map in our supply chain. Many of which supply us with multiple raw materials or components. EL would prefer to pay a fee knowing that the extension is guaranteed, other manufacturers subject to the registration requirements would likely agree. Additional time is particularly important due to the need for further clarification of several of the requirements under the statute, and further guidance on the information required for submittal, which have the potential to greatly increase the reporting burden for manufacturers. See additional comments on such items below.

Section 7026.0030, Subpart 1. B. PFAS Chemicals Used in the Product or its Components

We strongly encourage MPCA to provide a full list of PFAS substances covered by the new rules and their CASRNs. Without a specified list of chemical names and CASRNs, tracking a class of potentially thousands of chemicals across a complex global supply chain is incredibly difficult, especially for complex article manufacturers that are far down the supply chain. EL asks MPCA to consider developing a list of the specific CASRNs that apply to the statute and to the new rules. This approach is consistent with the United States Environmental Protection Agency's ("EPA") Toxic Release Inventory ("TRI") reporting requirements and Canada's CEPA PFAS reporting requirements.

We also strongly encourage MPCA to establish a threshold for reporting for all products. For example, limit reporting of products to those with intentionally added PFAS at or above a specified threshold based on a specific list of PFAS with CAS numbers.

This provides a better balance between risk to end users and reporting requirements for the manufacturer.

7026.0080 Due Diligence

Furthermore, MPCA should further clarify the due diligence standard for reporting under Section 7026.0080. Currently this section states that supply chain information requests are acceptable but that manufacturers must request detailed disclosure of information required in part

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7026.0030 from their supply chain until all required information is known. This standard is more burdensome than other PFAS reporting standards, including EPA's PFAS reporting requirements under TSCA, which requires reporting of "known to or reasonably ascertainable" information. We request MPCA provide further definition or guidance on this topic as the follow-up with suppliers can go on endlessly with no further information provided by the suppliers. This adds additional, burdensome requirements on the manufacturers required to report PFAS information for products. We are not in control of how our suppliers respond to these requests. Many suppliers are in countries that have no experience with PFAS or legal obligation to disclose PFAS to their customers. We request MPCA utilize the due diligence standard allowing the manufacturer to rely on information or certifications provided by suppliers and other information to the extent it is known or reasonably ascertainable to the manufacturer. This aligns with the TSCA PFAS reporting due diligence requirement.

Coordination with Other Jurisdictions

As a global company, EL is subject to many laws and regulations worldwide. EL appreciates MPCA's inclusion of Subdivision 3 and every effort MPCA can make to adopt regulations consistent with federal and other state laws.

Thank you again for the opportunity to provide these comments on the upcoming PFAS in Products Reporting Rule. We welcome further consultation with MPCA in this process, and if you have any questions about our comments, please reach out to our head of government relations, Tillie Fowler, at tfowler@essilorluxottica.com or 202-313-1342.

Sincerely,

Nia Christoforakis

Nia Christoforakis
Vice President Environmental, Health & Safety North America
EssilorLuxottica

RECEIVED
By: OAH on 5/21/2025

Ivan Rydkin Attachment

May 21, 2025

Submitted electronically via MPCA Portal

Re: Proposed Permanent Rules Chapter 7026

Daikin Applied Americas Inc. (DAA) appreciates the opportunity to provide comments regarding the Minnesota Pollution Control Agency's (MPCA) Proposed Permanent Rules Chapter 7026, which were developed pursuant to Minn. Stat. § 116.943. DAA acknowledges the considerable work by MPCA that led to this proposal, and DAA is committed to continuing our engagement in the rulemaking process.

Manufacturing in Minnesota

Headquartered in Plymouth, Minnesota since the inception of the business in 2006, DAA manufactures, sells, and distributes air conditioning, heating and ventilation (HVAC) equipment for many applications, including schools and universities, data centers, multi-family housing, manufacturing facilities, commercial businesses. The company has three plants in southern Minnesota, employs more than 2,600 people across the state, and is supported by a network of over 1,000 suppliers, ranging from large multinational companies to small, local Minnesota businesses. While DAA understands that MPCA is bound by the reporting timeframes set in statue, we want to highlight the challenges that companies expect to face when trying to comply with the reporting requirements. Obtaining the detailed information from suppliers in a complex, multi-tiered supply chain in a compressed timeframe is challenging and may not produce sufficient or actionable data.

Reporting Requirements - Providing Information as a Seller and a Distributor

DAA already has considerable experience in this type of data gathering and reporting in order to comply with Canadian reporting requirements. To date, DAA has been in monthly communication with our main 225 suppliers (of more than 1,000) focusing on our top ~55,000 most purchased parts. Beginning this work in **August 2024**, we have observed a limited response rate of only 39.7% through April 1, 2025. In addition, the reported data was not as robust as the full scope of information in the MCPA rule, such as CAS numbers, function of the material, etc. Inclusion of these additional requirements, which entails petitioning our more than 1,000 suppliers, would require considerably

Daikin Applied
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763-553-5330

more reporting time. Rushed results are likely to be laden with errors and omissions and would require a re-survey of those already reporting.

Due to the complex nature of HVAC unit construction, with a typical unit containing over 80,000 sub-components, such as PCBs and complicated mechanical parts like compressor motors, DAA cannot adequately validate beyond the supplier provided certification the chemical makeup of every individual component included in the final product. Reporting meaningful and robust information from all suppliers would be unworkable if required by January 1, 2026.

The strict requirement in MPCA's proposal—for reporters to continue hounding suppliers "until all information is known" —for every individual component purchased from suppliers is an untenable standard to meet. Canada's ECCC, and the US EPA have adopted and use the "information known to or reasonably ascertainable by the manufacturer" language. Therefore, DAA requests that the MCPA proposed rule be modified to replace the requirement of "until all information is known," with "information known to or reasonably ascertainable by the manufacturer," allowing manufacturers to submit information for their products that is known or reasonably ascertainable in harmonization with reporting requirements for the US EPA and Canada's ECCC.

Reporting Timeframe

Given the significant burden for proposed information gathering requirements, DAA is also concerned that the proposed January 1, 2026 deadline for implementation presents significant challenges. Primarily, the absence of a finalized rule, and no published Currently Unavoidable Use (CUU) rule, creates uncertainty and makes it difficult for affected parties to begin the necessary preparations for compliance. Changes in the final rule, or adopted provisions in a CUU rule, could necessitate significant and costly adjustments to any preliminary steps taken.

DAA acknowledges that the draft regulation provides the Commissioner with the authority to delay the reporting requirements. Therefore, DAA requests the MCPA Administrator to exercise this authority and extend the reporting requirement timeframe to at least 6-12 months post the time that the reporting system is tested and ready to receive reports from manufacturers. And 6-12 months following the subsequent publication of the finalized CUU rule.

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A longer implementation timeframe would allow for finalization of the rule with clear, unambiguous requirements, enabling adequate time for manufacturers to perform due diligence and ensure compliance.

Conclusion

As drafted, the reporting requirements and timelines cannot be understood and fully implemented by the regulated community, and these delays would leave manufacturers without the information they need to report. If finalized, the supply chain's inability to meet the extensive reporting requirements would put DAA's manufacturing plants in Faribault and Owatonna at risk of shutting down production, jeopardizing DAA employees and customers of essential Heat Pumps and other HVAC equipment and services.

DAA believes that a delayed and well-planned implementation that addresses the requirement of all information known will ultimately lead to more effective and accurate reporting, and greater long-term compliance. DAA is committed to working collaboratively with the MPCA to achieve the goals of this regulation and ensure its successful implementation.

Thank you for your consideration of these comments.

Sincerely,

Philip Johnston, P Eng
VP, Environmental Promotion Office
Daikin Applied Americas Inc.

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CONSERVATION MINNESOTA

May 21, 2025

Minnesota Office of Administrative Hearings
600 Robert St N
Saint Paul, MN 55101

Office of Administrative Hearings,

Most Minnesotans agree we all deserve safe drinking water. Yet the drinking water in dozens of Minnesota communities is contaminated with toxic PFAS pollution. We know that once PFAS enters the environment, the chemicals are difficult to track and even harder to remove. Minnesotans know we need to take action to stop companies from polluting our environment and our bodies with intentionally added PFAS in their products.

In 2023, Minnesota passed a nation-leading ban on PFAS, which went into effect in January. This law grants the Minnesota Pollution Control Agency more authority to effectively track and limit the use of PFAS chemicals. The proposed reporting and fee rule allows the agency to fulfill its directive to better track data on intentionally added PFAS. The proposed rule will help the agency clarify important definitions and processes for controlling the intentional use of PFAS, ultimately reducing the negative health impacts to humans and the environment.

We collected 302 signatures who support the proposed rule to ensure the MPCA is upholding the safest interpretation of the 2023 PFAS legislation. Members have signed on with this statement:

“I support the full and complete implementation of the 2023 PFAS law. Minnesotans have the right to know what’s in the products they use every day. Informed consumers make better choices—for themselves, their families, and their communities.

We don’t want harmful substances hidden in the things we buy. The first step toward safer products is transparency from manufacturers. Just like we check food labels to protect our families, we should also be able to check whether clothing, cookware, or other items contain PFAS.

Everyone deserves to shop with confidence, knowing that they’re making safe, informed decisions.”

Thank you for your consideration,

Nels Paulsen
Policy Director
Conservation Minnesota

Petition Signers (continued)

1 Richard Fish, Minneapolis
2 Mary Creighton, Virginia
3 Terry Richmond, Minneapolis
4 Kay Randall, Moorhead
5 Barb Powell, Northfield
6 Diane Crane, Saint Paul
7 Richard Lamb, Minneapolis
8 Barbara Thomborson, Minneapolis
9 Michele Vaillancourt, Saint Paul
10 Sue Halligan, Stillwater
11 Kay Drache, Minneapolis
12 Susan Jordan, Minneapolis
13 Juliann Rule, Avon
14 Dennis Cuchna, Alexandria
15 Scott Richner, Isle
16 Diane Borgmann, Saint Paul
17 Arthur Yeske, Prior Lake
18 Mary Faulkner, Minneapolis
19 John Wozniak, Saint Paul
20 Brad Snyder, Maple Grove
21 Maureen McCarter, Saint Cloud
22 M McQuillen, Chaska
23 Dawnette Davis, Grand Rapids
24 Michael Overend, Cohasset
25 Frank Bures, Winona
26 Susan Andrews, White Bear Lake
27 Emily Moore, Minneapolis
28 Tracy Whitney, Wayzata
29 Barb Knoth, Cannon Falls
30 Bob Nesheim, Grand Marais
31 Karen Graham, Ely
32 Jerome Comeau, Minneapolis
33 Barbara Ronningen, Afton
34 Monique Strong, Apple Valley
35 Steven Huff, Apple Valley
36 Valerie Eastland, Apple Valley
37 Brick Fevold, Bemidji
38 Amy Goerwitz, Northfield
39 Bruce Stark, Minneapolis
40 Dawn Baker, Minneapolis
41 Barb Knutsen, Montevideo
42 Brian Adams, White Bear Lake
43 Linda Burns, Minneapolis
44 Ken Swanson, Brimson
45 Carla Albers, Excelsior
46 Carlen Lovejoy, Minneapolis
47 Charmaine Stillwell, Minneapolis
48 Chuck Stanley, Lake Elmo
49 Cheryl Gonia, Winona
50 David Engelstad, Hopkins
51 Dale Anderson, Minneapolis
52 Mike Ferguson, Kasota
53 George Schoephoerster, Saint Cloud
54 Elaine Rosner, Saint Paul
55 Gary Fifield, Saint Paul
56 Gary Deason, Long Lake
57 Jon Grinnell, Saint Peter
58 Barbara Aslakson, Minneapolis
59 John Harford, Bayport
60 James Boyle, Hopkins
61 Emma Jerndal, Minneapolis

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Petition Signers (continued)

62 John Buzza, Saint Paul
63 Keri Igo, Duluth
64 Mary Kaysinger, Hopkins
65 Keith Monsaas, Duluth
66 Jennifer Johnson, Saint Paul
67 Kurt Simer, Minneapolis
68 Donna Young, Newport
69 Eileen Levin, Hopkins
70 Luis Olvera, Hopkins
71 Maribeth Schulke, Maple Lake
72 Nancy Conger, North Branch
73 Paul Ryals, Stanchfield
74 Lisa Hensel, Buffalo
75 R Fuller, Woodbury
76 Kathy Reinhardt, Minneapolis
77 Sanda Oslin, Grand Marais
78 River Gordon, Minneapolis
79 Steve Christopher, Saint Paul
80 Ron Sjostrand, Hallock
81 Tony Kruse, Lino Lakes
82 Alan Olander, Nevis
83 Shawn Kakuk, Saint Cloud
84 Cathie Duncan, Saint Paul
85 Betsey Porter, Minneapolis
86 Philip Vieth, Hastings
87 Sandra Wing, Mound
88 Robert Giddings, Andover
89 Eugenie de Rosier, Saint Paul
90 Susan Beseke, Maplewood
91 Jonathan Walseth, Cottage Grove
92 Gary Huss, Minneapolis
93 Rolf Jacobson, Saint Paul
94 Susan Soule, Minneapolis
95 Kathryn Cox, Jordan
96 Ashley McCormick, Minneapolis
97 Raymond Kaiser, Saint Paul Park
98 Kathleen Stoddart, Saint Paul
99 Marsha Odom, Crookston
100 Mary Cousineau, Edina
101 Chari Eckmann, Maple Grove
102 Eric Hammang, Saint Paul
103 Sue LeGros, Burnsville
104 James Rickard, Afton
105 Mike Bull, Northfield
106 Elaine Barber, Minnetonka
107 Kerry Priglmeier, Saint Cloud
108 Steven Poncin, Hastings
109 Heidi Foreman, Windom
110 Susan Leek, Saint Paul
111 George Kelzer, Eden Prairie
112 Adeline Riha, North Mankato
113 Katie Parke-Reimer, Saint Paul
114 Linda Ashland, Minneapolis
115 Deena Reisman, Afton
116 Laurie Windisch, Stillwater
117 Maxwell Fuller, Savage
118 Dan Newman, Aitkin
119 Daniel Dummer, South Saint Paul
120 Robert Ries, Plymouth
121 Jason Husby, Minneapolis
122 M Richardson, Saint Paul

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Petition Signers (continued)

123 Philip Rampi, Saint Paul
124 Jim Clapp, Detroit Lakes
125 William Nusbaum, Minneapolis
126 Nels Paulsen, Hopkins
127 Bryan Wyberg, Roseville
128 Greg Solberg, Roseville
129 JL Charrier, Wayzata
130 Robert Lawser, Burnsville
131 Amelia Narigon, Saint Paul
132 Aaron Geringer, Saint Peter
133 Jane Gfrerer, Minneapolis
134 Jennifer Baker, Pine City
135 Margaret Corens, Wayzata
136 Candace Kragthorpe, Shakopee
137 Gloria Karbo, Minneapolis
138 Autumn Kaye, Watertown
139 Susan Huhn-Bowles, Minneapolis
140 Chris Fastner, Aitkin
141 Patrick Byron, Winona
142 Jeff Newberger, Burnsville
143 Matt Holmes, Minneapolis
144 Maggie Kessell, Saint Paul
145 Corrine Haulotte, Winona
146 Rebeccca Dale, Saint Paul
147 Audrey Kramer, Chanhassen
148 Gerald Friest, Eagan
149 Linda Seaton, Minneapolis
150 Ryan Baka, Minneapolis
151 Linda Bisdorf, Apple Valley
152 Lori Ekholm, Minneapolis
153 Diana Olson, Saint Paul
154 Billy Curmano, Winona
155 Alice West, Grand Marais
156 Gabriela Santiago, Saint Paul
157 Lise Schmidt, Saint Paul
158 Sheila Dillon, Willmar
159 Megan Brennan, Minneapolis
160 James Erickson, Saint Paul
161 Bernie Nierman, Austin
162 Diane Martinson, Saint Paul
163 Carol Mertesdorf, Anoka
164 Rosemarie Schmidt, Bemidji
165 Tyler Owens, Mankato
166 Lauren Kofsky, Minnetonka
167 Gretchen Corkrean, Woodbury
168 Susan Macpherson, Saint Paul
169 Gina DeBreto, Britt
170 Sarah Silva, Bayport
171 Susan Warner, Paynesville
172 Annette Sauer, Brook Park
173 Lois Nokleby, Hampton
174 John Kniprath, Saint Paul
175 Kurt Cegielski, Saint Paul
176 Susan Haugh, Minneapolis
177 Kathy Parkin, Annandale
178 Kathleen Schultz, Oak Park Heights
179 Barry Knapp, Rochester
180 Brittany Jacobson, Big Lake
181 Eric Parrish, Worthington
182 Patty Gilmore, Rochester
183 Linnea Tellekson, Duluth

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Petition Signers (continued)

184 Hansen Kathryn, Wyoming
185 Janet Shannon, Hastings
186 Allison LaBorde, Little Falls
187 Matthew Beckler, Minneapolis
188 Jennifer Eckes, Saint Paul
189 Leo Stern, North Oaks
190 Anthony Hirschman, Plymouth
191 NJ Deever, Hermantown
192 Patricia Felstead, Rochester
193 Tara Myhran, Maple Plain
194 John Smith, Rochester
195 Ben Hullander, Shakopee
196 Debra Riggs, Lakeville
197 Seymour Gross, Minneapolis
198 Frieda Wilson, Minneapolis
199 Mackenzie Hojnacki, Ramsey
200 Pam Hartwell, La Crescent
201 Harvey Bartz, Stillwater
202 Staci Revers, Minneapolis
203 Jodie Nelson, White Bear Lake
204 James Whitehurst, Saint Paul
205 Jody Goldstein, Rochester
206 Sharon Schwartz, Stillwater
207 Michael Jost, Saint Paul
208 Harmon Abrahamson, Minneapolis
209 Nick Spreeman, Hugo
210 Loretta Boegeman, Prior Lake
211 Lindsey Lundby, Saint Paul Park
212 Daniel Abramson, Esko
213 Jeffrey Lockhart, Winona
214 Rachel Battles, Minneapolis
215 Karina Curbelo, Minneapolis
216 Patricia Huberty, Mendota Heights
217 Jeff Klaassen, Rochester
218 Michelle Lange-Pearson, Rochester
219 Jacob Lindhorst, Duluth
220 Carolyn Jahns, Minneapolis
221 Ann Davis, Minneapolis
222 Marie Redlin, Hastings
223 Rachel Geissinger, Excelsior
224 Victoria Dan, Minneapolis
225 Patricia Moore, Stillwater
226 Daniella Manea, Chaska
227 Ashley Broeker, Two Harbors
228 Holly Palmersten, Eden Prairie
229 Catherine Perry, Saint Paul
230 Michael Katner, Mankato
231 Barbara Ahlstrom, Minneapolis
232 Angela Woods, Plymouth
233 Jason Knedlhans, Plymouth
234 Lynne Rasmussen, Wayzata
235 Trevor Russell, Saint Paul
236 Scott Torgrimson, Mankato
237 Pamela Thompson, Brimson
238 Rose Martinez, Minneapolis
239 Kristen Bandurski, Red Wing
240 Mark Snyder, Minneapolis
241 Mary Parlin, Winona
242 Regina Stemm, Minneapolis
243 Elizabeth Hirschman, Plymouth
244 Benjamin Hubert, Coon Rapids

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Petition Signers (continued)

245 Karen Monsen, Stillwater
246 Sarah Hunt, Saint Paul
247 Tim Sexton, Minneapolis
248 Kate Hansen, Elk River
249 Mary Nienaber, Saint Paul
250 Susan Huhn-Bowles, Minneapolis
251 Ruth Grant, Minneapolis
252 Mark Binder, Hutchinson
253 Christy Steinbach, North Mankato
254 Mary Flatten, Mound
255 Pamela Dumke, Maple Grove
256 Becky Zingler, Apple Valley
257 David Peterson, Remer
258 Mariya Javed-Payne, Eden Prairie
259 Brindalyn Foster, Minneapolis
260 Holly Zillmer, Stillwater
261 Steven Marsh, Burtrum
262 Carlene Ewalt, Princeton
263 Andrea Egbert, Lakeville
264 Karen Meinz, Saint Cloud
265 Fern DeRubeis, Minneapolis
266 Jill Doerfler, Duluth
267 Kacy Rainaldo, Minneapolis
268 April Johnson, Woodbury
269 Kristen Anderson, Lino Lakes
270 Doug Hlavacek, Afton
271 Kerry Lipanot, Maple Grove
272 Emily Laurin, Minneapolis
273 Kimberly Johnson, Hugo
274 Paul Stoki, Wyoming
275 Melissa Mangan, Minneapolis
276 Kenneth Fordahl, Rushford Village
277 Marian Rubenfeld, Minneapolis
278 David Fryd, Arden Hills
279 Matt Anderson, Savage
280 Mel Hendrix, Minneapolis
281 Dee Pipitone-Sarkar, Woodbury
282 Patrice Johnson, Mankato
283 Richard Bergslien, Shorewood
284 Michael Moore, Saint Cloud
285 Nora Atwood, Wayzata
286 Brian Buck, Minneapolis
287 Laurel Hemstad, White Bear Lake
288 Therese O'Connor, Rochester
289 Tess Weaver, Saint Cloud
290 Kristina Gronquist, Minneapolis
291 Sandra Strom-Gieseke, Nisswa
292 Heather Griffis, Minneapolis
293 Kelsey Sieg, Minneapolis
294 Don Baldus, Mazeppa
295 Suzanne Rooney, Newport
296 Julie Smith, Minneapolis
297 Kevin Costley, Mendota Heights
298 Kristine Granias, Mounds View
299 Shawn Kempenich, Little Falls
300 Joseph Johnson, Stillwater
301 Joanne Gustafson, Stillwater
302 Christopher Miller, Owatonna

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THE VOICE FOR MEDICAL INNOVATION
MDMA

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May 21, 2025

Via Electronic Submission

The Honorable James Mortenson
Office of Administrative Hearings
Minnesota Pollution Control Agency
600 North Robert Street
St. Paul, Minnesota 55164-0620

RE: Comments on the Proposed PFAS in Products: Reporting and Fee Rule, OAH Docket Number 5-9003-40410

Dear Judge Mortenson:

On behalf of the Medical Device Manufacturers Association (MDMA), I am submitting comments on the proposed rule, PFAS in Products: Reporting and Fee Rule. Since the proposal places a unique and exceptional large burden on medical device manufacturers, we request that Minnesota Pollution Control Agency (MPCA or "Agency") extend the compliance date by an additional year for our sector. The practical effects of this additional time will be minimal since medical devices and their manufacturer are highly regulated by the U.S. Food and Drug Administration (FDA) and are exempt from Minnesota's statutory ban on intentionally added PFAS.

MDMA's members share MPCA's commitment to public health and plans to gather additional information on PFAS use to comply with MPCA's final rule. MDMA is a national trade association that provides educational and advocacy assistance to approximately 300 innovative companies in the field of medical technology. Our members, the majority of which are small to mid-sized medical device companies, have a strong record of delivering breakthrough therapies to treat chronic diseases and life-threatening conditions while lowering the cost of care. MDMA's mission is to ensure that patients have timely access to the latest advancements of safe and effective medical technologies that improve health outcomes. MDMA has many members that manufacture, develop, and sell medical devices in Minnesota.

The proposed rule poses a unique challenge to medical device manufacturers since Minnesota is the first jurisdiction to require reporting on PFAS content of the device and in the manufacturing process of medical devices. Other U.S. states with PFAS reporting requirements have exempted medical devices from any reporting requirement. The U.S. Environmental Protection Agency's (EPA) PFAS reporting programs also do not require the scale of reporting of MPCA's proposed rule. Medical devices and some medical device manufacturing is exempt from PFAS reporting under Section 8(a)(7) of the Toxic Substances

and Control Act. Required reports of PFAS use, treatment, and disposal under EPA's Toxic Release Inventory program cover only a small part of the required information in MPCA's proposed rule.

As a result, unlike many other manufacturing sectors, medical device manufacturers would have to gather the extensive and detailed information in MPCA's proposed rule for the first time. We do share with other manufacturing sectors a complex supply chain: components and materials sourced from all over the globe, a diverse array of vendors, and the corresponding challenge of identifying the thousands of PFAS compounds covered by the proposed rule. For example, a pacemaker or hearing aid can have hundreds of components that are manufactured in multiple locations and then shipped to another location for final assembly in Minnesota.

For these reasons, we ask MPCA to extend the reporting deadlines for one year for the medical device manufacturing sector. With additional time, manufacturers can gather more accurate and complete information for MPCA's use. A sector-wide extension is less administratively burdensome to MPCA than if many medical device companies filed for individual company extensions under the proposed rule's provisions.

Granting an additional year for reporting will not hamper MPCA's administration of other parts of the statute or reduce the incentive to limit PFAS use. The principal requirement in Minnesota PFAS law is a ban on selling non-exempted products containing intentionally added PFAS; medical devices regulated by FDA are exempt from this ban. Medical devices, their chemical composition and characteristics, their packaging, and their handling are regulated by FDA. Manufacturers cannot change a device's use of fluoropolymers without FDA review. Further, while the reporting burden of the proposed rule may create an incentive to seek alternatives to PFAS, maintaining FDA's approval is much more important and vital to protect patient safety. Patient safety governs our industry's choices for materials.

Thank you for your attention to our comments. We are also attaching technical comments in Addendum A for your consideration as MPCA prepares a final rule. If we can provide additional information, please contact Clayton Hall at MDMA at chall@medicaldevices.org.

Sincerely,

Mark Leahey

Mark B. Leahey
President & CEO
MDMA
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Suite 400 West
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www.medicaldevices.org

Addendum A: Technical Comments from Member Companies[1]

Line Number	Rule Part / Subpart	Proposed Regulatory Language and Recommended Revisions (if any)	Comment/Explanation of Revision	Category/ Topic
1.11	7026.0010, subp. 4	"character limited description of a product"	• MPCA should clarify what is meant by this proposed language. • MPCA should clarify who decides how many characters are allowed.	
1.20	7026.0010, subp. 5	"A particular chemical may have more than one chemical identifying number, and one chemical identifying name may correspond to different names for the same chemical.	• Our recommended added language will help reporting entities be aware of potential variations in potentially responsive information. • The vast and complex global supply chains from which MPCA is seeking to information for reporting already has to negotiate an immense volume of data that contains variations in names/numbers and data management systems that significantly intensifies the resources and time needed to provide the requested information. The additional complexity from the variations in chemical names/numbers compounds this challenge and emphasizes the need for additional time.	Complexity Regulatory Burden
2.6	7026.0010, subp. 9	"distribute for sale in the state"	• If a product is shipped to Minnesota, placed on a truck, and then transported to Wisconsin, it would be out of scope.	
2.12	7026.0010, subp. 11	"intentionally incorporated at any stage"	• It is unclear how this will modify the statutory definition of "intentionally added," which includes the requirement of "the continued presence of PFAS is desired in the final product or one of the product's components to perform a specific function." If a polymer processing aid was deliberately added to the polymerization pot to perform a specific function (e.g., emulsification), but has no function once the polymer has been made and is not desired in the final polymer, it would not be "intentionally added" per the statute.	Complexity
3.6	7026.0010, subp. 15	"harmonized tariff schedule (HTS) code"	• There are different levels of HTS codes (6 digit level, 8 digit, 10 digit) with the higher number being more specific. Ensuring the 6 digit level is acceptable would reduce the reporting burden.	Regulatory Burden
3.10-3.12	7026.0010, subp. 17	"Publicly available" means lawfully available to the public from federal, state, or local government records or disclosures made to the public that are required by federal, state, or local law. For purposes of this rule only, publicly available also includes non-trade secret reporting information submitted to MPCA as required by this rule.	• Once MPCA has received required reporting information, that information should be made available to manufacturers subject to this reporting rule to reference and/or incorporate into their incorporating responses. • MPCA can establish mechanisms to receive data to facilitate access to regulated reporting entities. (For example, reporting portal could intake data in specific format with ability to populate/search certain fields for MPCA data.)	MPCA Data
3.21-3.23	7026.0010, Subp. 19	ADD: Substantially equivalent information also includes reporting	• Manufacturers should be able to leverage data submitted to MPCA by their suppliers even if the suppliers do not provide a notification.	MPCA Data

[1] The table included in this addendum combines the technical comments from various individual member companies. As such, each comment included in the table reflects a concern and/or recommendation of one or more member company/ies, but does necessarily reflect the position of MDMA or of all member companies.

Line Number	Rule Part / Subpart	Proposed Regulatory Language and Recommended Revisions (if any)	Comment/Explanation of Revision	Category/ Topic
		information submitted to MPCA under this rule.		
4.4-4.7	7026.0020, subp. 1	PREFERRED OPTION: A manufacturer or group of manufacturers of a product sold, offered for sale, or distributed in the state must submit the required reporting information under this rule ~~a report~~ for each product or component that contains intentionally added PFAS. The initial submission of this reporting information is referred to in this part as the "initial report." OTHER OPTION – ADD: "A manufacturer may file a single consolidated report for all products and components for which it is required to submit the specified reporting information."	• There is concern about protecting CBI under group reporting. • The incredibly short amount of time creates additional challenges for the group reporting option. • Our recommended additional language is necessary to allow a manufacturer to submit a single report with the required information on products and components in scope. Otherwise, the volume of independent reports would be overly burdensome and when tied to the fee requirement ($1000 filing fee for a report) suggests a fee is required for every product and not just the manufacturer's overall submission.	Report Form; Fees
	7026.0020 subpart 1 *See cmt on 7026.0090*	ADD: "Exemptions include medical devices or drugs that are otherwise used in a medical setting or in medical applications regulated by the United States Food and Drug Administration"	• Publicly available records demonstrate the use of certain fluoropolymers in the function of some medical devices or their components. • The substantial regulatory burden imposed by this proposed regulation on an accelerated timeline on both medical device manufacturers and their vast network of suppliers is concerning and has prompted some market reactions. • Accordingly, consistent with the important public interest in maintaining a safe and stable supply of the materials necessary for the manufacture and distribution of life-saving medical devices to patients worldwide, MPCA needs to provide an exemption to medical devices for reporting. This exemption could help alleviate some pressure within the supply chain at a time when feasible alternatives may not yet be available or approved by regulatory bodies.	
	7026.0020, subp. 2	"enter into an agreement"	• This language would mean that a seller of product component would be required to know all actual uses and users through the downstream supply chain.	Regulatory Burden
	7026.0030, subp 1.A. 2.C.(1)(a)	ADD definition for practical detection limit	• Definition is necessary to support consistency in reporting.	
5.23	7026.0030, subp. 1	"If the product consists of multiple PFAS-containing components…"	• the communication up and down the supply chain needed for the manufacturer of a complex product to put together this report on a component basis before Jan 1 will require extensions.	Regulatory Burden Extension
6.17	7026.0030, subp. 1	"the harmonized tariff schedule code for imported products"	• The HTS option should be available for any product where it's relevant, not just for imported products.	Required Content

Line Number	Rule Part / Subpart	Proposed Regulatory Language and Recommended Revisions (if any)	Comment/Explanation of Revision	Category/ Topic
7.16	7026.0030, subp. 1	"the total organic fluorine, determined using commercially available analytical methods"	• If suppliers will not provide information because of CBI concerns (which was an issue in Maine), is there sufficient analytical capacity and capability to measure total organic fluorine? Also, TOF will capture more than PFAS, including potentially inorganic fluorine. Maine requires reporting of total product weight if PFAS content is not otherwise known.	
7.19	7026.0030, subp. 1.D	REVISE: "function, if known at time of reporting, that each PFAS chemical provides to the product or its components"	• Function, like concentration, is not always known to manufacturer in any given reporting year when PFAS is added by third-party supplier.	Required Content
7.6	7026.0030, subp. 1.C	PREFERRED OPTION: WIDER RANGES ALIGNED WITH THE TSCA 8(a)(7) RANGES	• Aligning with TSCA 8(a)(7) ranges may ease the burden for many industries in the U.S. who have already collected data to meet EPA's requirement. • For some products, the part construction can be identical but depending on the stack up, ranges can be vastly different due to the low weight of PTFE membranes and coatings vs the backers, adhesives and molded plastic components. Identical parts with different backers (different density of the backers) could result in 10 percent vs 16 percent wt difference due to the low density of the membranes.	Required Content
8.18-8.20	7026.0030, subp. 3	PREFERRED OPTION: DELETE SUBPART 3 and REPLACE WITH EXISTING STATUTORY LANGUAGE ON REMEDY THROUGH NOTICE AND TESTING ONLY OTHER OPTION – ADD: MPCA shall not impose any administrative penalty on a manufacturer that either (1) submits an initial report that does not contain all information necessary to be deemed complete for a particular product or component or contains known or reasonably ascertainable information for a particular product or component, even if such information may not fully address all reporting elements, or (2) does not file any initial report based on absence of information reviewed in due diligence that triggers reporting requirement.	• MPCA stated enforcement remedy is inconsistent with the Minnesota legislature's specified remedy in the statute.	Remedy
9.10	7026.0040, subp. 2	"Annual recertification."	• The regulation speaks to "recertification," but "certification" is neither used nor defined in the regulation or the statute. MPCA needs to clean up the language or clarify what they mean by "recertification." E.g., "Annual resubmittal" or "Annual confirmation".	Updates

Line Number	Rule Part / Subpart	Proposed Regulatory Language and Recommended Revisions (if any)	Comment/Explanation of Revision	Category/ Topic
10.1-10.21	7026.0050, subp. 1	REVISE: "~~Upon request of a manufacturer or group of manufacturer, t~~The commissioner must ~~waiver all or part of the information~~ grant agency-initiated waivers and/or manufacturer-initiated waivers from all reporting requirements under part 7026.0030 or from the deadline for initial report for certain reporting groups (specific products/manufacturer categories) if the commissioner determines that substantially equivalent information is publicly available.	• Waivers are appropriate and effective mechanisms to allow appropriate flexibility on some/all substantive or timing requirements for category of products or manufacturers or based on case-specific considerations	Waiver
10.1-10.21	7026.0050, subp. 2	ADD: specific basis for manufacturer-initiated waiver of deadline for all reporting or for period of time (e.g., one year waiver for filing initial report)	• Waivers are appropriate and effective mechanisms to allow appropriate flexibility on some/all substantive or timing requirements for category of products or manufacturers or based on case-specific considerations	
10.22-10.23	7026.0050	REVISE EXISTING LANGUAGE: "a link to or copy of all publicly available and substantially equivalent information described by the manufacturer unless the substantially equivalent information was received by MPCA pursuant to the reporting requirements of this rule, in which case the manufacturer need only direct MPCA to that information.	• See comments above regarding need for manufacturers to have access to reporting information submitted to MPCA under this rule	
11.10-12.15	7026.0060, subp. 1	DELETE ENTIRE PART and REPLACE WITH STATUTORY LANGUAGE	• Statute provides more expansion ability to obtain extension and MPCA should not seek to unreasonably limit the availability or duration of extensions inconsistent with statutory language.	Extension
11.10-12.15	7026.0060, subp. 3	ADD specific one-year extension, with opportunity for additional time, when needed for initial report submission	• 90-day extension is insufficient based on complexity of undertaking, particularly when proposed rule greatly expands the obligation shortly before the reporting deadline.	Extension
12.19	7026.0070, subp. 1	REVISE: "A manufacturer or group of manufacturers may request that the commissioner maintain trade secret data as not public information according to part 7000.1300. Trade secret data that is eligible ~~to be considered not public information~~ for protection is defined in Minnesota	• The incredibly short amount of time for responding to a denial of protection of trade secrets. • 7026.0070 will have to be modified to address information that will be required to be submitted as part of a CUU determination, unless amended as suggested in first bullet. • Re: chemical identifying number: both concentration and function of the PFAS should be considered as criteria that could be a trade secret.	Trade Secret Data

Line Number	Rule Part / Subpart	Proposed Regulatory Language and Recommended Revisions (if any)	Comment/Explanation of Revision	Category/ Topic
		Statute 13.37, and includes but is not limited to:" ADD: data categories eligible to be considered: concentration of PFAS (particularly but not necessarily exclusively for the concentration ranges at the low end, 7026.0030 Subp 1.C(1)(a), (b) and (c)); function of PFAS		
13.9-13.12	7026.0080, subp. 1	A manufacturer must assume responsibility for reporting known or reasonably ascertainable information for products containing intentionally added PFAS unless (1) MPCA has already received the necessary information, which must be made available to manufacturers subject to reporting requirements at least 3 months in advance of the initial reporting deadline and annual recertification deadlines; (2) notification from another manufacturer is received or otherwise available for agency review according to part 7026.0020,subpart 2, confirming that the reporting requirements under part 7026.0030 have been fulfilled; or (3) manufacturer can provide other written documentation confirming MPCA has received the required information from report submissions.	• Preferred alternative is to modify the due diligence standard to incorporate "known or reasonably ascertainable information" in all reporting elements. • Requiring annual recertification of expansive data without leveraging the volume of public data previously provided to MPCA is an unreasonable and overly burdensome regulatory requirement. • MPCA should make available reporting data it collects to facilitate, and reduce the regulatory burden of, reporting for manufacturers who are incurring substantial costs to obtain this information and submit detailed reports/fees. • When manufacturers can offer evidence showing submission of the required data, it would be arbitrary and capricious of MPCA to disregard such evidence and enforce unnecessary, cumulative, and burdensome requirements. • A structured reporting system that ingests specific and uniform data fields could facilitate this capability, create consistency in reporting, and help manufacturers implement with template.	Regulatory Burden Reporting Data – Availability
13.13-13.15	7026.0080, subp. 2	PREFERRED OPTION 1 • Delete entire subpart OPTION 2 • Delete current language and replace with: "Manufacturers should include in their reports any information they have obtained from suppliers within their supply chain that is within the scope of information required for submission. This	• An affirmative and potential ceaseless obligation to request information from an undefined "supply chain" is improper as a matter of law because, among other things, it (1) is impermissibly vague and unenforceable given the absence of a reasonable definition of "supply chain," particularly when the term that can, for even a single product subject to the reporting law, require detailed information from a complex global web of suppliers for necessary materials / components; (2) seeks to improperly expand the rule-making beyond MPCA statutorily-defined authority under Subdivision 2 of the stature; (3) imposes an unprecedented and expansive burden to affirmatively and repeatedly seek to force companies far removed from Minnesota to provide information.	Due Diligence

Line Number	Rule Part / Subpart	Proposed Regulatory Language and Recommended Revisions (if any)	Comment/Explanation of Revision	Category/ Topic
		regulation does not require manufacturers to undertake any action to request information from any third-party, particularly any third-party that has no independent reporting obligation.	• The provision is also unlawful because it improperly imposes a disparate impact on manufacturers that rely on suppliers that are not independently required to report under Minnesota's law. Manufacturers who rely more heavily or extensively on suppliers who already sell/distribute their products in Minnesota can more easily obtain timely and complete information with limited additional burden. Manufacturers whose suppliers do not already have such obligation may not understand the requirement; may not have mobilized with readily available responses; may provide incomplete, inaccurate, or untimely responses; or may simply be unable or unwilling to provide the information despite repeated, costly, and frustrating requests Forcing only these manufacturers to compete in the Minnesota market while bearing the substantial additional costs for pursuing, perhaps futilely, this third-party information "until all information is known" is unlawful.	
13.16-13.22	7026.0080, subp. 3.A	REPLACE EXISTING SUBPART 3.A WITH: A manufacturer or group of manufacturers must maintain sufficient documentation to, upon request, demonstrate to MPCA that known or reasonably ascertainable reporting information has been provided to MPCA for products or components in scope of the reporting requirement or, if the manufacturer has not yet submitted complete information, that manufacturer has undertaken the reasonable and customary business due diligence practices to review reasonably available information within its custody and control to complete the reporting requirements. This documentation could include communications (e.g., emails, letters, forms) exchanged with suppliers. Alternatively: "A manufacturer or group of manufacturers must maintain documentation of its relevant reporting responsibility agreements with and/or notifications from other manufacturers as provided in part 7026.0020, subpart 2."	• This is incredibly overbroad and onerous (especially given the retention period proposed. • The data management requirements to maintain, particularly for years and years, EVERY email with all suppliers is an unnecessary and unreasonably costly requirement. It is inconsistent with and far more expansive that other product or chemical reporting laws. • The language about maintaining all documents relating to reporting and compliance all sweeps up other company documents that should not be subject to the record retention requirements or considered as due diligence.	Due Diligence; Record-keeping

Line Number	Rule Part / Subpart	Proposed Regulatory Language and Recommended Revisions (if any)	Comment/Explanation of Revision	Category/ Topic
14.1-14.3	7026.0080, subp. 3.C	A manufacturer or group of manufacturers must maintain <u>required</u> records according to this subpart for five years <u>after any report that relies on such records to demonstrate completeness of submission or compliance with due diligence obligations.</u> ~~products containing intentionally added PFAS are removed from the supply chain.~~	• The timeframe for maintaining this volume of data and information (even after a company has ceased selling product into the state) is unreasonable, impracticable, and overly costly. • It is also inconsistent with other, established approaches for record-keeping and due diligence requirements for regulated entities.	
14.4-14.16	7026.0090	DELETE "and" in line 14.13 DELETE period in line 14.16; REPLACE with "<u>; and</u>" AND ADD NEW EXEMPTION AS "F": <u>Medical devices or drugs that are otherwise used in a medical setting or in medical applications regulated by the United States Food and Drug Administration</u>.	• See comments above on basis for exemption and comment bubble on additional arguments in event MPCA refuses to use exemption as mechanism to reduce burden or allow flexibility/additional time	
14.21-14.24	7026.0100, subp. 2	Regardless of the number of products or components for which a manufacturer must submit reporting information in a particular reporting year, a manufacturer must pay a <u>single</u> $1,000 fee <u>for that reporting year</u> to submit the initial report under part 7026.0030, subpart 1.	Existing language on requirement to submit an initial report on each product or component within scope combined with a per-report fee of $1000 imposes indefensible administrative and financial burdens on companies who may have thousands of products or components in scope due to the presence of even one material containing intentionally-added PFAS.	
15.1-15.5	7026.0100, subp. 3	ADD at end of existing language: "<u>If annual certification does not contain any new or different information, no filing fee is required for a complete submission of the annual certification. If the commissioner determines under part 7026.0080 that reasonable due diligence was exercised to include known or reasonably ascertainable information in a manufacturer's initial report that lead to incomplete information, the inclusion of more</u>	• There is limited regulatory burden on MPCA from receiving a simple confirmation of completeness in reporting, and no fee is therefore appropriate. • In addition, by eliminating the fee requirement for annual certifications once complete information is reported, manufacturers are incentivized to submit complete information as early as possible. • The inclusion of the due diligence component corresponds to abovementioned recommendations to modify the due diligence standard to incorporate "known or reasonably ascertainable information." If reasonable due diligence lead to an incomplete report in year 1, but more information is received in year 2, this should not be considered	

Line Number	Rule Part / Subpart	Proposed Regulatory Language and Recommended Revisions (if any)	Comment/Explanation of Revision	Category/ Topic
		information in subsequent annual certifications shall not require filing fee."	"new or different information" nor a "revision" but a continuation of year 1's due diligence process.	

RECEIVED
By: OAH on 5/21/2025
Matthew Windrum Attachment

PLUMBING MANUFACTURERS INTERNATIONAL

May 21, 2025

Honorable James Mortenson
Administrative Law Judge
Office of Administrative Hearings
600 North Robert Street
P.O. Box 64620St. Paul, MN 55164-0620

Ms. Quinn Carr
Minnesota Pollution Control Agency
520 Lafayette Road North
St. Paul, MN 55155-4194

RE: **Comments on Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees, Minnesota Rules Chapter 7026 (OAH Docket No. 5-9003-40410, Revisor's ID No. R-4828)**

Dear Judge Mortenson and Ms. Carr:

Plumbing Manufacturers International (PMI) appreciates the opportunity to submit comments on the Minnesota Pollution Control Agency's (MPCA) proposed permanent rules relating to reporting requirements for products containing intentionally added Per- and Polyfluoroalkyl Substances (PFAS).

PMI represents manufacturers of plumbing fixtures and fittings and is deeply committed to ensuring that regulations are clear, achievable, and effectively balance environmental protection with practicality for manufacturers. PMI is an international, U.S.-based trade association representing manufacturers that provide 90% of the plumbing products sold in the United States. PMI members manufacture water-efficient toilets, urinals, faucets, showerheads, and other plumbing products at more than 70 locations across the country for the residential and commercial, and industrial marketplace. These products are readily available at home improvement stores, hardware stores, showrooms, and distributor facilities in all 50 states, as well as online. **In Minnesota, plumbing manufacturers contribute $532.4 million to the economy, provide more than 2,600 jobs with their distribution and retail partners, and generate $185 million in wages.**

Our specific concern pertains to Chapter 7026.0060 Subpart 3 (B.) regarding the 90-day period allowed for extensions when manufacturers seek additional time to comply with reporting requirements.

Given the complexity of domestic and global supply chains and the challenges manufacturers face in documenting the presence of intentionally added PFAS across numerous product

components, PMI respectfully requests that MPCA consider increasing the allowable extension period from 90 days to 180 days. The additional time is necessary to allow manufacturers adequate opportunity to:

1) Engage effectively with complex, domestic and international supply chains, often involving numerous suppliers who require extended periods to provide accurate and verifiable PFAS data.

2) Conduct thorough chemical analyses and obtain third-party laboratory results, as current analytical laboratories frequently experience significant backlogs and delays in testing due to increasing PFAS regulatory demands nationwide.

3) Ensure the accuracy and completeness of data submissions, thereby enhancing manufacturer compliance and reducing administrative burdens for the MPCA.

An extension period of 180 days realistically reflects the operational and logistical challenges inherent in domestic and global manufacturing and supply chain management and improves the overall effectiveness and reliability of PFAS reporting data provided to the MPCA.

Thank you for considering our recommendation. PMI welcomes the opportunity to further discuss our comments and provide additional information to support MPCA's rulemaking process. If you have any questions regarding our comments, please do not hesitate to contact me.

Sincerely,

PMI Members

*Blanco *Bradley Company, LLC *Brasscraft Manufacturing Company *CSA Group Testing & Certification, Inc. *Delta Faucet Company *Dornbracht Americas, Inc. *Duravit USA, Inc. *Falcon Water Technologies, LLC *Fisher Manufacturing Company *Fluidmaster, Inc. *Gerber Plumbing Fixtures, LLC *GF *Hansgrohe, Inc. *Haws Corporation *IAPMO *International Code Council – Evaluation Service (ICC-ES) *KEROX LTD *Kohler Company *LAUFEN Schweiz AG *Lavelle Industries, Inc. *LIXIL *LSP Products Group, LLC *Marcone Plumbing *MOEN, Inc. *NEOPERL, Inc. *NSF International *Pfister Faucets *Reliance Worldwide Corporation *Sloan Valve Company *Sprite Industries *Symmons Industries, Inc. *T & S Brass and Bronze Works, Inc. *TOTO USA *UL *Viega, LLC *Waterpik, Inc. *WCM Industries, Inc. *Zurn Elkay Water Solutions

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Erin Herlihy Attachment

OUTDOOR INDUSTRY ASSOCIATION

May 21, 2025

Katrina Kessler, Commissioner
Minnesota Pollution Control Agency
520 Lafayette Road North
St. Paul, MN 55155-4194

By Website Submission

Re: **Outdoor Industry Association Comments on MPCA's Proposed Permanent Rules on Reporting and Fee Obligations for Manufacturers of Products Containing Per- and Polyfluoroalkyl Substances**

Dear Commissioner Kessler,

On behalf of the Outdoor Industry Association (OIA), we present these comments in response to the Minnesota Pollution Control Agency's (MPCA's) request for comment on its proposed permanent rules at Minnesota Rules, Chapter 7026.

A member-based collective, OIA is a passionate group of business leaders, sustainability experts, policy makers, and outdoor enthusiasts committed to sustainable economic growth while protecting—and growing access to—the benefits of the outdoors for everyone. OIA has worked as a catalyst to lead the outdoor industry in understanding and eliminating harmful chemicals and materials from their supply chains.

Outdoor gear and apparel are designed to protect the user in a variety of circumstances. In the outdoors, qualities like water repellency, oil and grease repellency, durability, breathability, and heat resistance can make an incredible difference for comfort and survival. In extreme conditions, water repellency can be a life-saving function. The outdoor industry has used durable water repellant (DWR) treatments to make moisture bead up and roll off outer fabric and membrane layers. Historically, these treatments have relied on per- and polyfluoroalkyl substances (PFAS).

The outdoor industry is uniquely positioned to support Minnesota's vision of a thriving and environmentally responsible economy. Responsible chemical management is a critical piece of that puzzle. That is why outdoor brands have led the way in researching and deploying innovative technologies that will phase out PFAS entirely while maintaining protective qualities. Through that work, our brand leaders have developed unique expertise in the identification and phaseout of these chemicals. However, with that knowledge, we are concerned about the challenges that our members will face with the growing patchwork of state and federal PFAS reporting regulations. We submit these comments to address

challenges posed to our members by MPCA's proposed regulations governing PFAS reporting and associated submission fees.

I. Provide Opportunity for Achievable Compliance

As currently written, MPCA's proposed rules create burdensome reporting obligations that will likely be unachievable for many OIA members. The Minnesota state legislature empowered MPCA to design a reporting process for PFAS in products. The proposed rules instead effectively function as a ban on products that have PFAS. Adopting clear, achievable reporting standards would benefit both OIA's members and MPCA, as brands could continue to sell non-banned products containing PFAS and the MPCA would collect more information on the uses of PFAS in consumer products.

A. Accommodate Partial Submission of Chemical Specific Information

OIA asks MPCA to allow reporters to develop an alternative solution for reporters to submit valid reports where some chemical specific information is unknown, including chemical name and Chemical Abstracts Service Registry Number (CASRN).[1] MPCA's draft regulations already provide avenues reporters to provide partial information in other circumstances: reporters may state that the amount of a certain PFAS chemical in a product is unknown,[2] and may also use Total Organic Fluorine content as a proxy for the concentration of a PFAS chemical in a product.[3] These allowances reduce the compliance burden for many reporters and balances the continued sale of products with MPCA's interest in collecting information. Similar provisions allowing reporting of PFAS content without identifying specific chemicals would benefit OIA members, as they could use commercially available testing for Total Organic Fluorine when information on specific chemicals is unavailable.

Brands often face difficulty identifying specific chemical substances in their products. There are no currently approved test methodologies that can provide test results for all PFAS individually. In fact, there are no EPA approved test methods for PFAS in consumer products. ASTM has convened a subcommittee to discuss the issue but has yet to coalesce around test methods. Further, in complex global supply chains, suppliers often do not know or do not want to disclose information regarding chemical inputs. As currently written, MPCA's proposed rules would require companies to submit reports with information that often cannot be obtained. Failure to report unobtainable information would ban products from the Minnesota market.

[1] *To be codified at* Minn. Rules, § 7026.0030(1)(B).
[2] *Id.*, § 7026.0030(1)(C)(1)(i).
[3] *Id.*, § 7026.0030(1)(C)(2).

We ask that MPCA take an approach that matches the realities of testing and supplier knowledge. We recommend that MPCA allow reporting of Total Organic Fluorine where information on specific PFAS chemicals is not obtainable. Such an approach will provide the public with the information needed to make informed choices, while also providing clarity on how brand leaders can comply with those reporting obligations. Otherwise, the reporting requirements will simply function as a prohibition by another name.

B. Conform Due Diligence Requirements to Federal Standards

MPCA's proposed rules contain a strict and burdensome due diligence requirement. Under the draft regulations, reporters must continuously contact suppliers for information on PFAS in their products, including chemicals identities and CASRNs, "until all required information is known."[4] This strict standard makes no exceptions for instances where suppliers do not know or will not disclose required information. Further, the strict standard creates uncertainty around unknown—but intentional—additions of PFAS in a company's supply chain. Supply chains are complex, and a chemical supplier, material supplier, or other entity several steps up the supply chain may intentionally add PFAS to a product without communicating that addition down the supply chain due to trade secrets. It is not clear how the absolute due diligence requirement would treat such unknown intentional PFAS contamination.

We ask that MPCA align its due diligence requirements with EPA's standard in its PFAS Reporting Rule promulgated under the Toxic Substances Control Act (TSCA).[5] This one-time federal reporting rule requires all manufacturers, including importers, of PFAS and PFAS-containing products to report to EPA on chemicals manufactured or imported January 1, 2011 to December 31, 2022.[6] EPA's due diligence standard requires collection and submission of all information on PFAS that is "known or reasonably ascertainable" to the reporter.[7] If a submitter fails to find reportable data after conducting due diligence, the submitter may report "reasonable estimates" of the required information.[8] If reasonable estimates cannot be made, a submitter may indicate the information is "Not Known or Reasonably Ascertainable" ("NKRA").[9]

EPA's due diligence standards accounts for the reality that in some cases, reporters will not be able to collect and submit chemical specific information for every PFAS used in their products. EPA's guidance instructs reporters to undertake good faith efforts to locate

[4] *Id.*, § 7026.0080(2).
[5] 40 C.F.R. § 705.
[6] *Id.* § 705.15
[7] 40 C.F.R. § 704.3; *see also* EPA, Instructions for Completing Section 8(a)(7) Reporting, at 4-3 to 4-5 (Nov. 2024), https://www.epa.gov/system/files/documents/2024-12/tsca-8a7-reporting-instructions_11-25-24.pdf.
[8] 40 C.F.R. § 705.15
[9] *Id.*, § 705.15(b)(iii).

reportable information, including contacting suppliers.[10] However, if due diligence efforts fail to uncover reportable information, manufacturers can still meet their reporting obligations. We request that MPCA align its draft regulations with EPA's PFAS Reporting Rule by adjusting its due diligence standard to require reporting of "known or reasonably ascertainable information." We also ask that the final regulations allow reporters to submit responses with reasonable estimates or indications that certain pieces of information, namely chemical specific information, are unknown or not reasonably ascertainable.

C. Extend Exemptions to Include Time of Manufacture Limitations and Safe Harbor Content Limits

MPCA's proposed rules exempt a limited number of product categories from reporting requirements, including products governed by preempting federal law, firefighting foam and gear, and used products.[11] To avoid placing an unnecessary burden on brands that have already worked to phase out PFAS from their products, we ask that MPCA add exemptions for products manufactured before the reporting requirement goes into effect. Such exemptions have been adopted in several states.[12] Those exemptions protect retailers and brands alike from inventory management challenges that have plagued other states implementing PFAS regulations. Brands may have little knowledge of historical product composition, as well as the location of those products across the marketplace. Such an exemption would allow manufacturers to focus on forward-looking products rather than engage in a needless inventory investigation.

Further, to prevent submissions for products made without intentionally added PFAS, we ask that MPCA develop numerical safe harbor limits below which reporting will not be required. MPCA should institute a *de minimis* level for Total Organic Fluorine detection. Any product with a Total Organic Fluorine detection below the level would not be deemed as containing intentionally added PFAS, while those with detections above the maximum would be subject to the presumption that PFAS had been added as part of the manufacturing process. We recommend, for example, a level of 100 ppm to mirror California's safe harbor level that will go into effect in 2025.[13] MPCA could also implement a higher safe harbor limit on Total Organic Fluorine to account for common cross contamination found in outdoor products that were manufactured without intentionally added PFAS.

II. Ensure Equitable Distribution of Costs

[10] Instructions for Completing Section 8(a)(7) Reporting, *supra* note 9 at 4-5.
[11] *To be codified at* Minn. Rules, § 7026.0090.
[12] *See* N.H. Rev. Stat. § 149-M:64(II)(b)(2) ("The following are exempt from the PFAS ban imposed by this section: … Products manufactured prior to the ban imposed by this section."); WAC 173-337-110(3)(b-c) ("The restriction in (c) of this subsection takes effect on January 1, 2026… this does not apply to a: (A) Priority consumer product described in (a) of this subsection manufactured before January 1, 2026, even if the priority consumer product was refurbished after January 1, 2026.")
[13] Cal. Health & Saf. Code § 108970(g)(2)(A).

D. Adjust Fee Requirements To Account for Reporter Differences

Finally, OIA asks that MPCA adjust the fee provisions in its proposed regulations to account for significant differences between reporting entities. The draft regulations require reporters to pay a $1,000 fee to submit each report and $500 thereafter to update or recertify reports on an annual basis.[14] Companies seeking a reporting waiver must also pay an initial fee of $1,000 and companies requesting an extension must pay a $300 fee.[15]

We request that MPCA create a tiered fee structure that accounts for the size of the reporter and the number of PFAS-containing products sold into Minnesota. While some OIA members are large multinational brands, others are much smaller with a limited number of relevant products. The current fee structure does not distinguish between these very different entities, therefore placing an unduly high burden on smaller companies. Instituting a tiered fee system tied to global or Minnesota-specific revenue combined with the number of PFAS-containing products sold or distributed into the state is a more equitable method for funding MPCA's implementation of PFAS reporting for consumer products.

III. Conclusion

We appreciate the opportunity to comment and welcome continued engagement. Please contact Julie Brown, OIA's Director of Sustainable Business Innovation, at jbrown@outdoorindustry.org if you have any questions or would like additional information.

Best,

Kent Ebersole
President
Outdoor Industry Association
P.O. Box 21497
Boulder, CO 80308

[14] *To be codified at* Minn. Rules, § 7026.0090(2-3).
[15] *To be codified at* Minn. Rules, § 7026.0090(4-5).

RECEIVED
By: OAH on 5/21/2025

Valmet

May 21, 2025

Submitted via OAH eComments website at https://minnesotaoah.granicusideas.com/

The Honorable Jim Mortenson
Minnesota Office of Administrative Hearings
600 North Robert Street PO Box 64620
St. Paul, Minnesota 55164-0620

Re: **Comments of Valmet, Inc. and Valmet Flow Control Inc.**
MPCA Proposed New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS);
Reporting and Fees, Revisor's ID Number R-4828;
OAH Docket No. 5-9003-40410

Dear Judge Mortenson:

On behalf of Valmet, Inc. and Valmet Flow Control Inc. (collectively, "Valmet" or the "Company") we appreciate the opportunity to comment on the Proposed New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS), Revisor's ID Number R-4828.

Valmet is a leading global developer and supplier of process technologies, automation and services for the pulp, paper, tissue, energy and other process industries. A number of Valmet's technologies use fluoropolymer containing components, which are critical for a wide range of industrial applications.

Valmet is a member of the Valve Manufacturers Association (VMA), and supports the comments also submitted by the VMA. However, while Valmet believes the VMA's proposed comments improve the Rules, Valmet desires to offer the following additional comments.

Valmet Maintains that MPCA should identify certain exemptions in the Planned Rule

In general, as MPCA develops rules to implement its PFAS in Products Law, the agency must also consider which products it believes are "currently unavoidable uses" of PFAS and should not be banned for health and safety reasons. Codified at Section 116.943 of the Minnesota Statutes, the law defines a "currently unavoidable use" as a "use of PFAS that the commissioner has determined by rule under this section to be essential for health, safety, or the functioning of society and for which alternatives are not reasonably available." This definition is sufficiently flexible to authorize MPCA to exempt entire classes of PFAS from the phaseout requirements of the law.

To this end, Valmet respectfully requests that MPCA promulgate a rulemaking designating fluoropolymer (and fluoropolymer-containing products) used in industrial applications as "currently unavoidable uses" and, therefore, exempt from any future sale or distribution prohibitions in the State of Minnesota pursuant Section 116.943.

Although fluoropolymers fall within the statutory definition of PFAS under Section 116.943, Subdivision 1, they differ significantly from more hazardous non-polymeric PFAS substances. Fluoropolymers are characterized by high molecular weight (typically over 100,000 Da), low reactivity, low water solubility, and lack of bioavailability or bioaccumulation potential—resulting in minimal human and environmental health concerns.[1]

In industrial operations such as Valmet's, fluoropolymers are essential in components like gaskets, seals, pumps, coatings, and valves. These components are critical to the production of renewable energy systems, pulp and paper products, and technologies supporting decarbonization and hydrogen infrastructure. In most cases, no viable alternatives exist. Thus, instituting a prohibition on fluoropolymers will compromise both the availability and efficacy of many existing products used in industrial, commercial, and consumer applications.

Given these realities, Valmet sees that fluoropolymer products in industrial use should be determined as "currently unavoidable uses" of PFAS and, therefore, would be exempt from any future prohibitions on the sale or distribution in the State of Minnesota to enable their essential use in many application areas critical for society.

Specific comments on the Minnesota Rule Chapters 7026.0010, 7026.0020, 7026.0030, 7026.0050, 7026.0060, and 7026.0080.

In the following sections of this comment letter, Valmet offers input on specific aspects of the above-mentioned rules.

Comments Regarding Chapter 7026.0010 DEFINITIONS, Subp 6. Chemical Name

The MPCA's proposed regulation defines the term "chemical name" as a "systematic nomenclature that follows internationally recognized conventions established by the International Union of Pure and Applied Chemistry (IUPAC)". In most cases, it is possible to find the IUPAC chemical names for PFAS substances. However, for substances whose chemical compositions may vary depending on the specific ingredient type and manufacturer – such as FKM and FFKM – the IUPAC chemical names cannot be easily determined. Therefore, we respectfully propose that widely-recognized general chemical names, as used in commerce, research, and by governments could also be used, similarly to what is allowed under subp.5. in the definition of chemical identification number.

Comments Regarding Chapter 7026.0020 PARTIES RESPONSIBLE FOR REPORTING

Subpart 1 Scope states that "A manufacturer or group of manufacturers of a product sold, offered for sale, or distributed in the state must submit a report for each product or component that contains intentionally added PFAS."

Valmet respectfully requests that the term "offered for sale" be removed from the list of reporting requirements, as it is excessively broad and not well-suited to the nature of project-based

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[1] Améduri, B., *Fluoropolymers as Unique and Irreplaceable Materials: Challenges and Future Trends in These Specific Per or Poly-Fluoroalkyl Substances*,

industrial operations. Valmet makes this suggestion based on the realities of how it and similarly situated companies put their products into state commerce.

Specifically, our business model is based on customized project quotations tailored to specific customer needs in the process industries. To meet diverse customer expectations, we currently work with approximately 25,000 active suppliers. It is typical that, at the time of submitting an initial quotation, we do not yet have full visibility of all the specific details regarding which suppliers will be involved or what specific materials will be required for that particular project. Furthermore, not all quotations result in actual deliveries or sales.

In such circumstances, imposing reporting obligations on businesses that offer products for sale can result in an undue and excessive burden to industry. Specifically, requiring companies to report all potential alternative solutions in advance – already at the quotation phase, prior to contractual commitment - would create an excessive administrative burden for both companies in a similar project-based industries and the supervising authorities. Businesses will invariably seek to offset the costs of this unnecessary burden. This, in turn, would also lead to unnecessary delays and increased costs in companies' business operations, without delivering meaningful benefits in terms of regulatory oversight or safety.

For purposes of clarification, we also recommend that the term "offered for sale" be stricken from the parallel provisions in:

7026.0010 DEFINITIONS, subp. 9,
7026.0030 REPORT; REQUIRED INFORMATION, subpart 1, and
7026.0040 REPORTING UPDATES, Subpart 1. A(3).

We therefore urge the removal of the "offered for sale" criterion from the scope of reporting obligations, particularly in the context of industrial operations and capital goods and their repairs.[2]

Comments Regarding Chapter 7026.0030 REPORT; REQUIRED INFORMATION

Subpart 1.C of this provision requires reporting regarding: "(1): the concentration of PFAS chemicals in a product or components of a product made up of homogenous material. A manufacturer must report the concentration of PFAS chemicals as identified in subitem (1) or (2)." Subitem (1) provides a set of reportable ranges of PFAS concentrations, while Subitem requires reporting of the total organic fluorine content using commercially available analytical methods if other due diligence efforts do not discern the amount of PFAS.

Regarding Subitem (1), Valmet does not object to the principle that PFAS concentrations may be reported as ranges. However, the analytical methods should be standardized and clearly specified in legislation.

We also propose the consideration of whether concentrations at or below 1% in products are relevant in light of the context of the rule's objectives and their potential impact on human health

[2] If it is not possible to remove the term "offered for sale", we respectfully request that the MPCA considers redefining it in a way that better reflects the distinction between the concepts of "quotation" (when no goods have physically entered the state) and "offered for sale".

and the environment. Alternatively, we propose that the first reporting range could be set as a range from "the practical detection limit up to 1,000 < 10,000 (one percent), in order to reduce the administrative burden on both companies and supervising authorities.

We therefore propose combining of 7026.0030, Subpart 1. C. (1) (a) (b) and (c) to one item "from the practical detection limit up to 1,000 ppm < 10,000 (one percent)".

As to Subitem (2), Valmet objects to the use of total organic fluorine content as a proxy for an analytical method tailored to identifying PFAS content. As the Agency knows, total organic fluorine testing can give rise to misleading results regarding PFAS identity and concentration. It is therefore not a particularly useful tool and one, moreover, that can conflate fluorinated organic compounds that are not poly- or perfluorinated with PFAS. Valmet suggests that a specific method be identified, such as the same methods applied by the U.S. Environmental Protection Agency (EPA).

Comments Regarding Chapter 7026.0050 WAIVERS and 7026.0060 EXTENSIONS.

The text of the proposed regulation states that, if the waiver or extension request is denied, the reporting must be submitted within 30 days. Valmet considers this timeframe insufficient and proposes it to be extended to 45 days.

Comments Regarding Chapter 7026.0080 DUE DILIGENCE.

Subp. 2 of this proposed regulation states: "A manufacturer or group of manufacturers must request detailed disclosure of information required in part 7026.0030 from their supply chain until all required information is known."

Valmet respectfully proposes that the MPCA adopts the same formulation as used by the U.S. Environmental Protection Agency (EPA) in its PFAS reporting rule under TSCA Section 8(a)(7). In that context, the EPA uses the standard "known to or reasonably ascertainable by" as the basis for due diligence:"'Known to or reasonably ascertainable by' means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know."

* * *

Thank you for the opportunity to comment and we look forward to further engagement on this important topic. Please contact the undersigned if you would like more information from us.

Regards,

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RECEIVED
By: OAH on 5/21/2025
Chris Cleet Attachment

ITI Promoting Innovation Worldwide

To: Minnesota Pollution Control Agency

Date: May 16, 2025

Subject: Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees, Revisor's ID Number R-4828, Chapter 7026

The Information Technology Industry Council (ITI) welcomes the opportunity to provide feedback to Minnesota Pollution Control Agency's Notice of Intent to Adopt New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS), Revisor's ID Number R-4828, OAH docket number 5-9003-40410

ITI is the premier global advocate for technology, representing the world's most innovative companies. Founded in 1916, ITI is an international trade association with a team of professionals on four continents. We promote public policies and industry standards that advance competition and innovation worldwide. Our diverse membership and expert staff provide policymakers with the broadest perspective and thought leadership from technology, hardware, software, services, and related Industries. ITI members have a long history of reducing or eliminating harmful chemicals in electronics. We respectfully submit our concerns and proposed recommendations to the rule below.

1) **The timeline for reporting is unworkable, particularly for complex products such as electronics, which pose unique reporting challenges, including needing additional time to comply with reporting requirements**

Issue: The timeline for reporting – currently January 2026, does not provide enough time to review and comply with final rules and submit reports in a new reporting system. In fact, the MPCA's current rulemaking process schedule anticipates the final adoption of rules by January 1, 2026.[1] Without the clarity and information provided by a rulemaking conducted well in advance of the reporting requirement deadline, it will be difficult for many electronics manufacturers to provide the data necessary to comply. Manufacturers are unsure of the specific information required or how to provide that information to the Agency. Our subsequent comments below on the MPCA rule underscore the need for precise guidance on numerous technical points that we request be clarified in a final rule – and only after exact reporting requirements are issued can manufacturers effectively begin to collect many of the data elements needed. In most cases, OEMs will need to request additional information from suppliers to report PFAS content in the correct context. Additionally, the timeframe does not provide enough time to set up legal agreements on reporting responsibilities between component suppliers and customers as per 7036.0020 Subpart 2.

[1] See public notice webpage at https://www.pca.state.mn.us/getengaged/pfas-in-products-reporting-and-fees

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Finally, since electronic devices are manufactured through a complex global supply chain, companies require sufficient lead time to implement any notification requirement. A single electronic product can have thousands of components which are sourced from multiple suppliers from which manufacturers will need to facilitate information requests, create databases to generate necessary reports, conduct supplier training to understand the information requests, validate and clarify any information received, and then link all received information to products sold. In addition, all of these information requests will have to go through this process through multiple levels of the value chain.

Recommendation: Revise Part 7036.0030 to align with EPA's TSCA PFAS reporting (now due October 2026)[2] or require reporting at least 12 months after the reporting rule, reporting processes, and online platform (if MN plans to develop one) is finalized. Further, MPCA should issue a blanket extension for manufacturers of complex electronic products (including their components) and products with electronic components. Given the complexity of the issue and the extensive reporting requirements outlined in the law, we respectfully ask that the Agency grant an extension to the electronics sector for at least 24-48 months after the final adoption of their rulemaking.

2) The reporting timeline for submissions is internally inconsistent and ambiguous

Issue: Lines 5.4 – 5.7 require manufacturers of new products to be introduced to the Minnesota market after the January 1, 2026 reporting deadline to submit a report "before the product can be sold, offered for sale or distributed in the state." However, the statute does not require submission of a report before introduction into the Minnesota market; instead, the statutory requirement is only that a report be submitted "whenever a new product that contains intentionally added PFAS is sold, offered for sale, or distributed in the state." The statute uses the past tense to refer to sale, offer for sale, and distribution, meaning that requiring submission of a report beforehand is inconsistent with the law's text. Furthermore, submitting a report before a product launch would likely breach confidentiality requirements and put companies at a competitive disadvantage. To add to these concerns, lines 5.4 – 5.7 are in tension with line 9.8 which would require manufacturers to report new products as part of the annual update by February 1 of each year.

Recommendation: We suggest these be combined into one annual report to remove unnecessary administrative burden. If reports are at the product level, this implies multiple reports would be submitted annually. This piecemeal solution is cumbersome, drives unnecessary administrative work and may stop the timely flow of products into MN. The rule should be amended to clarify that a single report per manufacturer should be required annually that includes information for all products shipped into MN within the prior twelve-month period. In addition, provision should be made for scenarios where groups of manufacturers offer the same or similar products in the state. Finally, the requirement for reporting new products in lines 5.4 – 5.7 should be deleted so that the requirement in line 9.8 governs this issue.

[2] EPA Extends Reporting Period for PFAS Manufacturers | US EPA

3) To both reduce the burden on manufacturers and the MCPA, the proposed rule should harmonize with reporting concepts from other states and with US EPA/TSCA

Issue: The MCPA rule differs from several existing reporting requirements, including the State of Maine and US Environmental Protection Agency (EPA). Harmonization with these reporting requirements will both reduce the administrative burden on reporting manufacturers and the compliance burden of the Agency.

First, EPA's PFAS Reporting Rule (40 CFR Part 705) includes the definition of "Known to or reasonably ascertainable by" which means "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know." This requirement places a clear responsibility for reasonable knowledge of a manufacturer, including when the manufacturer may not receive information from a supplier.

Second, companies should be allowed to use EPA's TSCA generic chemical name guidance in selecting a chemical subclass if chemical name is claimed as trade secret, and if actual data is not known, the regulation should allow for reasonable estimates using approaches such as mass balance calculations, emissions factors, or best engineering judgment.

Third, the State of Maine's reporting requirement applies only to products sold in Maine after an applicable sales ban takes effect, and for which the Maine Department of Environmental Protection (DEP) has made an unavoidable use determination. Minnesota should look to harmonize reporting definitions, scope and requirements.

Fourth, the State of Maine exempts "non-consumer laboratory equipment or electronics."[3] Products considered as B2B professional products are not consumer products, not intended for use at home or by consumers should be excluded from registration or limited to only product category registrations.

Recommendation: Harmonize the rules to reporting requirements from the US EPA and State of Maine.

First, add to Section 7026.0010 of the rule (Definitions) the following:

> *Known to or reasonably ascertainable by. All information in a person's or manufacturer's possession or control, plus all information that a reasonable person or manufacturer similarly situated might be expected to possess, control, or know.*

Second, lines 13.2 – 13.5 of the proposed rule explain that, if the chemical identity is claimed as trade secret, manufacturers "must submit a chemical subclass to designate as public data." There is no guidance in the proposed rule or SONR on how manufacturers must select this chemical subclass. The MPCA should indicate in the rule that a generic chemical name created in accordance with this is sufficient for designating a chemical subclass under the rule. Linking to this guidance will help ensure regulatory certainty and will avoid the MPCA needing to develop its own guidance in time for companies to report by the upcoming reporting deadline. Specifically, the MPCA should provide clarifying guidance, or add the following sentence after the existing sentence in line 13.5:

> *A generic chemical name created in accordance with the U.S. Environmental Protection Agency's Guidance for Creating Generic Names for Confidential Chemical Substance Identity*

[3] See https://www.maine.gov/dep/spills/topics/pfas/PFAS-products/

Reporting under the Toxic Substances Control Act (as announced in 83 Fed. Reg. 30173, June 27, 2018) shall be sufficient for designating a chemical subclass under this subpart.

For reporting or compliance reasons it is much more practical for the regulators to provide a list of chemical CAS numbers that can be used by industry participants to evaluate whether these chemicals are present in products. Conducting evaluations by chemical structure is difficult and error-prone because product chemical databases are not set up to identify chemicals in this way and because chemicals may have many synonymous names. Listing them by name will also be error prone.

Third, Minnesota should modify its reporting to mirror Maine's new reporting program only for those product categories that receive a Currently Unavoidable Use (CUU) determination from the Department

Finally, as in Maine, the reporting requirements should only apply to consumer products.

4) Reporting thresholds are inconsistent with other states' requirements

Issue: Minnesota's PFAS reporting rule establishes eight reporting thresholds, compared to Maine's six, starting with "practical detection limit." Minnesota should harmonize with Maine's thresholds and also add a de minimis threshold for reporting intentionally added PFAS. Alternatively, Minnesota could exempt reporting below the practical detection limit. The current draft rules require manufacturers to report all intentionally added PFAS, regardless of the concentration present in a product or component. Administering a chemical reporting scheme untethered to a concentration threshold is overly burdensome and difficult to implement, especially for PFAS present at trace levels—well below meaningful environmental or health thresholds—and can be difficult or impossible to quantify accurately through supplier declarations or commercial formulations. In many cases, supply chain partners either do not disclose exact concentrations, or are unaware of the presence of PFAS at such low levels. Testing to determine PFAS concentrations below 50 ppm —either as part of reporting due diligence or to respond to a request for information from the Commissioner— would be prohibitively expensive, wasteful, and unreliable for most manufacturers.

The lack of a de minimis threshold risks skewing reported data to focus overwhelmingly on amounts of low-concentration data that has little regulatory utility and may divert resources away from identifying higher-risk uses of PFAS. Reporting all intentionally added PFAS with no de minimis threshold also conflicts with other major chemical reporting frameworks—several of which apply clear concentration thresholds to ensure reporting is scientifically and practically meaningful.

Recommendation: The rule should establish a de minimis threshold of 50 parts per million (ppm) by weight, such that reporting is only required for intentionally added PFAS present at or above this level in a product or component. Specifically, Rule 7026.0010 should be revised to add a definition of de minimis reporting so that manufacturers are only required to report intentionally added PFAS when the concentration is equal to or greater than 50 ppm. For example,

"De minimis reporting threshold" means a concentration of intentionally added PFAS equal to or greater than 50 parts per million (ppm) by weight in a product or component. This threshold aligns with and reflects practical reporting limits used in other international chemical regulations.

5) **Reporting should not be at the component level; and the definition of "component" is unclear.**

Issue: If a product consists of multiple PFAS-containing components, lines 5.23 – 6.10 of the proposed rule require manufacturers to report each component. The statute does not impose this requirement, and for good reason. First, determining what is a "component" is subjective. Also, MPCA's definition of "component" is likely to lead to variations in how reporting is done among manufacturers. Reporting at the component level would be overly burdensome for manufacturers of complex products that often contain hundreds or thousands of components. Uniform standards for breaking down complex products into components is a challenging topic that is the main focus of a 100+ page EU guidance document. MPCA should avoid this issue to the extent feasible. Finally, variations among a manufacturer's suppliers will likely mean that there are variations in PFAS levels among components. For example, a laptop may have batteries manufactured by several different battery suppliers. There will be some variations in the amount of PFAS in each of those batteries.

Recommendation: Lines 5.23 – 6.10 of the proposed rule should be deleted. Manufacturers should be permitted to report PFAS concentration at the product level but may report at a more granular level depending on whether these PFAS concentrations are known. Other regulators have permitted reporting PFAS concentrations this way, including under Canada's PFAS reporting notice (see page 8 of Canada's Guidance Manual where it is explained that concentration should be calculated at the component level, but if this information is not reasonably accessible the concentration can be calculated for the entire manufactured item).

6) **The rule should allow reporting of product groups by using conservative assumptions of worst-case potential PFAS content since there are variations in PFAS content between products within a product group due to multi-sourcing and differences in configuration.**

Issue: Lines 5.13 – 5.22 and 5.23 - 6.10 permit manufacturers to report by product group, (e.g., a laptop PC), if the PFAS composition in the products are the same, the PFAS fall into the same reporting concentration ranges, the PFAS provide the same function in each product, and the products have the same basic form and function with only minimal differences that do not impact PFAS composition. However, this product grouping requirement is too exacting to be of practical use to manufacturers of complex products, such as electronics, due to variations of PFAS concentrations in multi-sourced. Multiple interchangeable supplier parts, such as batteries, may have different PFAS content due to differences in PFAS content among suppliers and differences in configuration (e.g., if a laptop has one or two battery packs in it). Allowing this type of grouping will allow companies to efficiently report different product versions and variability in PFAS content and will ultimately allow the MPCA to focus its analysis of reported data on significant variations and trends rather than on minute PFAS variations across product versions. Furthermore, use of the recommended conservative assumptions will help ensure PFAS data is not underestimated.

Recommendation: An additional romanette (v) should be added after line 5.22 stating the following:

> *Notwithstanding the foregoing, manufacturers may group different versions of the same product that have variations in the type, number and concentration of PFAS used, provided that (i) all specific PFAS that could be present in any one unit of product sold across all product versions within the product group are identified, and (ii) the highest potential concentration of each identified PFAS within the grouped product is reported. It is understood that not all units of products sold under a product group will contain all PFAS disclosed in the report, however, the report contains the worst-case of PFAS that may be present in any one unit of product sold.*

Line 7.3 of the proposed rules needs to be modified to account for the uncertainty in PFAS content between units of product sold under the same higher level product group, where not all PFAS reported will be present in each unit of product due to multi-sourcing and differences in product configuration versions within a product group. A disclaimer is needed to state the concentration ranges are worst-case potential PFAS content based on known variation in the type of PFAS used due to differences in supplier component PFAS content due to multi-sourcing, and configuration differences between product versions within a higher-level product group.

7) The rule should confirm that manufacturers do not need to conduct PFAS testing in preparation for reporting.

Issue: MPCA indicated several times in the SONR that testing products for PFAS is difficult, costly, and often inaccurate given the lack of PFAS testing methods (e.g., page 45 where the MPCA explained how such testing is an "intrusive and costly endeavor"). However, the proposed rule – particularly under the current "known" reporting standard used – envisions that companies may conduct PFAS testing if necessary to generate reportable data. If companies are aware that PFAS is in a product but are not aware of the concentration range, we read the proposed rule as allowing companies to either indicate that PFAS is present, but the amount or concentration range is unknown (line 7.15) or test the product for total organic fluorine (line 7.16-7.18). In other words, companies are not required to test. MPCA should confirm this.

Recommendation: In conjunction with incorporating the KRA standard as discussed above, the MPCA should add the following statement to the rule or at the very least in a guidance document. This statement is similar to a statement EPA made for the TSCA PFAS reporting rule on page 70535 of the preamble to that rule.

> *This rule does not impose a requirement to conduct PFAS testing of products. Instead, manufacturers must report information they already have, or can reasonably ascertain, on PFAS in their products.*

8) The fee structure may create situations where manufacturers may submit several reports

Issue: The rule states that "A manufacturer must pay a $1,000 fee to submit the initial report under part 7026.0030, subpart 1." However it is not clear if this $1000 fee is defined per manufacturer or per report. The regulation allows to group products per report which means each manufacturer may be submitting several reports.

Recommendation: We request that the flat fee be applied per manufacturer, and not per report. We would like to discourage the use of fees on a per product/product category basis without sufficient transparency as to how and what the fees will be used for.

ITI appreciates this opportunity to provide input on the Minnesota PFAS reporting rule and welcomes the opportunity to work with the Agency. If you have any questions, please contact Chris Cleet at ccleet@itic.org.

Regards,

Chris Cleet, QEP
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2022 IMERC Report Attachment A – ITI collective reporting changes, zero sales and phase-outs

The following companies phased out mercury use in 2019 and are no longer reporting in 2021:

- Agilent Technologies
- Lenovo (United States), Inc
- P&F USA (including Funai Corporation)
- Samsung Electronics America Inc.

The following companies report that they have phased out all mercury use in 2021:

- 3M Touch Systems
- LG Electronics USA, Inc
- Toshiba Global Commerce Solutions, Inc.

The following products have changes reporting from 2019 to 2021:

Flat Panel Displays (Misc.)

- 5-10mg
    - Garmin had no sales of this product

Business, Office, Mfr

- <5mg
    - Panasonic is no longer selling this product
- 10 – 50mg
    - Xerox noted a reporting error with the amount of mercury in one of their bulbs and has adjusted their reporting for 2021

Digital Projectors

- 5-10mg
    - Dell had no sales of this product
- 50-100mg
    - Panasonic is no longer selling this product

Home Appliance with lamp

- Panasonic has discontinued this product

Personal Care Products Council
Committed to Safety, Quality & Innovation

May 21, 2025

Commissioner Katrina Kessler
Minnesota Pollution Control Agency
520 Lafayette Road
St. Paul, MN 55155

Submitted to the Minnesota Office of Administrative Hearings via electronic portal at http://minnesotaoah.granicusideas.com

Re: Proposed Final Rules Governing Reporting and Fees Paid by Manufacturers Upon Submission of Required Information about Products Containing Per- and polyfluoroalkyl substances (PFAS), Revisor's ID Number R-4828

The Personal Care Products Council (PCPC)[1] respectfully submits the following comments to the Minnesota Pollution Control Agency (MPCA) in response to the proposed final rule on PFAS reporting and fees rule (Minn. Stat. § 116.943). PCPC previously submitted comments and had a meeting with MPCA in January 2025. PCPC appreciates MCPA's apparent willingness to help ensure that the resulting PFAS law is reasonable and enforceable. Nevertheless, PCPC remains concerned about the definition of "product component" as it relates to cosmetic packaging.

Minn. Stat. § 116.943(1)(l) defines intentionally added PFAS as "PFAS deliberately added during the manufacture of a product where the continued presence of PFAS is desired in the final product or one of the product's components to perform a specific function." Further, §116.943(1)(q) defines "product component" as "an identifiable component of the product, regardless of whether the manufacturer of the product is the manufacturer of the component."

During a webinar offered by MPCA on July 25, 2024, the following statement was displayed on screen:

"Only the product packaging which is integral to contain, protect, or dispense the product is considered a product component and is included in the 2025 prohibition….Ex: a manufacturer is selling lip balm, the lip balm and the tube used to contain the lip balm are considered a cosmetic

[1] Founded in 1894, the PCPC is the leading national trade association representing the cosmetics and personal care products industry. PCPC is dedicated to promoting product safety, quality, and innovation, serving as a unifying voice that champions science-based standards and responsible practices to support health, well-being, and economic growth. PCPC's global members are some of the beloved and trusted brands in beauty and personal care today, providing millions of consumers with the diverse products they rely on every day – from sunscreens, toothpaste and shampoo to moisturizer, makeup, and fragrance

product and are subject to the 2025 prohibition. The plastic mold adhered to the cardboard used to handle and display the lip balm would not be considered a product component."

This same language was subsequently found on the MPCA website and lined in a Q&A document.

MPCA's interpretation of "product component" is vague, broad, and ambiguous. Despite concerns raised by PCPC in comments submitted in December 2024 and during a meeting with MPCA officials in January 2025, the proposed final rules fail to provide sufficient guidance on what MPCA considers a "product component" when it comes to cosmetic product packaging. PCPC requests that the Administrative Law Judge not accept and enact the proposed final PFAS rules until MPCA either (a) refines the definition of "product component" to clearly exclude packaging, or (b) provides the industry with specific, enforceable guidance on how "integral" packaging is defined and evaluated.

Respectfully,

Emily Manoso
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Personal Care Products Council

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Staff Counsel, Legal & Regulatory Affairs
Personal Care Products Council

RECEIVED
By: OAH on 5/21/2025
Riaz Zaman Attachment

AmericanCoatings ASSOCIATION℠

May 21, 2025

Katrina Kessler
Commissioner
Minnesota Pollution Control Agency
Office of Administrative Hearings
600 North Robert Street
St. Paul, MN 55164-0620

Re: REQUEST FOR COMMENTS on Rules Governing Reporting and Fees Paid by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS)
Submitted online at: www.minnesotaoah.granicusideas.com
Submitted prior to 4:30 p.m. Central Standard Time

Dear Commissioner Kessler:

The American Coatings Association ("ACA")[1] appreciates the opportunity to provide comment regarding implementation of Minnesota Session Law, Ch. 60, Art. 3, Sec. 21 (Minnesota Statutes 116.943), subdivision 2, known as "Amara's Law." The Association's membership represents 90% of the U.S. paint and coatings industry, including downstream users of chemicals who manufacture end-use formulated products such as paints, coatings, sealants and adhesives. ACA appreciates the agency's willingness to interact with stakeholders during this process.

ACA and its members respectfully submit the following suggestions:

I. Additional time to report is needed.

ACA requests that the agency extend the reporting date from January 1, 2026 to January 1, 2027, to accommodate detailed reporting requirements in the final rule and additional data

[1] ACA is a voluntary, non-profit trade association working to advance the needs of the paint and coatings industry and the professionals who work in it. The organization represents paint and coatings manufacturers, raw materials suppliers, distributors, and technical professionals. ACA serves as an advocate and ally for members on legislative, regulatory and judicial issues, and provides forums for the advancement and promotion of the industry through educational and professional development services. ACA's membership represents over 90 percent of the total domestic production of paints and coatings in the country.

elements. The final rule will include specifications for reporting of PFAS volumes, collective reporting, reporting of product identity, etc., that were not included in the act. Since these rules are currently in the proposal phase, entities would have a very short time frame to comply with the January 1, 2026 deadline. Realistically, with the administrative review process, the rules could easily take until November to finalize. In any case, the upcoming January 1, 2026 deadline is already too short of a time to comply. The administrative strain is compounded on manufacturers of formulated products that may need to submit multiple reports to cover varying product types.

In addition to those noted above, the proposed rules include several new data elements not included in the act, prior "concept drafts" or related webinar materials. New data elements include:

- Packaging – The proposed rule includes a new consideration of packaging as being reportable when *the packaging is inseparable or integral to the final product's containment, dispensing, or preservation*. (See definition of *Component*, Proposed Rule, Section 7026.0010 Definitions).
- Product identification – MPCA is proposing a hierarchy of codes used for product identification, establishing a preference for GPC (Global Product Classification) system, including brick or universal product codes or the harmonized tariff schedule code for imported products. These methods of product identification are not as common as identification by SKU (stock keeping units). Under the act and in prior concepts drafts, SKU numbers were deemed equivalent to GPC and related identification. If the current proposal is finalized, companies would need to conduct additional due diligence to provide the preferred identification.
- Manufacturers will require additional time to organize groups and advance group reporting, under the framework of the proposed rules.
- MPCA is now providing additional reporting specifications related to *function* of PFAS in a product. Manufacturers will require additional time to identify this data element from their supply chain.

MPCA has authority to extend the reporting deadline under Amara's Law at Subd. 3.Information requirement waivers; extensions:

> (d) The commissioner may extend the deadline for submission by a manufacturer of the information required under subdivision 2 if the commissioner determines that more time is needed by the manufacturer to comply with the submission requirement.

II. MPCA should extend the time period allowed for reporting extensions.

ACA requests modification of the proposal to allow 180 days as the standard extension period, from the current proposal 90 days under Subpart 3 of Section 7026.0060. This is needed to gather the complex set of information required for reporting, as described in the section directly above. Further, the extension requests anticipate testing or other protocol to gather information, requiring companies to submit a plan for completion as part of an extension request. The proposed 90-day period is simply too short to gather information and/or complete any required tests.

III. Fees must be more clearly aligned with administrative costs and fees must be capped.

MPCA's language related to fees indicates a one-time reporting fee per manufacturer. ACA recommends clarifying language at Section 7026.0100 so that companies filing more than one report are not subject to multiple fees. A registration fee of $1,000 per initial product registration can be excessive for manufacturers registering multiple products. Moreover, the fee does not appear to be reflective of administrative costs on the agency. Agency expenses would relate to establishing and maintaining an online reporting system and review of submissions. ACA would recommend further evaluation of actual costs for administration or making any previously conducted analysis available to justify the fee.

ACA recommends modifying language to clearly note that fees are capped to a one-time charge per manufacturer for each registration period, to recognize potentially excessive fees from companies registering multiple products. This can be accomplished with the following change to Section 7026.0100, Subpart 2 (FEES):

> Subp. 2. ***Initial report.*** *A manufacturer must pay a $1,000 fee to submit the initial report under part 7026.0030, subpart 1. If a group of manufacturers is reporting or a manufacturer is reporting on behalf of multiple manufacturers as allowed under part 7026.0020, subpart 2, each individual manufacturer must pay a $1,000 fee. A manufacturer submitting reports for multiple products, whether through a group or individually, is only required to submit the initial fee for one report per reporting period.*

IV. Rules should allow for *reasonable estimates* of PFAS quantities

Paint and coatings manufacturers may be able to estimate PFAS quantity in an end-use product based on percent in concentration of a raw material, depending on supplier notifications and information. While noting that downstream users of chemical raw materials face many challenges in obtaining information from suppliers, ACA requests that the agency update language at Section 7026.0030, Subpart 1(C) to note that a reported range can be based on a reasonable estimate, if the coatings manufacturer can obtain data to inform estimates from its supplier. The following change would add clarity:

C. the concentration of PFAS chemicals in a product or components of a product made up of homogenous material. A manufacturer must report the concentration of PFAS chemicals or provide a reasonable estimate as identified in subitem (1) or (2):

Providing some clarity around using reasonable estimates will assure more accurate information to the agency, since analytical methods for PFAS measurements in products are costly and often imprecise. Further, measurements of total organic fluorine are an inaccurate substitute for PFAS content.[2] ACA appreciates the proposed use of reporting bands to provide for some variance in PFAS measurements.

ACA is concerned about the lack of viable test methods for detection and reporting of fluorinated chemicals in products, leading to disparity in reporting methods and inaccurate reports. Manufacturers must be able to provide reasonable estimates. MPCA proposes an option to use commercially available analytical methods. Currently, manufacturers are not aware of standardized analytical methods for PFAS identification in articles and chemically formulated products. EPA's test methods are not designed for products. On its PFAS webpage, EPA identifies analytical methods identifying PFAS in water and air. EPA explains that it is currently developing test methods for PFAS to understand PFAS contamination across other environmental media. Notably, EPA has not developed analytical methods for PFAS in products. As explained on EPA's PFAS webpage:

> *EPA scientists are developing validated analytical methods for drinking water; groundwater; surface water; wastewater; and solids, including soils, sediments, biota, and biosolids, which may eventually become standard methods or research methods*.[3]

MPCA also proposes an alternative measurement of total fluorine as an indicator of PFAS. Total fluorine testing does not distinguish the variety of PFAS chemistries from overall fluorine content, resulting in inaccurate and over-inclusive reporting. Noting limitations of total fluorine measurements, a study concludes, "Measurement of total fluorine (TF) is inexpensive, but it is not as reliable of a proxy for PFAS because it includes inorganic fluoride in addition to organic fluorine."[4]

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[2] See Young, Anna, et. al., *Organic Fluorine as an Indicator of Per- and Polyfluoroalkyl Substances in Dust from Buildings with Healthier versus Conventional Materials*, Environ. Sci. Technol. 2022, 56, 23, 17090–17099, available online at: https://pubs.acs.org/doi/10.1021/acs.est.2c05198#

[3] See additional information here: PFAS Analytical Methods Development and Sampling Research | US EPA

[4] See Young, Anna, et. al., *Organic Fluorine as an Indicator of Per- and Polyfluoroalkyl Substances in Dust from Buildings with Healthier versus Conventional Materials*, Environ. Sci. Technol. 2022, 56, 23, 17090–17099, available online at: https://pubs.acs.org/doi/10.1021/acs.est.2c05198#

V. The standard of due diligence is not viable

The purpose of a due diligence standard is to notify entities of actions necessary to fulfill their compliance obligations, even in situations where the information is not ascertainable. The proposed standard of due diligence is vague and does not provide entities with the needed compliance framework. It simply states that reporting manufacturers must request reportable information from their supply chain *until all required information is known.* The agency should be aware that downstream users of chemicals will face situations where despite best efforts to request reportable information from suppliers, the downstream manufacturer will not obtain all reportable information from their suppliers. The proposed due diligence standard does not directly address this issue.

U.S. EPA typically requires that companies must report information *known to or reasonably ascertainable by* the reporting entity. This requires a thorough review of all documentation held within a company, including any information that a similarly situated company can be expected to have or have access to. This would include safety data sheets and any information provided by suppliers. Targeted external inquiries would be appropriate where the information is not held internally and documentation identifies an external source. In practice, downstream chemical users request information from their suppliers as needed.

Adopting this standard of due diligence would assure that companies conduct a thorough search for reportable information, while providing companies assurance against inconsistent enforcement or an inadvertent violation after a good faith effort to comply.

ACA suggests the following change to Section 7026.0080 Subpart 2:

> **Supply chain requests.** A manufacturer or group of manufacturers must report all information known to or reasonably ascertainable by them, including by requesting detailed disclosure of information required in part 7026.0030 from their supply chain. ~~until all required information is known~~.

VI. Protection of trade secrets

ACA appreciates the agency's inclusion of a process for protection of trade secrets. The proposed process allows for trade secret claims of chemical name, chemical identification number and defined supply chain information. The trade secret section (Section 7026.0700) introduces an ambiguous phrase, *chemical subclass,* in subpart 2 of the section:

> If the required data under subpart 1 is trade secret information as defined in Minnesota Statutes, section 13.37, then in addition to the information required under part 7026.0030, subpart 1, item B, the manufacturer or group of manufacturers must submit a ***chemical subclass*** to designate as public data. (bold and italics added)

ACA requests further explanation or a definition of the phrase *chemical subclass*.

VI. The proposed definition of "consumer" should not be finalized

ACA recommends not finalizing the proposed definition of "consumer." The definition seeks to establish a novel definition of *consumer* within the context of this law. The proposed definition conflicts with common understanding, the understanding within industry and common use in other legislation. Redefining *consumer* for the purpose of this rule, causes confusion, instead of bringing clarity about the scope of the rule.

MPCA proposes defining "consumer" as:

> *a person who acquires a product from a manufacturer for personal, residential, commercial, or industrial purposes.*
>
> (See definition of *consumer*, Proposed Rule, Section 7026.0010 Definitions)

The Department of Commerce establishes a more clear and common understanding of the term. The department defines the term *"consumer"* to mean *an individual who obtains, through a transaction, products or services which are used primarily for personal, family, or household purposes, and also means the legal representative of such an individual.*[5]

Noting common understanding, the Oxford dictionary includes the following definition:

> A consumer is *a person who purchases goods and services for personal use*.

MPCA's proposed definition is confusing and antithetical to the common and existing legal definition of *consumer product*. ACA recommends not finalizing this definition.

VII. Establish a date of manufacture triggering the reporting requirement.

Due to challenges in controlling distribution of existing products, ACA requests that MPCA include a date of manufacture that triggers the reporting requirement. That is, manufacturers must report all products *manufactured after* January 1, 2026 containing intentionally added PFAS placed on the market in Minnesota. These manufacturing dates are readily discernable from standard product labels and/or SKU numbers.

This change could be affected by a change to Section 7026.0020, as noted below:

> Subpart 1. Report required. A manufacturer or group of manufacturers of a product that is sold, offered for sale, or distributed in the state and that contains intentionally added PFAS must submit a report to the commissioner on or before January 1, 2026, only if it will continue to be manufactured with PFAS after January 1, 2026. A manufacturer or group of manufacturers of a new product with intentionally added PFAS after January 1, 2026, must submit a

[5] 15 USC 7006(a), available online at: https://www.law.cornell.edu/uscode/text/15/7006#1

report before the product can be sold, offered for sale, or distributed in the state.

Manufacturers typically relinquish control of distribution when they sell their product to a distributor or retailer. This distributor or retailer then uses stock to fulfill orders and/or direct sales, shipping a product to various locations. A manufacturer typically is not involved with this level of sales or distribution. Manufacturers can provide instructions to their downstream distributors and retailers to no longer sell specific products into Minnesota, but the manufacturer cannot control distribution. Some larger retailers may have the ability to quickly track distribution. SMEs (Small and Medium Enterprises) do not have this capacity.

Placing the compliance burden on manufacturers could result in disparities in enforcement. Manufacturers could be fined for distribution and sales over which they have no control. They could also be fined for products that have been discontinued, due to sales in Minnesota of warehoused products by a distributor.

Online sales compound the challenge of tracing distribution. Distributors may provide products to a third-party online sales distribution platform. Here, the distribution is even further removed from the point of manufacture then distribution directly to a business or retailer.

VIII. Eliminate redundancy in reporting new products.

MPCA proposes that manufacturers introducing a new product to the market after the reporting deadline, currently set for January 1, 2026, file a report prior to product introduction (*See* Section 7026.0030, proposed rules). MPCA then proposes filing another report under Section 7026.0040, during the annual reporting period. This section requires reporting of any new products introduced to the market in the prior 12 months by Feb. 1 of each year. This dual reporting requirement is redundant and unnecessary. ACA recommends maintaining the annual reporting requirement (in Section 7026.0040) for new products introduced in the prior 12 months, while eliminating the report prior to product introduction in Section 7026.0030. This approach provides consistency in scheduling reports for both manufacturers and the agency for processing, review and publication.

IX. Fluoropolymers should be exempted from this rule.

ACA recommends MPCA add fluoropolymers to the list of reporting exemptions in 7026.0090. Fluoropolymers are unique in that they are not water-soluble and have a high molecular weight. Fluoropolymers are critical for many applications and without viable alternatives health, safety, and economic stability could be severely impacted. We recommend amending 7026.0090 to add:

> F. a product that contains fluoropolymers consisting of polymeric substances for which the backbone of the polymer is either a per- or polyfluorinated carbon-only backbone or a perfluorinated polyether backbone that is a solid at standard temperature and pressure.

Fluoropolymers are considered "polymers of low concern" (PLC) recognized by several regulators, since they are chemically stable, non-toxic, non-bioavailable, non-water soluble and non-mobile. Recently, Ecology, when considering fluoropolymers as part of its review of PFAS under *its Safer Products for Washington* program, concluded:

> Fluoropolymers have been found to have thermal, chemical, photochemical, hydrolytic, oxidative, and biological stability (Henry et al., 2018; Korzeniowski & Buck, 2019a). They are almost insoluble in water and not subject to long-range transport. With very high molecular weight (greater than 100,000 Da), fluoropolymers cannot cross the cell membrane. They are neither bioavailable nor bioaccumulative. Clinical studies of their use in medical devices has [sic] demonstrated lack of chronic toxicity or carcinogenicity and no reproductive, developmental, or endocrine toxicity.[6]

The two studies Ecology relies on, from *Henry, et. al*. and *Korzeniowski*, evaluated criteria to conclude that fluoropolymers are not mobile, bioavailable or bioaccumulative. Further, they do not transform into long chain, non-polymeric chemistries associated with PFAS contamination. Fluoropolymers are a fundamentally different chemistry from non-polymeric PFAS chemicals associated with contamination, including the C-6 compounds indicated in Ecology's Draft Report. Because of these qualities, fluoropolymers have been classified as "polymers of low concern" by regulators.[7] For these reasons, Canada proposed to exclude fluoropolymers from its definition of PFAS for regulatory purposes, proposed in its *Updated Draft State of Per- and Polyfluoroalkyl Substances (PFAS) Report.*[8]

DoE (Department of Energy) recently concluded that fluoropolymers are distinct from non-polymeric PFAS chemicals in its report, *Assessment of Fluoropolymer Production and Use with Analysis of Alternative Replacement Materials* (published January 2024). DoE explains that due to relatively smaller molecular weight, non-polymeric PFAS are mobile in a variety of media, increasing particle dispersion. Significantly higher molecular weight of all forms of fluoropolymers, over non-polymeric PFAS, makes fluoropolymers stable and non-water soluble compared to non-polymeric forms. The report notes that literature suggests that fluoropolymers are generally non-mobile and cannot permeate the cell membrane. Some

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[6] Washington Department of Ecology, *Per- and Polyfluoroalkyl Substances Chemical Action Plan*, p. 97, Sept. 2022 revision of original publication from April 4, 2021, available online at: https://apps.ecology.wa.gov/publications/documents/2104048.pdf.

[7] See Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J. and Hernandez, O. 2018, *A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers*, Integr Environ Assess Manag, 14: 316-334, available online at: https://doi.org/10.1002/ieam.4035;
See also Korzeniowski, S.H., Buck, R.C., Newkold, R.M., El kassmi, A., Laganis, E., Matsuoka, Y., Dinelli, B., Beauchet, S., Adamsky, F., Weilandt, K., Soni, V.K., Kapoor, D., Gunasekar, P., Malvasi, M., Brinati, G. and Musio, S. 2022. *A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers*. Integr Environ Assess Manag, available online at: https://doi.org/10.1002/ieam.4646.

[8] See the Executive Summary in the Canadian Gazette, July 2024: https://www.gazette.gc.ca/rp-pr/p1/2024/2024-07-13/html/notice-avis-eng.html#ne3.

reports disputing these conclusions note evidence related to polymers rather than fluoropolymers.

The DoE further explains that,

> The unique characteristics of fluoropolymers can enhance product durability, sustainability and safety. Products that are lighter and longer-lasting will generally have lower life cycle costs, embodied energy, transportation-related emissions, and safety risks.

X. Conclusion

ACA appreciates the opportunity to comment regarding MPCA proposed rules affecting PFAS reporting and fees. Please consider the following suggestions, as described above:

- Cap fees to a one-time charge per manufacturer or group of registrants.
- Provide further evaluation of administrative costs justifying fees.
- Provide allowances for reasonable estimates of PFAS amounts.
- Modify the standard of due diligence to *known to or reasonably ascertainable by*.
- Provide an explanation of *chemical subclass* as used in the trade secret section.
- Extend the reporting deadline by a year.
- Do not finalize the proposed definition of *consumer*.
- Establish a date of manufacture triggering the reporting requirement.
- Require reporting of new products at the annual reporting period only.
- Add an exemption for fluoropolymers.

Please contact me if I can provide any additional information.

Sincerely,

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May 21, 2025

Minnesota Pollution Control Agency
Resource Management and Assistance Division
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RE: Response to Request for Comments to the Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees (c-pfas-rule1-06) and Statement of Need and Reasonableness for PFAS in products reporting and fees rulemaking (c-pfas-rule1-07)

To Whom It May Concern,

AdvaMed, the MedTech Association, is writing in response to the Minnesota Pollution Control Agency's (MPCA) Request for Comment to the Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees (c-pfas-rule1-06) and Statement of Need and Reasonableness for PFAS in products reporting and fees rulemaking (c-pfas-rule1-07) as directed by Minn. Stat. § 116.943. AdvaMed is the largest national trade association representing over 600 of the world's leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems.

Medical devices made by AdvaMed members help patients stay healthier longer, expedite recovery, allow earlier detection of disease, and improve effectiveness and efficiency of treatment. Understanding the complexity and importance of this Rule, and Minnesota's role as one of the first states developing a broad PFAS data reporting system, our goal is to work with the MPCA to ensure that the framework for PFAS data reporting is clear, scientifically possible, and protects patient access to medical devices regulated by the Food and Drug Administration (FDA).

Below are the areas that AdvaMed would like to provide comments on:

Reporting Exemption for Medical Devices

We appreciate that MPCA has recognized the unique nature of PFAS in medical devices and exempting these products from the ban. However, we respectfully reiterate our request that the exemption in Minn. Stat. § 116.943 Section. 2,

Subd.8.b.: "prosthetic or orthotic device or to any product that is a medical device or drug or that is otherwise used in a medical setting or in medical applications regulated by the United States Food and Drug Administration." apply not only to subdivision 4 and 5 but to the reporting requirements in Minn. Stat. § 116.943 Subd. 2 as well. Medical devices and drugs are thoroughly assessed and regulated by the FDA and are subject to federal requirements. Connecticut, New Mexico and Maine's amended law have exempted medical devices in their PFAS laws. These states recognized the highly complex and regulated nature of medical devices and drugs and understood that the state should instead focus its resources on gathering PFAS data and information on products that are subject to their states' PFAS bans. Additionally, New Mexico exempted fluoropolymers from their recently passed law recognizing not all PFAS is the same. A reporting exemption for medical devices, drugs, and their packaging would also allow MPCA to focus on PFAS-containing products that are not subject to the same rigorous regulatory scrutiny as medical technologies.

We believe that the current language under exemptions (7026.0090) in the proposed rule lacks some clarity and leaves room for interpretation. It is for these reasons that we respectfully request a full exemption from the law for medical devices and drugs, which are critical for lifesaving care for patients.

The Role of PFAS in Medical Devices

Per- and polyfluoroalkyl substances, known as PFAS, are a broad class of over 12,000 substances that are found in a variety of consumer, commercial and industrial products, including medical devices and their packaging. PFAS can essentially be divided into two separate classes: water-soluble PFAS and water insoluble PFAS. PFAS used in medical devices is water insoluble. Water insoluble PFAS (e.g., fluoropolymers) are a larger, higher molecular weight PFAS that are inherently stable, insoluble in water, and less bioavailable. Due to their unique properties of thermal stability, chemical resistance, and low friction, devices like catheters, pacemakers, and wire coatings in radiological machinery rely on PFAS, as well as packaging for surgical tools, implantables, and syringes that require sterilization. These unique properties make fluoropolymers essential in medical devices and medical products regulated by the FDA.

The FDA considers human health and safety risks, optimal product quality, and assessment of who will be utilizing the device (practitioner or patient) in their approval processes for medical devices and medical products. The health risks of these medical devices are thoroughly assessed by the FDA before they make it on

the market and must undergo multiple tests to prove biocompatibility in compliance with the international biocompatibility standard, ISO 10993.

As part of FDA's regulatory process for medical devices coming to market, materials of the product as well as the packaging may be considered a component of the device itself, or it could be a part of the final design specifications of the device as it is meant to be sold and distributed. FDA must validate these products as safe, non-toxic, and resilient enough to withstand sterilization, transport, storage, and normal use so that it can function as intended without any damage or harm to the patient.

The Adoption of a One-Year Reporting Delay

While the MPCA has been working towards the January 1, 2026 statutory deadline for reporting, we believe that there are many areas of this rule that still need to be refined. AdvaMed urges the MPCA to adopt at minimum a one-year reporting delay rather than the options for 90-day delays at the discretion of the Commissioner. By adopting a fixed length delay, it will help focus all stakeholders on a new date rather than moving in 90-day increments. Manufacturers need to have sufficient time to understand and implement these requirements. AdvaMed is concerned that the outstanding questions and issues detailed below and the lack of clarity on the reporting framework will pose challenges for compliance and in turn will not provide MPCA with useful data.

A one-year extension would further allow MPCA to develop and receive comments on the proposed reporting platform, beta testing of that platform, and the proposed guidance to ensure certainty for medical device innovators. Without this information for stakeholders to review, stakeholders will be providing incomplete feedback and will be inadequately prepared to comply with this rule. Further, guidance and FAQs will be needed for those reporting to understand how to use the portal when it is time for submissions.

In the case of medical devices, they can be complex products potentially with supply chains that are sometimes eight to ten layers deep that will need to be reviewed and notified. It is unreasonable for those subject to reporting to be in a position to meet the January 1, 2026, implementation if the rule is not finalized yet.

Broad Reporting and Compliance Challenges

AdvaMed members have raised concerns that the reporting mechanisms are not clarified to the level that the full process can be understood and feasible. In a

supply chain that is highly complex and multiple layers deep, often, a component material supplier views their component design as their intellectual property (IP), including the specific material used. In those instances, the FDA has a regulatory approach for those suppliers to divulge information to the FDA but not to the manufacturer. As a result, medical device manufacturers will struggle to achieve full disclosure to MPCA in a timely manner. While this information is provided to the FDA and the materials in the products are highly regulated, the information provided to medical device manufacturers is not always consistent or standardized regarding the materials in the product.

We have multiple instances of AdvaMed members who are well over a year into their PFAS supply chain identification that may still need several more years to even identify where regulated PFAS substances occur in their supply chains. Pursuing this lengthy and uncertain due diligence must precede any mitigation and process changes a manufacturer can begin to implement. Further, there is no "commercially available" technique that can assess all 12,000+ PFAS chemicals at one time which makes this process time consuming and labor intensive.

In fact, European Chemical Agencies PFAS restriction proposal, Annex XV Report of the Registry of Restriction Intention states that chemical standards for only 40 PFAS exist for quantitative analysis. Additionally, as analytical techniques can only assess what can be extracted out of a device, it becomes near impossible to identify what is present rather than what can leach out. Furthermore, the very nature of fluorine means it is naturally monoisotopic and, therefore, extremely difficult to identify de novo in extracts as part of an unknown. Commercially available software algorithms have an inherent bias to deduce a chemical formula containing fluorine through the use of high-resolution mass spectrometry. This inherent bias leads to a high number of false positives.

While there are well over 12,000 PFAS substances, this is an evolving and growing number. Less than 1% of these PFAS have a commercially available analytical reference standard (CAARS) and since a CAARS is needed to perform a quantitative analysis of a given material to determine the amount of all PFAS potentially in the sample, this simply is not practically achievable, unless and until, an analytical reference standard is available commercially for each of the 12,000+ PFAS. Even then, the burden of trying to test a given sample for 12,000+ different PFAS to potentially certify that no PFAS are present, will be a massive burden on obligated parties as well as the test labs performing the work, given that potentially thousands of manufacturers will simultaneously need this testing.

Definitions

We request the following additions and clarifications to the Definitions (7026.0010) in the proposed rule:

Intentionally Added PFAS: AdvaMed would ask that MPCA include a definition in the final rule for "intentionally added PFAS" to reiterate the definition found in Minn. Stat. § 116.943.

Additionally, AdvaMed would request clarification as to what intentionally added captures. For example, if a PFAS used as a polymer processing aid was deliberately added to the polymerization pot to perform a specific function (emulsification), but has no function once the fluoropolymer (a different PFAS) has been made and isn't desired in the finished fluoropolymer, and the finished fluoropolymer is used to make an article (such as a medical device), it is our understanding that the fluoropolymer would be intentionally added to the medical device, but any trace residual of the polymer processing aid potentially incorporated into the medical device because it remained in the finished fluoropolymer would not be an intentionally added PFAS. We would ask the MPCS to please confirm our understanding.

Chemical identifying number: It is also possible that one chemical identifying name may correspond to different names for the same chemical, so we would ask this definition to be updated to include: "A particular chemical may have more than one chemical identifying number, *and one chemical identifying name may correspond to different names for the same chemical."*

Distribute for sale: AdvaMed asks that MPCA clarify that "distribute for sale" refers to distribute for sale in Minnesota. As the definition currently reads, if a product was shipped to Minnesota but then transferred out of the state for sale without being sold in Minnesota, it would be subject to this rule. We believe products that are shipped through the state but not sold there should not be subject to this rule.

Manufacturer: Additional clarity is needed around the term manufacturer. There are circumstances in which two different entities meet the current definition for the same product. One manufacturer may manufacture the product, and another may legally affix their name to that product. In this

circumstance it is unclear who the "manufacturer" is and which entity is responsible for reporting.

Additionally, this proposed rule does not adequately account for manufacturers whose products are sold by distributors and may be unaware that their products are being offered for sale in Minnesota. In this situation, they may be unable to report under this rule and we would recommend that there be an ability for the distributor to report instead of the manufacturer in situations like this. There could also be a similar situation in which a manufacturer licenses their logo-branded product but does not sell the product. In this situation, there should also be a provision for the reporting requirement to be managed by the licensee not the licensor. A similar situation would arise in which the original manufacturer is not the entity completing the sale through an online platform and may not be able to track that transaction or have control over it.

Numeric Product Code: 7026.0010, Subp. 15. (lines 3.3-3.7) references HTS codes. There are three different levels of HTS codes (6 digit, 8 digit, and 10 digit), with the higher digit codes having more specificity. AdvaMed would request that the use of the 6 digit HTS code is acceptable. Further, we ask that the HTS option be available for any product where it is relevant and not just for imported products.

Packaging: AdvaMed appreciates the MPCA addressing packaging in a previous FAQ and would ask that interpretation and clarification from MPCA is included in the final rule to help provide additional guidance.

Parties Responsible for Reporting

AdvaMed appreciates that the MPCA created an opportunity for manufacturers to report as a group, however we believe that this will not enable streamlined reporting as intended. There are no provisions related to reasonably ascertainable information, and because of that the due diligence requirement would be impossible to meet in many circumstances. For medical devices and other products with deep, global supply chains, this is particularly challenging. As we shared earlier in this comment letter, it is not unusual for a component material supplier to view their component design as their intellectual property, including the specific material used.

In 7026.0020, Subp.1., AdvaMed asks for clarification on the requirement of "each product or component", is it the finished product, each component part, or both?

We also ask MPCA to clarify that the reporting on behalf of other manufacturers (Subp. 2.) only relates to products that are components of the final product and not for every component that a manufacturer may produce.

AdvaMed would also ask for guidance on how to report if a supplier has gone out of business during a reporting period and the manufacturer cannot access information to complete reporting.

Required Reporting Information

AdvaMed is concerned with the lack of clarity around the reporting requirements (7026.0030). Medical devices are complex products, and we are concerned about the feasibility of the reporting.

> New products: In Subp. 1., we are concerned that a new FDA regulated product with intentionally added PFAS must submit a report before the product can be sold, offered for sale, or distributed in the state. We do not believe that this is a reasonable approach and could hamper patient access to necessary medical technologies. At a minimum, we would ask that new products be reported within 12 months of being sold, offered for sale, or distributed into the state. For example, this could directly impact federal procurement for medical devices, such as medical imaging equipment and other vital technologies for Veterans Administration (VA) facilities. It is not unusual for a VA contract to stipulate that the manufacturer must provide the latest model when it comes time for delivery and installation. Furthermore, it could also have a chilling effect and impact patient access to novel or specialized medical devices and drugs when timely access is critical.
>
> Concentration Disclosure Requirements: In 7026.0030, Subp. 1.C.1.a. (line 7.7) we are concerned that the concentration range is too detailed. We would propose the first range be 100 ppm to <1,000 ppm (0.1 percent) as levels below that could potentially be inadvertent. Additionally, some companies do not capture PFAS less than 1,000 ppm. We would also appreciate an alignment with the existing TSCA 8(a)(7) ranges as it will ease the reporting burden on many industries in the United States that already report to the United States Environmental Protection Agency (EPA).

AdvaMed is also opposed to the inclusion of 7026.0030, Subp. 1.C.2. (lines 7.16-7.18) of the option to report total organic fluorine (TOF) and would instead propose the option to report as "(i) present but the amount or concentration range is unknown" (line 7.15) and include a due diligence standard so that manufacturers can update the concentration information once they have obtained the information. When Maine was updating their PFAS law, their initial bill included TOF testing, but it was removed after much opposition of it being too broad of a testing method. Instead, Maine requires reporting of the total product weight. TOF captures more than just PFAS and could potentially include inorganic fluorine. TOF is also a very lengthy and expensive process for many complex products, and it would further hinder compliance with this rule.

Manufacturer information: AdvaMed would ask for clarification on 7026.030, Subp. 1.E. through 7026.030, Subp. 1.G. (line 8.10). Does the manufacturer referenced here refer to the PFAS manufacturer or the manufacturer of the product overall?

Product grouping: AdvaMed requests broader flexibility on the grouping of products to account for products that have commonalities but not necessarily the same concentrations. We propose the striking of Subp. 1.A.1.a.ii. (lines 5.16-5.17) and Subp. 1.A.1.b.ii. (lines 6.4-6.5) and adding *"v. if the PFAS chemicals in the products fall into different concentration ranges, the highest concentration range must be reported so it is understood that all products in this reporting group contain that concentration range or less."* This flexibility would help streamline reporting for manufacturers that have tens of thousands of products or components subject to reporting.

Additionally, the proposed language in 7026.0030, Subp. 3. is inconsistent with the existing statutory language on remedy through notice and testing only.

Reporting Updates

In 7026.0040, Subp. 2., AdvaMed is concerned that the annual recertification, if an update is not required, is an administrative burden with no added value. Without access to even a beta portal to review, there is no way of knowing if the information submitted is carried over year-to-year or if it would have to be re-entered every year. If it is the latter, that would be a large annual undertaking for companies that are reporting tens of thousands of products or components subject

to reporting. We believe that the relevant information would be captured in the updates required in Subp. 1.

AdvaMed appreciates the inclusion of a voluntary update.

Waivers

AdvaMed would appreciate clarity regarding publicly available information that is used as substantially equivalent information. It is possible that verified, publicly available information may be dated and could be used to support this request. We would request that MPCA allow this as part of the Waiver process.

We would also appreciate the inclusion of language that allows MPCA to grant or a manufacturer to request a waiver for all reporting requirements or deadlines for certain groups (either products or manufacturers) subject to reporting.

Extension Requests

In 7026.0060, Subp. 3. (starting line 12.1) there is no timeframe in which the commissioner has to decide whether to approve the petitioning manufacturer or group of manufacturers an extension request or not. Additionally, it does not specify whether the manufacturer will be out of compliance if the reporting due date passes while waiting for the extension to be approved or denied. This is an unreasonable amount of leeway to grant MPCA.

AdvaMed is also concerned that a 90-day extension is insufficient given the complexity of some products and multi-layered supply chains. Medical devices can be exceptionally complex, and there could be tens of thousands, if not more, component pieces. Ninety days is unlikely to be enough time to continue to work through a supply chain that is eight or ten layers deep. AdvaMed recommends the extension be lengthened to 180 days to take into account the complexity of products.

Due Diligence

The requirements set forth in this section make it unreasonable and impossible for those subject to the rule to reach compliance.

In considering due diligence requirements, the TSCA reporting rule requires for reporters to provide information that "Such information would be reported for each

year since 2011 in which a covered PFAS was manufactured, to the extent such information were known to or reasonably ascertainable by the reporter." AdvaMed believes that a similar alignment would be appropriate for MCPA.

In the case of supply chain requests, (7026.0080, Subp. 2.) we are concerned that suppliers will not provide their trade secret information to a customer inquiry unless they have confidence that it will continue to be protected as a trade secret. There are also circumstances that the supplier's trade secret may not be their customer's (an upstream manufacturer) trade secret. Therefore, we request that "until all required information is known" (line 13.15) is updated to "and take reasonable steps to obtain responses."

AdvaMed is also concerned that the documentation and recordkeeping language in 7026.0080, Subp. 3. A-C. (lines 13.16-14.3) is overly broad and unreasonable. We propose that "A manufacturer or group of manufacturers must maintain documentation of its relevant reporting responsibility agreements with and/or notifications from other manufacturers as provided in part 7026.0020, Subp. 2." Additionally, Subp.3.C. (lines 14.1-14.3) would create a permanent retention policy for products that are not subject to the ban or obtain a critical use exemption and are not reformulated. We would ask that MPCA revise the language to specify a length of time (ex: 3 years) or while the reporting responsibility agreement remains in effect.

Trade Secret Data Request

In addition to the data outlined in 7026.0070, Subp. 1.A-C. (lines 12.21-12.23), AdvaMed requests the addition of PFAS concentration range and the function of the PFAS be part of the data that can be requested that the Commissioner maintain as trade secret data. Both possess economic value, are not generally known, and manufacturers, as well as their suppliers, have taken reasonable steps to protect this information.

Reporting and Fee Payment Process

AdvaMed supports the per-manufacturer fees rather than per-product fees as some manufacturers could have tens of thousands of products that would fall under this rule. We believe that this is the intent in this proposed rule but would still appreciate more explicit language as it is an important distinction.

Additional Comments

AdvaMed urges MCPA to consider expeditiously issuing a request for comments on "current unavoidable use" of PFAS, under subdivision 5. While FDA regulated medical technology is exempt from subdivision 5, our suppliers are not. The industry is extremely concerned about the resiliency of our supply chain if additional suppliers exit the market without substitutes that meet the unique properties necessary to maintain FDA standards for medical devices and packaging.

Advancing the rulemaking process for subdivision 5(c). and issuing a list of products not subject to the ban well in advance of 2032 would provide clarity to manufacturers about the potential supply chain risks and prevent disruptions to critical infrastructure, including health care.

We are also encouraging MPCA to pursue some form of information collection request (ICR) to better inform the regulator of the current state on PFAS by industry type before finalizing a rule. This could be done confidentially without the need for disclosing proprietary information and would allow for a more considered approach to addressing this issue. This has been done in the past and did give the regulator a better footing for a risk reduction-based approach in a final rule.

***

AdvaMed appreciates the opportunity to respond to MPCA's Request for Comments and we look forward to working with MPCA as a technical resource on this complex and precedent setting rulemaking.

Sincerely,

Adrienne Frederick
Director, State Government & Regional Affairs
AdvaMed

SIERRA CLUB
NORTH STAR CHAPTER

North Star Chapter
2300 Myrtle Ave, Suite 260
St Paul, MN 55114

RECEIVED
By: OAH on 5/21/2025
Lori Olinger Attachment

May 21, 2025

Honorable Judge Jim Mortenson
600 North Robert Street
St. Paul, MN 55101

Re: Minnesota Pollution Control Agency's Notice of Intent to Adopt New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per- and Polyfluoroalkyl Substances (PFAS), Revisor's ID Number R-04828, OAH docket number 5-9003-40410

Dear Judge Mortenson,

The North Star Chapter of Sierra Club appreciates the opportunity to submit these comments regarding the Minnesota Pollution Control Agency's (MPCA) proposed rule on PFAS in products: Reporting and Fees.

7026.0030 REPORT; REQUIRED INFORMATION.

We support the reporting date requirement of January 1, 2026. Since Amara's Law passed in 2023, manufacturers should have been aware of the reporting requirement and started collecting the required information. Also, most companies should have been collecting data for the EPA TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements. In addition, manufacturers have the option of requesting an extension if needed.

We agree with the rules that require identifying the PFAS chemicals used in a product and the functions that they perform. There are thousands of PFAS chemicals in use, but test methods only identify from 35-75 different analytes. To begin the process of finding PFAS alternatives, it is critical to have transparency for the chemicals being used in products.

7026.0100 FEES.

The Statement of Need and Reasonableness indicates that, "Subpart 2 establishes $1000 flat fee per manufacturer for the initial report." (page 40) It would be helpful to clarify in the rules that the fee is not by report but by manufacturer.

We appreciate that the Statement of Need and Reasonableness indicates that there will be public-facing reports. We ask that the reports include the PFAS chemicals and amounts along with product names, descriptions and categories. We also ask that the information be made available to the public as soon as possible so that consumers can use it to make safer product choices.

SIERRA CLUB
NORTH STAR CHAPTER

North Star Chapter
2300 Myrtle Ave, Suite 260
St Paul, MN 55114

Minnesota is a leader in addressing the serious health and environment problems caused by PFAS chemicals. We appreciate the work the MPCA has put into creating rules that will be an important step in providing needed transparency for manufacturers and the public.

Sincerely,

Lori Olinger
Co-Chair, Zero Waste Task Force
Sierra Club North Star Chapter

WINDOW & DOOR MANUFACTURERS ASSOCIATION
WDMA

May 21, 2025

The Honorable Katrina Kessler
Commissioner
Minnesota Pollution Control Agency
520 Lafayette Road North
St. Paul, Minnesota 55155

RE: MPCA PFAS Proposed Permanent Rule on PFAS Fees and Reporting (OAH Docket No. 5-9003-40410)

Dear Commissioner Kessler:

On behalf of the member companies of the Window and Door Manufacturers Association (WDMA), thank you for the opportunity to submit comments on the proposed permanent rules relating to PFAS in products, specifically addressing reporting and fees. As manufacturers of windows, doors, and skylights, our members are committed to reducing their environmental impact and ensuring the safety and sustainability of their products.

WDMA represents more than 80 companies that produce windows, doors, skylights, or components of those products for use in residential and commercial buildings. This industry is one of many with a rich legacy in Minnesota, with many companies having headquarters or manufacturing facilities in the state—or both. It is also an industry built by families who have always prized craftsmanship, innovation, quality, resilience, and sustainability.

While WDMA members are supportive of efforts in many states to limit—and ultimately eliminate—the use of PFAS in all products, we have several concerns about the proposed rule that we hope the MPCA will address to ensure its efficacy and ease of compliance.

WDMA members manufacture products and materials that are crucial to the integrity of a home or building enclosure. Windows, doors and skylights let light into our lives, help us live and heat our homes. They protect against air, moisture, and water intrusion. They contribute to the energy efficiency of a home or building. They are important factors in the health, safety, and wellness of our community. They are vital in protecting people where they live, work, play, learn, and heal. WDMA members believe great care should be taken to implement this rule without causing unintended harm to the quality of a home or building's enclosure.

Request for Delay in Reporting Requirements

We recognize the significant effort in drafting the proposed rules and systems for data collection. However, WDMA members believe the deadline for reporting beginning on January 1, 2026 is too limiting for such a complex issue. WDMA urges the MPCA to delay the reporting requirements for one year from the enforcement date. The delay would allow both MPCA and manufacturers sufficient time to ensure manufacturers can fully comply with their obligations under the law.

Further, WDMA requests that the rule's implementation be delayed so that MPCA can synchronize reporting requirements with the expected companion proposed rule addressing "currently unavoidable use" determinations. We believe each rule will have implications for the other, and the impact on manufacturers could be significant.

Harmonization and Regulatory Alignment

As more states follow the lead of Minnesota in addressing the use of PFAS, reporting requirements will present a significant challenge to WDMA members. The process itself will be complex, as it will involve gathering information from all levels of the supply chain. This will be especially burdensome to small and medium-sized enterprises (SMEs), which often lack the resources for such extensive reporting. We urge MPCA, as a leader in the movement to eliminate PFAS from supply chains, to work with other states and harmonize reporting requirements as the rule is completed and going forward.

Scope and Reporting Requirements

WDMA members find the thresholds for incidental use of PFAS to be confusing and difficult to interpret. Many manufacturers use certain PFAS in the production process that do not remain in the final product. Our members respectfully request clarification on the triggers that would activate a reporting requirement. Clear guidelines on this issue will mitigate the time and effort spent collecting required information and limit under-reporting by our members.

Additionally, we would ask MPCA for clarification on several specific aspects of the proposed rule:

- How should equipment suppliers with complex products, consisting of multiple components and subassemblies, report to the MPCA?
- The rule requires manufacturers to report new PFAS-containing products before sale and submit annual reports on new products introduced during the year. This appears duplicative. Can MPCA confirm whether this is intentional?

- Should PFAS reporting occur at the parent company level, or should it extend to subsidiaries or local entities?
- In cases where a manufacturer is unaware that its products are sold in Minnesota through a distributor, should the reporting obligation fall on the manufacturer, distributor, or both?
- Many products incorporate recycled materials that may contain trace or near-de minimis levels of PFAS from prior uses. Has Minnesota considered an exemption from reporting for such cases?

Joint Reporting

We welcome the introduction of joint reporting options, which could simplify compliance for our industry. However, WDMA members do have questions about the structure of this opportunity:

- Could manufacturers with comparable products report collectively through their trade association or in a bilateral fashion?
- How should manufacturers decide whether their product meets the threshold for joint reporting?

Reporting Fees

We understand the need for these fees to support the enforcement of the rule. However, manufacturers of complex products such as windows, doors, and skylights want to fully understand their compliance obligations. The fee structure will have a dramatic impact on how reports are produced. Our questions are:

- Will the $1,000 or $500 fee be assessed per report, per product, or per manufacturer? If a manufacturer submits multiple product reports, are these fees applied to each individual report?
- Is it permissible to submit a single report covering multiple products or product families, or is a separate report needed for each individual product or family?

Trade Secret Protections

We support the proposed rule's provisions allowing manufacturers to request confidentiality for proprietary information, such as chemical names and supply chain data, under trade secret protections. We urge MPCA to ensure that the process for requesting such protection is streamlined and consistent with federal standards, including those related to the Toxic Substances Control Act (TSCA). This will ensure manufacturers can protect their proprietary

information efficiently, without undue administrative burden.

Conclusion

We urge MPCA to consider a longer lead time for implementation of this rule. Regardless of that timeline, we ask MPCA to address the concerns outlined above in the final rule to ensure it is effective and practical for manufacturers, particularly small and mid-sized companies. We appreciate consideration of our comments and look forward to collaborating further to improve the rule.

If you have any questions or requests, please do not hesitate to contact me at jcrosby@wdma.com or Michael Pierce, our Director of Government Relations, at mpierce@wdma.com.

Sincerely,

John Crosby
President & CEO
Window and Door Manufacturers Association

mema.
The Vehicle Suppliers Association

May 21, 2024
Katrina Kessler
Commissioner
Minnesota Pollution Control Agency
520 Lafayette Road N
St. Paul, MN 55155

RE: Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees

Dear Commissioner Kessler,

MEMA, The Vehicle Suppliers Association, submits these comments to the Minnesota Pollution Control Agency (MPCA) on its proposed permanent rules relating to PFAS in Products; Reporting and Fees[1].

MEMA, The Vehicle Suppliers Association, established in 1904, is the leading trade association in the U.S. for vehicle suppliers, parts manufacturers, and remanufacturers. The mobility sector depends on the resiliency and strength of suppliers. MEMA's members design and manufacture the technology, components and services that enable the production of new vehicles as well as the essential maintenance and repair of the more than 295 million highway vehicles that are currently on the road in the U.S.

Automotive and commercial vehicle suppliers are the largest employer of manufacturing jobs in the United States employing over 900,000 people throughout the country. Direct, indirect, and induced vehicle supplier employment accounts for over 4.8 million U.S. jobs and contributes 2.5 percent to U.S. GDP.

Vehicle suppliers play a crucial role as the innovators and manufacturers of a multitude of technologies and wide range of components, systems, and materials that improve vehicle safety, emissions, and efficiency. PFAS are critical to the production of motor vehicle parts and components, due to their durability and ability to withstand extreme use and high temperatures. PFAS play a crucial role in allowing vehicle suppliers to meet these safety and sustainability goals. The industry seeks to minimize the use of PFAS where possible, but for many components there are no currently available substitutes.

MPCA Must Provide Flexibility to the Motor Vehicle Sector

As MPCA finalizes its reporting requirements, it is critical that the agency adopt a scope that reflects the complexity of PFAS use in the motor vehicle industry. Motor vehicles are

[1] Office of the Revisor of Statutes Administrative Rules "*Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees.*" 2025

composed of about 30,000 parts[2]. Suppliers provide 77% of the value of a vehicle, ensuring the safe and efficient function of the vehicle, including new motor vehicles and the aftermarket components necessary for repair and maintenance[3]. The number of parts involved illustrates the need for flexibility to be granted to the industry to allow for the necessary research, development, and safety certifications to take place. For example, a 2023 -Department of Defense report found that it would take over 10 years to find suitable replacements where available for PFAS in semiconductor fabrication and energy storage[4]. Both semiconductors and batteries serve a critical role in advanced vehicle technologies.

Due to the large number of vehicle parts and anticipated reporting, MEMA urges MPCA to consider additional flexibility for the motor vehicle industry. For example, MEMA appreciates MPCA's use of Global Product Classification or Harmonized Tariff Schedule codes but cautions against the use of non-harmonized units such as stock keeping units (SKUs). It can be difficult to predict the demand for aftermarket parts to this level. It is possible that these requirements may lead to delays in the repair process, as there may be instances where a product has not yet been registered.

Further, MEMA urges MPCA to consider the adoption of de minimis language. MPCA has indicated its understanding of intentionally added PFAS to begin around 100 parts per million (ppm). In written follow-up from its July 2024 PFAS Rule Development webinar, the agency stated, "in general, we understand intentional additions of PFAS to be around 100 parts per million (ppm) or above; below that might be intentional but is more likely to be contamination (NOT intentional)[5]." MEMA is concerned by the inclusion of concentration limits below 100 ppm in the concentration ranges in the proposed permanent rule. Such a requirement is not practicable for the motor vehicle industry, which would have to test thousands of parts and may experience batch variability. This difficulty is compounded by the complexity of the supply chain. MEMA urges the agency to consider adopting a higher de minimis threshold, which will provide flexibility to reporting entities, and provide suppliers with leeway in instances where there is unreported data further down the supply chain.

MEMA appreciates the efforts taken by MPCA to provide flexibility to manufacturers in its proposed rules, specifically its proposal to allow manufacturers to group similar products. However, the criteria outlined to group products are restrictive to the motor vehicle industry, which sees a variance in the form, fit and function of its products in order to meet the needs of consumers. For example, the commercial vehicle industry is highly specialized to meet the needs of the end users, which range from construction to emergency services, to the transportation of goods. As a result of this necessary customization, the flexibility provided by MPCA is inaccessible to the motor vehicle industry, which as noted above has a large range

[2] Sabhadiya, Jingesh *"40 Basic Parts of a Car."* February 2021
[3] AAPEX "Automotive Aftermarket Industry Analysis." 2023
[4] Department of Defense. *"Report on Critical Per- and Polyfluoroalkyl Substance Uses."* August 2023
[5] Minnesota Pollution Control Agency *"Progress on PFAS Rule Development Webinar."* September 2024

of products that may be subject to reporting requirements. MEMA urges MPCA to consider adopting further flexibilities for manufacturers of complex products like motor vehicles.

MPCA Must Adopt a Practicable Due Diligence Standard

MEMA urges MPCA to reconsider the due diligence requirement outlined in its proposed rules. It is critical that for such a complex and expansive reporting requirement that MPCA adopt a practicable due diligence standard. This is especially important for the motor vehicle industry, which has a complex, global supply chain.

The supply chain is several levels deep and global in scope. There are manufacturers who supply new original equipment, such as finished parts, components and systems directly to the new vehicle manufacturers. Some manufacturers produce a niche of specialty components and other content to be incorporated into finished parts, components, and systems. There are also members of the vehicle supply chain that provide critical raw or semi-finished materials, such as metals, both for specialty and finished parts, components, and systems. These supply chains vary based on the component being produced or sourced. All layers of the supply chain are highly interdependent- one change to the supply chain will cause ripple effects across the industry.

Vehicle suppliers require flexibility to meet the proposed due diligence standards, which currently state that manufacturers must request detailed information from the supply chain until all required information is known. MEMA urges MPCA to adopt a standard that would allow for accommodation where responses are not provided further down the supply chain. This is an important consideration for the motor vehicle industry, which has a high number of parts supplied by a global supply chain.

For this reason, MEMA urges MPCA to adopt a "known and reasonably ascertainable" standard as it finalizes its reporting standard. This is a provision that has been adopted by EPA, which the industry has been preparing to comply with since a final rule was promulgated in October 2023. EPA defines the standard as "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to know[6]." Adoption of a similar reporting standard to EPA would streamline the process and allow reporting entities to focus on providing the highest quality data.

MPCA MUST EXTEND ITS REPORTING DEADLINE

In accordance with Minnesota Session Law- 2023, Chapter 60, H.F. No. 2310, manufacturers must submit reports by January 1, 2026, a date that is a mere seven months away. MEMA urges MPCA to extend its reporting deadline to allow for the finalization of its proposed rules and the development of its reporting platform.

[6] U.S. Environmental Protection Agency "*Instructions for Reporting PFAS Under TSCA Section 8(a)7.*" May 2024

The Vehicle Suppliers Association

It is critical that industry have access to the permanent rules and the reporting tool well in advance in order to ensure compliance. Given the short timeframe before reports are due, MEMA urges MPCA to extend the deadline to allow for these critical developments.

CONCLUSION

As MPCA develops its final rules relating to PFAS in products, MEMA urges the agency to provide flexibility to the vehicle supplier industry and adopt a more practicable due diligence requirement. MEMA also urges MPCA to consider providing an extension to the reporting timeline, to allow time for the development and testing of a reporting tool.

MEMA appreciates MPCA's consideration of our comments on its proposed permanent rules for PFAS in products. For more information or questions, please contact Emily Sobel, senior manager of regulatory policy at esobel@mema.org.

Sincerely,

Ana Meuwissen

Senior Vice President of Government Affairs

AEM
Association of Equipment Manufacturers

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RECEIVED
By: OAH on 5/21/2025

Jason Malcore Attachment

Maine Department of Environmental Protection
Spills & Site Cleanup
17 State House Station
Augusta, Maine 04333-0017
PFASproducts@Maine.gov

Re: PFAS in Products

To Whom it May Concern:

The Association of Equipment Manufacturers (AEM)[1] appreciates the opportunity to comment on the Maine Department of Environmental Protection (MDEP), *Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances*[2] hereafter referred to as the proposed rule. We look forward to sharing the expertise and technical knowledge of our industry sectors. We believe it is critically important when developing regulations, that the interest of all stakeholders be considered and understood.

The off-road equipment manufacturing industry understands the value and importance of using sound science to inform future policymaking decisions. AEM strives to be a key stakeholder in these policymaking discussions. To ensure that new rules meet their objectives with accurate and complete data, AEM wants to support MDEP's approach as well as make a request that MDEP take into consideration the following point:

1. MDEP harmonize their refrigerant requirements and restrictions under the PFAS in Products program to those of the EPA SNAP program.

Restrictions on the Use of PFAS in Maine:

On December 20, 2024, MDEP released their Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalky Substances proposed rule. Under Section 5F of this rule, MDEP states:

> *The prohibition of this subsection does not apply to any such products sold, offered for sale or distributed for sale in used condition or to parts and other servicing needs for cooling, heating, ventilation, air conditioning or refrigeration equipment, including refrigerants used in servicing such equipment as long as the refrigerant is listed as acceptable, acceptable subject to use conditions or acceptable subject to narrowed use limits by*

[1] AEM is the North American-based international trade group representing heavy-duty nonroad equipment manufacturers and suppliers with more than 1,000 member companies and over 200 product lines in the construction, agriculture, mining, forestry and utility industries. The equipment manufacturing industry in the United States supports 2.8 million jobs and contributes roughly $288 billion to the economy every year. Our industries remain a critical part of the U.S. economy and represent 12 percent of all manufacturing jobs in the United States. Our members develop and produce a multitude of technologies in a wide range of products, components, and systems that ensure heavy-duty nonroad equipment remains safe and efficient, while at the same time reducing carbon emissions and environmental hazards. Finished products have a life cycle measured in decades and are designed for professional recycling of the entire product at the end of life. Additionally, our industry sectors strive to develop climate friendly propulsion systems and support robust environmental stewardship programs around the world.

[2] https://www.maine.gov/dep/rules/index.html#13139124

> *the EPA pursuant to the Significant New Alternatives Program at 42 U.S.C. 82(G), as long as the refrigerant, foam, or aerosol propellant is sold, offered for sale or distributed for sale for the use for which it is listed pursuant to that program.*

This paragraph permits manufacturers to service existing equipment in the field with refrigerants that may contain PFAS chemicals.

Under a recent Federal Rule, as of October 24, 2023, EPA promulgated their Final Rule[3] to restrict the use of certain hydrofluorocarbons in specific sectors or subsectors. The Final Rule established a Global Warming Potential (GWP) limit of 150 for refrigerants manufactured, distributed, or exported for use in motor vehicle air conditioning systems in nonroad vehicles, with a compliance date of January 1st, 2028. This restriction would apply to all products, except for those products sold or distributed, or in existence in the nonroad sector prior to December 27, 2020.

The established restriction limit of 150 GWP would effectively forbid the use of certain refrigerants, such as HFC-134a, in the nonroad sector but does allow for manufacturers to use low GWP refrigerant alternatives, like HFO-1234yf, or blends of different refrigerants to meet the new requirement. However, in practice the only realistic refrigerant that allows Original Equipment Manufacturers (OEM) to meet the requirements of the rule is HFO-1234yf.

The Proposed Rule, on the other hand, bans the use of all PFAS substances used in new heating and air conditioning equipment, and the refrigerant chemicals themselves, by 2040. This creates a unique standard for manufacturers to meet when looking to sell or service new equipment in Maine. Off-road equipment requires an efficient and operational heating and air conditioning system, not only for the comfort of the operator, but also for meeting health and safety requirements promulgated by OSHA.

At this point in time, there are no known substances that can adequately replace HFO-1234yf for use in off-road equipment. This risks the longevity of the entire off-road equipment sector in Maine. The EPA's SNAP program is a robust and well-known standard for assessing the viability and availability of refrigerants used in different sectors. This ensures manufacturers can meet environmental goals, while at the same time mitigate risks to industry. The SNAP program also ensures a harmonization of requirements across the United States.

For these reasons, AEM requests that MDEP harmonize their own requirements under the PFAS in Products program to those of the EPA SNAP program.

AEM Appreciates your consideration of these comments.

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[3] https://www.federalregister.gov/documents/2023/10/24/2023-22529/phasedown-of-hydrofluorocarbons-restrictions-on-the-use-of-certain-hydrofluorocarbons-under-the

Please feel free to contact Jason Malcore, AEM's Senior Director, Safety & Product Leadership at Jmalcore@aem.org if you have any questions or require any further information.

Best Regards,

Jason Malcore
Senior Director, Safety & Product Leadership
Association of Equipment Manufacturers (AEM

May 21, 2025

Submitted via the Minnesota Office of Administrative Hearings eComments Website

Commissioner Katrina Kessler
Minnesota Pollution Control Agency
520 Lafayette Road N
St. Paul, MN 55155-4194

Re: Comments from SEMI and SIA on the Proposed Reporting and Associated Fees Rules for PFAS-Containing Products

Dear Commissioner Kessler:

On behalf of SEMI[1] and the Semiconductor Industry Association (SIA)[2], we write to offer comments on the Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees (the Proposed Rule) being developed by the Minnesota Pollution Control Agency (MPCA or the Agency), as authorized in Minn. St. § 116.943 (Section 116.943). This submission is in response to the Notice of Hearing issued by the Minnesota Office of Administrative Hearings.[3] SEMI has previously provided comments to the MPCA on the development of these rules in November 2023 and December 2024,[4,5] and our comments below highlight the importance of the semiconductor industry and provide specific recommendations on the

[1] SEMI® represents more than 3,000 member companies to advance the technology and business of electronics manufacturing. SEMI members are responsible for the innovations in materials, design, equipment, software, devices, and services that enable smarter, faster, more powerful, and more affordable electronic products. Electronic System Design Alliance (ESD Alliance), FlexTech, the Fab Owners Alliance (FOA) and the MEMS & Sensors Industry Group (MSIG) are SEMI Strategic Association Partners, defined communities within SEMI focused on specific technologies. Since 1970, SEMI has built connections that have helped its members prosper, create new markets, and address common industry challenges together. SEMI maintains offices in Bangalore, Berlin, Brussels, Hsinchu, Seoul, Shanghai, Silicon Valley (Milpitas, Calif.), Singapore, Tokyo, and Washington, D.C. For more information, visit www.semi.org.

[2] SIA has been the voice of the semiconductor industry for over 45 years, representing 99 percent of the U.S. semiconductor industry by revenue and nearly two-thirds of non-U.S. chip firms. Semiconductors are one of America's top export industries and a key driver of America's economic strength, national security, and global competitiveness. The semiconductor industry directly employs over 345,000 workers in the United States, and U.S. semiconductor company sales totaled $318 billion in 2024. Through this coalition, SIA seeks to strengthen leadership of semiconductor manufacturing, design, and research by working with Congress, the Administration, and key industry stakeholders around the world to encourage policies that fuel innovation, propel business, and drive international competition. Additional information is available at www.semiconductors.org.

[3] https://minnesotaoah.granicusideas.com/discussions/40410-pollution-control-agency-notice-of-hearing-on-pfas-in-products-reporting-and-fee-rule

[4] In 2023, the MPCA released separate requests for comment on the planned new rules concerning PFAS reporting and PFAS reporting fees. SEMI submitted one comment document addressing both rulemakings, which can be viewed at https://speakup-us-production.s3.amazonaws.com/uploads/attachment/file/65664755f2b670e09c003e6e/SEMI_Comments_on_MPCA_PFAS_Reporting_Regulation_-_final.pdf.

[5] SEMI also submitted comments in December 2024 in response to the MPCA's second request for comments on the development of the Proposed Rule. Those comments can be viewed at https://www.pca.state.mn.us/sites/default/files/c-pfas-rule1-04.pdf.

Proposed Rule. SEMI and SIA incorporate these previous public comments into these comments by reference.

While SEMI and SIA fully support the goal of limiting the release of PFAS into the environment and appreciate the hard work that went into the Proposed Rule, SEMI and SIA still have serious concerns about the potential scope of these regulations as well as their incompatibility with Minnesota's own ambition to expand its semiconductor industry. With the indispensable role semiconductors play in the Minnesotan and American economy and in national security, it is critical that regulatory efforts avoid restricting semiconductor manufacturing, its corresponding supply chain, and future innovation.

I. THE RULES HAVE POTENTIAL TO DAMAGE CRITICAL INDUSTRIES AND THE HIGH-TECH ECONOMY IN MINNESOTA

a. PFAS are Essential to the Semiconductor Industry

PFAS are essential to the semiconductor industry because of their low surface tension, high heat and chemical resistance, high thermal stability, radiation stability, electrical characteristics, compatibility with other chemicals, and other unique properties.[6] These properties enable PFAS to fulfill the purity criteria required for semiconductor manufacturing. PFAS are used by the industry to meet many needs within the manufacturing process and can be found in various equipment, materials, and other critical components, including in the following:

- Control and distribution systems (e.g., pipes, pumps, valves, etc.);
- Various types of processing tools;
- Equipment (e.g., tubing, gaskets, containers, filters, etc.);
- Lubrication (e.g., oils and greases);
- Heat transfer fluids and refrigerants for high-precision temperature control units and process chillers;
- Facility systems in semiconductor manufacturing factories; and
- Process chemicals in photolithography, dry etching, and other processes to reduce the potential for defects and to enable high aspect ratio microstructures.

[6] Semiconductor PFAS Consortium, "Background on Semiconductor Manufacturing and PFAS," May 17, 2023. https://www.semiconductors.org/background-on-semiconductor-manufacturing-and-pfas/

In short, the semiconductor manufacturing process is enormously dependent on PFAS, the majority of which currently have no viable alternatives. Additionally, PFAS may be present in the final, packaged semiconductor device[7] that is subsequently incorporated into another subcomponent or a final product.

b. The Semiconductor Industry is a Crucial Part of Minnesota's Economy and Could Be Severely Damaged by the Rules

Subdivision 2(d) of Section 116.943 makes it unlawful for companies to sell, offer for sale, or distribute for sale in the state a product containing intentionally added PFAS unless the manufacturer has reported the required information. In addition, subdivision 5 makes it unlawful for companies to sell, offer for sale, or distribute for sale in the state a product containing intentionally added PFAS starting January 1, 2032, unless the MPCA has determined by rule that the use of PFAS in the product is currently unavoidable.

Without the requested waiver from reporting and exemption from the material restriction for semiconductors, as discussed in more detail below, Minnesota's robust semiconductor industry would suffer enormous damage. The state is home to one of the strongest semiconductor value chains in the United States, including a well-developed and robust design and fabrication network.[8] In 2023, Minnesota-based companies exported over $1.1 billion in semiconductor-related components and imported nearly $796 million in semiconductor-related components that are then incorporated into other products. Semiconductor equipment manufacturers in Minnesota exported over $200 million worth of machinery.[9] According to the U.S. Bureau of Labor Statistics, the state's semiconductor manufacturing sector includes 43 firms supporting 2,444 jobs with an average annual wage of $129,631 and total annual wages of about $317 million.[10]

PFAS are critical to the development and manufacturing of semiconductors, meaning that an overly broad and restrictive regulatory approach will cost Minnesota-based businesses and workers a major opportunity to benefit from the robust federal industrial policy authorized in the *CHIPS and Science Act* (P.L. 117–167). Implementation of the Proposed Rule without incorporating the requests discussed in these comments will not only hinder Minnesota's high-tech economy and the many other sectors that rely upon it, but will also jeopardize the state's ability to capitalize on the billions of dollars that the federal government is investing in the semiconductor industry via the CHIPS Program. In particular, the $500 million Minnesota Forward Fund, which was established in part as a resource for matching federal CHIPS funds, would be rendered unusable for one of its original purposes.

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[7] In the semiconductor industry, a "package" refers not to the box in which the device is contained but to the combination of materials and structural elements that connect an integrated circuit (IC) to a printed circuit board (PCB), interposer or device, while protecting the package from environmental influences. The package allows the IC to be able to connect to other components on the PCB, protects the semiconductor die from the external environment, and can also provide other performance attributes or functions (e.g., heat dissipation, power efficiency, etc.).

[8] Minnesota CHIPS Coalition, *Commentary: Minnesota Can Be a Leader in the U.S. Chip Renaissance* (Mar. 28, 2023), https://finance-commerce.com/2023/03/commentary-minnesota-can-be-a-leader-in-the-u-s-chip-renaissance/.

[9] U.S. Census Bureau. HTS codes 8541, 8542, and 8486.

[10] U.S. Bureau of Labor Statistics, Quarterly Census of Employment and Wages, 2023 Annual Averages, https://data.bls.gov/cew/apps/table_maker/v4/table_maker.htm#type=0&year=2023&qtr=A&own=5&ind=334413&supp=0.

c. The Rules Could Run Counter to National Efforts to Support the Domestic Semiconductor Industry

Chip shortages resulting from manufacturing disruptions caused by the COVID-19 pandemic highlighted the country's dependence on overseas suppliers of semiconductors and chips. Addressing these shortages by reshoring semiconductor and chip manufacturing to the United States has been an area of bipartisan focus at the federal level. First, the law aims to reduce the dependence of the United States on foreign countries for critical semiconductor components, thereby ensuring a stable and secure supply chain. Second, the law aims to boost domestic innovation and competitiveness in the semiconductor industry by providing funding opportunities for research, development, and manufacturing capabilities. Finally, the law seeks to create high-quality job opportunities and strengthen the overall economy by revitalizing the domestic semiconductor manufacturing sector.

Additionally, in 2022, the U.S. Department of Defense weighed in on the issue of PFAS in its Report on Critical Per- and Polyfluoroalkyl Substance Uses.[11] The findings highlight the singular and currently irreplaceable role that PFAS play in the semiconductor manufacturing process:

> *Currently, no alternatives to PFAS have been identified that can provide the functional properties required for photolithography or some applications in semiconductor manufacturing equipment. Even if alternative chemicals and technologies were discovered today, due to the extremely complex qualification process throughout the value chain, it would take another 15 years to deploy them in high-volume manufacturing. Therefore, continued access to PFAS is a prerequisite for high-volume and advanced semiconductors. Lack of continued access to PFAS could lead to an inability to produce and supply semiconductor manufacturing technology.*
>
> *Replacing most PFAS uses in semiconductor fabrication would require industry-wide retooling and other process innovations, at a minimum. Some might be achievable within 10 years, but many would not. As stated above, there are some PFAS uses for which no alternatives are known. For these uses, it may be necessary to invent novel chemistries and processes. Replacing PFAS in semiconductor fabrication could be a 25-year effort and may not succeed in all respects if alternatives cannot be identified or qualified at the microchip level.*

These efforts recognize that semiconductors enable critical technologies and industries that form the foundation of the U.S. economy, including the automotive industry, defense, electronics, communications, data storage and analysis, legal and regulatory infrastructure, scientific (including materials) research, medicine and medical devices, the green energy transition, and much more. PFAS are used in all these sectors, and any regulatory effort that too hastily and broadly restricts, and requires burdensome reporting tied to a restriction, on PFAS risks irreparable harm given these uses. Moreover, broad PFAS restrictions and reporting schemes can have the unintended consequence of hampering efforts to develop PFAS alternatives rather than funding and supporting such efforts, since there is no commercially available test method for determining the exact amount of all PFAS in products and research and development for PFAS alternatives will take many years to complete.

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[11] U.S. Department of Defense, Report on Critical Per- and Polyfluoroalkyl Substance Uses (Aug, 2022), https://www.acq.osd.mil/eie/eer/ecc/pfas/docs/reports/Report-on-Critical-PFAS-Substance-Uses.pdf.

SEMI and SIA request that MPCA carefully consider the below suggestions for the Proposed Rule in order to further the above goals.

II. RECOMMENDATIONS FOR THE PROPOSED RULE

SEMI and SIA appreciate the hard work invested in the Proposed Rule and respectfully offer the below comments to help improve it.

a. MPCA Should Adopt EPA's "Known to or Reasonably Ascertainable By" Due Diligence Standard

The MPCA should harmonize its due diligence standard with other jurisdictions that have promulgated PFAS reporting requirements. The U.S. Environmental Protection Agency's (EPA's) due diligence standard under its *Toxic Substances Control Act* (TSCA) PFAS Reporting Rule is that companies must report in-scope information to the extent that information is "known to or reasonably ascertainable by" them (hereinafter "KRA standard").[12] Maine's PFAS reporting obligation was modified in April 2024 to also adopt the KRA standard.[13] Canada's PFAS reporting obligation has a "reasonably accessible information" reporting standard, which is defined as "information [a] company possesses or to which [the company] may reasonably be expected to have access."[14] This Canadian due diligence standard is functionally equivalent to EPA's and Maine's KRA standard. MPCA should adopt the same approach.

When it was developing the Proposed Rule, the MPCA noted in a 2024 Q&A document that a reporting standard must "acknowledg[e] the challenges posed by unknowns in best testing practices, the unavailability of data from all supplier levels, and the varying costs of information gathering across organizations with different resources."[15] The MPCA stated that its intention was to "ensure that due diligence efforts are reasonable and feasible for manufacturers."[16]

SEMI and SIA believe that the due diligence standard in the Proposed Rule is inconsistent with these MPCA goals. The Proposed Rule states on lines 13.13 – 13.15 that companies must request information from supply chain partners "until all required information is known." Requiring companies to continuously survey suppliers until all data elements are known, without regard to the level of effort, is unrealistic and infeasible. This is particularly the case for semiconductor manufacturing equipment, which includes some of the most complex and sensitive products in the world. Certain products manufactured by our members contain thousands or hundreds of thousands of components. Obtaining full information from all suppliers – particularly in the time allotted – would be infeasible. The MPCA should adopt the KRA standard, which recognizes these limitations.

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[12] 40 C.F.R. § 705.15.

[13] 38 M.R.S. § 1614(2)(A) ("The manufacturer shall submit to the department a written notification that includes, to the extent known to or reasonably ascertainable by the manufacturer…").

[14] Canada Gazette, Part I, Volume 158, Number 30: Supplement, Notice with respect to certain per- and polyfluoroalkyl substances (July 27, 2024).

[15] MPCA, Progress on PFAS Rule Development Webinar: Questions and Answers (September 2024), https://www.pca.state.mn.us/sites/default/files/c-pfas-rule1-00.pdf.

[16] *Ibid*.

Accordingly, SEMI and SIA suggest that the MPCA replace the existing text in lines 13.13 – 13.15 with the following:

> *Subp. 2.* ***Due Diligence Standard****. A manufacturer or group of manufacturers is required to report information under this part to the extent such information is known to or reasonably ascertainable by the manufacturer or group of manufacturers.*

b. Reporting Should be at the Product Level, Not Component Level

As mentioned above, some semiconductor manufacturing products contain thousands, or potentially hundreds of thousands, of components, which are often contained under multiple levels of assemblies within the overall top-level product. This is also true for many end products where semiconductor devices are used. Lines 5.23 – 6.10 of the Proposed Rule would require that for products with multiple components that contain intentionally-added PFAS, reporting must be done at the component level. This is simply infeasible for manufacturers of products as complex as semiconductor manufacturing equipment or many of the end products where semiconductor devices are used. It also does not account for the expected variability in PFAS content between individual units of a product sold under the same numeric product code due to multi-sourcing of interchangeable components.[17] Similarly, the Proposed Rule does not recognize that varying configurations can lead to differences in the quantity or types of PFAS-containing components or sub-assemblies that might be used to meet specific customer requirements.

It is unclear from the Proposed Rule how manufacturers would break products down into reportable components. The three-line "component" definition the MPCA proposes in lines 2.1 – 2.3 is inadequate to this challenging task. For example, many products sold in Minnesota contain printed circuit boards, which contain transistors, which in turn contain multiple identifiable materials. It is unclear from the definition at what level a material within such a transistor would need to be reported. It is highly likely that different companies would take different approaches to this question and the thousands of similar questions that would be involved for complex electronic equipment. This would severely limit the utility of information reported to the MPCA. Reporting at the component level is an inherently complex exercise. Expecting uniform application by industry would require complex and lengthy guidance that the MPCA may not have time or resources to develop.[18]

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[17] Multi-sourcing is widely used in the electronics equipment industry to reduce risk and encourage competition between suppliers of components used to assemble end products. For example, an electronic product containing 100 different components may have one or more supplier parts qualified for each of the 100 components used to build an individual unit of the product. While not all components contain PFAS, there may be certain components, for example a gasket, that may have two suppliers, each of which may use different PFAS substances in the formulation of the gasket rubber material. Though their PFAS content is different, both gaskets meet the technical functional requirements for the component in the product and are considered equivalent. This results in variability in PFAS content between units of product sold under the same numeric product code.

[18] Other regulatory chemical substance content disclosure databases for articles have addressed this issue. One example is the SCIP database established by the European Chemicals Agency (ECHA) under the Waste Framework Directive (WFD). The SCIP database allows for disclosure of potential presence of declarable substances of very high concern.

Additionally, the component-level reporting envisioned by the Proposed Rule goes beyond what the statute requires and authorizes. The only reference to components in Subdivision 2 of the statute states that manufacturers must report "the purpose for which PFAS are used in the product, including any product component." The statute does not require or envision reporting at the component level. Nor has the MPCA given a reason that component-level reporting is necessary or helpful for implementing the law.

SEMI and SIA suggest that the MPCA draft the rule so that companies are reporting at the product level. SEMI and SIA suggest doing so by removing lines 5.23 – 6.10 from the Proposed Rule and removing certain other references to components (e.g., from line 4.6).

c. The MPCA Should Grant a Reporting Waiver for Semiconductors, Since "Substantially Equivalent" Reportable Information in these Products is Publicly Available

SEMI and SIA request that the MPCA grant a waiver from all parts of reporting via subdivision 3(a) in Section 116.943 for semiconductor products, semiconductor product components, materials used in semiconductor manufacturing, semiconductor manufacturing and related equipment, supporting fab infrastructure, and other microfabricated products that utilize semiconductor-like manufacturing processes (e.g., micro-electromechanical systems (MEMS).

Subdivision 3(a) provides that the MPCA may grant a reporting waiver if "substantially equivalent information is already publicly available." The MPCA addressed this in lines 10.1 – 11.9 of the Proposed Rule. While section 7026.0050 of the proposed rule specifies a process for requesting a waiver, the MPCA should also consider granting waivers by rule, including for the semiconductor industry. Information substantially equivalent to the reportable information required under subdivision 2 as it relates to PFAS in semiconductors and semiconductor manufacturing can be found in technical papers authored by the Semiconductor PFAS Consortium ("the Consortium")[19] that are freely and publicly available on its website at semiconductors.org/PFAS.[20] While the technical papers of the PFAS Consortium do not provide information about specific company products (e.g., PFAS compositions, concentrations, quantities, etc.), the Consortium papers do provide the substantially equivalent information regarding where, how, and for what purpose PFAS is used in semiconductor manufacturing (NAICS Code 334413) and present in semiconductor products (HTS Codes 8541 and 8542). This substantially equivalent information, as described in detail in the Consortium technical papers, includes:

- Descriptions of semiconductor manufacturing chemicals and equipment;
- Descriptions of where PFAS is used throughout the semiconductor manufacturing process, equipment, fab infrastructure, and product; and

[19] The Semiconductor PFAS Consortium is an international group of 40 semiconductor industry stakeholders, including semiconductor device manufacturers and their equipment and materials suppliers, organized under the auspices of the Semiconductor Industry Association (SIA) to collect the technical data needed to formulate an industry approach to per- and poly-fluoroalkyl substances (PFAS) based on science. The Consortium has published 25 papers comprised of hundreds of pages of technical documentation on the use of PFAS in the semiconductor industry, the availability and viability of alternatives or lack thereof, socioeconomic analyses on the use of PFAS in the industry, and the mapping of environmental release pathways.

[20] Semiconductor PFAS Consortium Technical Papers, *available at* https://www.semiconductors.org/pfas/.

- Details on the purpose, performance attributes, and functionalities different PFAS provide to different materials and semiconductor manufacturing process steps.

For information regarding PFAS that may be present in the packaged semiconductor that may be sold into commerce in Minnesota to be incorporated into a larger subcomponent or final product, please refer to the Consortium paper on "PFAS-Containing Materials Used in Semiconductor Manufacturing Assembly Test Packaging and Substrate (ATPS) Processes." In particular, Section 1.3 of this paper identifies some of the various use applications for PFAS-containing ATPS manufacturing materials.

For information regarding PFAS that are used in semiconductor fab infrastructure or manufacturing equipment at Minnesota-based semiconductor manufacturing facilities, please refer to the Consortium paper on "PFAS-Containing Articles Used in Semiconductor Manufacturing." In particular, Sections 6 and 7 of this paper identify some of the various articles in semiconductor manufacturing equipment and fab infrastructure that contain PFAS.

For additional information regarding PFAS used in the semiconductor manufacturing process, the MPCA may be interested in the below papers:

- PFAS-Containing Surfactants Used in Semiconductor Manufacturing
- PFAS-Containing Photo-Acid Generators Used in Semiconductor Manufacturing
- PFAS-Containing Fluorochemicals Used in Semiconductor Manufacturing Plasma-Enabled Etch and Deposition
- PFAS-Containing Heat Transfer Fluids Used in Semiconductor Manufacturing
- PFAS-Containing Wet Chemistries Used in Semiconductor Manufacturing
- PFAS-Containing Lubricants Used in Semiconductor Manufacturing

The MPCA should consider providing a waiver to the semiconductor industry to avoid requiring separate and distinct reporting by the semiconductor industry of substantially equivalent information to the Semiconductor PFAS Consortium technical papers.

SEMI and SIA would also like the MPCA to be aware of work underway by the Consortium to identify and better understand the principal PFAS environmental release pathways in semiconductor manufacturing and to provide a generalized template for the development of specific semiconductor PFAS release quantification models and maps.[21] The semiconductor industry has been a leader in collecting the technical data needed to understand the use of PFAS in semiconductor manufacturing, and the industry looks forward to continued partnership with MPCA as it finalizes this proposed rule and continues work regarding its rule on "currently unavoidable uses" of PFAS.

d. The MPCA Should Confirm that Companies Are Not Required to Perform Testing

Requiring companies to perform product testing to comply with reporting requirements would be infeasible and inconsistent with the statute. SEMI and SIA do not read the Proposed Rule to envision such a testing obligation and strongly supports this position. SEMI and SIA request that MPCA confirm this position in the final rule or through guidance.

[21] Semiconductor PFAS Consortium, PFAS Release Models and PFAS Release Maps, https://www.semiconductors.org/pfas/ (click "Download all 7 PFAS Release Mapping Papers" and "PFAS Conceptual Release Model for Semiconductor Manufacturing Plasma Etch and Deposition").

Line 7.15 – 7.18 appear to envision that if a company believes a product contains intentionally-added PFAS but does not know the concentration band, the company would have a choice of: 1) indicating to the MPCA that PFAS is "present but the amount of concentration range is unknown;" or 2) performing total organic fluorine testing on the product and reporting the result. SEMI and SIA support such a structure. SEMI and SIA request that the MPCA confirm that testing will not be required to comply with reporting obligations.

e. The MPCA Should Exempt Fluoropolymers in 7026.0090

SEMI and SIA recommend that the MPCA add fluoropolymers to the list of Reporting Exemptions in 7026.0090. Fluoropolymers are unique in that they are not water-soluble and have a high molecular weight. Fluoropolymers are critical for many applications and without viable alternatives health, safety, and economic stability could be severely impacted. SEMI and SIA recommend amending 7026.0090 to add:

> *F. a product that contains fluoropolymers consisting of polymeric substances for which the backbone of the polymer is either a per- or polyfluorinated carbon-only backbone or a perfluorinated polyether backbone that is a solid at standard temperature and pressure.*

f. The MPCA Should Extend the Reporting Deadline

SEMI and SIA urge the MPCA to exercise its statutory authority to extend the reporting deadline for all product manufacturers. This is necessary and appropriate to help ensure that both the MPCA and industry are prepared for the deadline. The statute was enacted in Spring 2023 with a reporting deadline of January 1, 2026. Unfortunately, however, a proposed rule to implement the reporting requirement was not published until April 2025, and the Agency has stated it expects to finalize the rule and open the reporting portal in "late 2025."[22]

This timeline is inconsistent with timely reporting. Manufacturers in many diverse sectors have been telling the MPCA for years that it was necessary for the MPCA to finalize a rule well in advance of the reporting deadline. The magnitude and difficulty of the task of obtaining information from extremely complex supply chains requires significant time between the rules being finalized and the reporting deadline. That can no longer happen absent an extension.

The statute empowers the MPCA to "extend the deadline [for reporting] if the commissioner determines that more time is needed by the manufacturer to comply with the submission requirement." Such is the case now for all manufacturers, or at least manufacturers of complex articles. SEMI and SIA urge the MPCA to exercise this statutory authority to extend the deadline. The scope of the extension should at least include all manufacturers of semiconductor manufacturing equipment.[23]

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[22] MPCA, Progress on PFAS Rule Development (July 18, 2024), https://www.pca.state.mn.us/sites/default/files/20240718-presentation-pfas-in-products-rulemaking.pdf.

[23] It should be noted that EPA has recently announced its intentions to delay the submission period for the TSCA PFAS Reporting Rule by nine months to account for the fact it "requires more time to prepare the reporting application to collect this data." The full *Federal Register* notice is available at

g. The MPCA Should Enact a *De Minimis* Reporting Threshold

SEMI and SIA urge the MPCA to enact a *de minimis* reporting threshold. Products containing intentionally-added PFAS at concentrations less than 0.1% should not be subject to reporting. This 0.1% threshold would align with thresholds established for many chemicals at the U.S. federal and state level as well as in the European Union. The threshold would also help ease administrative burdens on the MPCA, allowing it to focus on products that contain meaningful concentrations of PFAS. SEMI and SIA therefore urge the MPCA to include the following provision in the finalized rule, as well as making conforming changes (e.g., by deleting lines 7.7 – 7.8):

> *This part does not apply to the sale, offer for sale, or distribution in the state of products containing less than 0.1% by weight of PFAS.*

h. MPCA Should Confirm that All Manufacturers That Report Will Be Subject to the Same Flat Fee

In its previous comments, SEMI advocated for the MPCA to assess flat reporting fees on a per-company basis (i.e., not on a per-product or per-component basis). SEMI and SIA request that the MPCA confirm that is what has been proposed. A per-product fee, for example, would be overly burdensome for industry and would likely violate the MPCA's statutory directive to only impose fees "to cover the agency's reasonable costs to implement" the statute. SEMI and SIA request that the MPCA confirm this in guidance or include the following text in the rule in part 7026.0100, subpart 1:

> *Each manufacturer is subject to only one fee, as described in this part, per calendar year.*

i. If No Information Changes Year-by-Year, Manufacturers Should Not Be Required to Submit Annual Updates

The Proposed Rule envisions in lines 15.1 – 15.5 that even if no relevant changes were made to a manufacturer's product lines year-by-year, the manufacturer would still be required to submit an annual update and pay an annual fee. SEMI and SIA believe that it is unduly burdensome to require manufacturers to submit annual reports and pay annual fees even if there are no relevant changes to their product lines. SEMI and SIA request that the MPCA remove all references to annual recertifications, including in lines 9.10 – 9.12, 9.19, 9.22, and 15.1 – 15.2.

j. The MPCA Should Clarify the Reporting Deadline for New Products

The Proposed Rule states at line 9.8 that if a company begins selling a new reportable product into Minnesota, the report for that product will be due February 1. SEMI and SIA read this to mean that for reportable products introduced to the market after January 1, 2026, companies must submit an update by February 1 in the calendar year following introduction to market. SEMI requests that the MPCA confirm this interpretation in guidance. SEMI and SIA request that the MPCA remove language from the Proposed Rule that is inconsistent with line 9.8, e.g., the following sentence at lines 5.4 – 5.7: "A

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https://www.federalregister.gov/documents/2025/05/13/2025-08168/perfluoroalkyl-and-polyfluoroalkyl-substances-pfas-data-reporting-and-recordkeeping-under-the-toxic.

manufacturer or group of manufacturers of a new product with intentionally added PFAS after January 1, 2026, must submit a report before the product can be sold, offered for sale, or distributed in the state." It is not required or envisioned by the statute that manufacturers submit a report to the MPCA before even putting a product on the market in Minnesota.

k. The MPCA Should Not Regard Complex B2B Equipment as "Offered for Sale" in Minnesota Simply Because it is Advertised on the Internet

The statute specifies that if a product that contains intentionally-added PFAS is "offered for sale" in Minnesota, the reporting requirement is triggered. The term "offered for sale" is not defined either in the statute or the Proposed Rule. SEMI and SIA believe the term "offered for sale" is best applied to certain equipment, particularly relatively low-cost equipment available for household use, available in physical stores in the state or that can be easily ordered over the internet by a Minnesota customer. The MPCA may regard availability for one-click ordering into Minnesota as an "offer for sale" in Minnesota. By contrast, complex electronics appropriate only for enterprise use are not available in physical Minnesota stores or through such one-click ordering and therefore should not be regarded by the MPCA as "offered for sale" in Minnesota simply by virtue of being advertised over the internet. SEMI and SIA urge the MPCA to consider guidance clarifying this or defining the term "offered for sale" in the rule.

l. The MPCA Should Provide Clarity About the Submission Process and Report Format

The proposed rule states within 7026.0030 Subpart 1 that reports must be submitted to the commissioner, in a format specified by the commissioner. The MPCA should provide clarification regarding the format of the report, as well as the submission process. Ideally, the MPCA would develop an online platform for submission instead of emailing a report to the commission. Furthermore, the MPCA would help reduce the reporting burden if it worked towards developing a joint online reporting platform with other states.

m. Clarify PFAS Concentration Ranges and Align with TSCA PFAS Reporting Rule

To simplify reporting and reduce unnecessary regulatory burdens, the MPCA should align its proposed concentration ranges with the TSCA PFAS Reporting Rule. When combined with the 0.1% *de minimis* threshold SEMI and SIA suggest, the appropriate concentration ranges that could be added in place of current lines 7.7 – 7.14 are:

- At least 0.1% but less than 1%;
- At least 1% but less than 30%;
- At least 30% but less than 60%;
- At least 60% but less than 90%; and
- At least 90%.

SEMI and SIA also suggest that the MPCA specify that these concentrations be calculated relative to the weight of the product. Calculating at the component level, for example, would add the unnecessary complication of defining "component," as discussed above. As part of these changes, SEMI and SIA suggest that the MPCA remove the reference to "practical detection limit" in line 7.7, since the term is undefined and ambiguous as used here. The concentrations should also be understood to be worst-case estimates of maximum content of each PFAS substance in a product group. The MPCA should also

acknowledge that variability is possible due to multi-sourcing of product parts from multiple suppliers and configuration differences in the quantity and type of parts used within products under the same high-level numeric product code. Not all PFAS reported will be present in any one unit of product sold under the numeric product code.

n. Existing References to "Homogenous Material" in the Proposed Rule are Extraneous, so the MPCA Should Remove Them

The term "homogenous material" is used only twice in the Proposed Rule (lines 5.14 and 7.4). Both uses reference a product or products "made up of homogenous material." Since all products are made up of many homogenous materials, the term has no regulatory meaning as used in the Proposed Rule. SEMI and SIA therefore recommend that all references to "homogenous material" – including the definition in lines 2.14 – 2.16 – be removed.

o. The Documentation and Recordkeeping Requirement Should Be Reduced

Lines 13.17 – 13.20 require that documentation of all communication between manufacturers regarding PFAS reporting compliance and responsibility agreements be maintained. This is overbroad and onerous, especially given the five-year retention period proposed in lines 14.1 – 14.3. Furthermore, these reporting responsibilities already exist between suppliers and customers who have on-going responsibilities to share information on product material substance content to comply with restricted and declarable substance regulations. SEMI and SIA instead recommend the following revision:

> *A manufacturer or group of manufacturers must maintain documentation of its relevant reporting responsibility agreements with and/or notifications from other manufacturers as provided in part 7026.0020, subpart 2.*

p. Enact Additional Appropriate Clarifying Edits

SEMI and SIA suggest the following additional edits to the Proposed Rule to improve clarity:

- There are different levels of harmonized tariff schedule (HTS) codes (six-digit, eight-digit, and 10-digit) with the higher number being more specific. The MPCA should ensure that the six-digit option is acceptable as requiring the 10-digit HTS code would lead to significantly more reporting.

- The existing sentence at lines 4.8 – 4.10 could be replaced with: "Each manufacturer for a given product must assume responsibility to report unless two or more manufacturers of the same product enter into an agreement to establish their respective reporting responsibilities."

- The term "PFAS chemical composition" in line 5.15 could be changed to "the identities of the PFAS chemicals."

- Consistently use the term "intentionally-added" to avoid the incorrect implication that unintentionally-present PFAS is regulated by the statute (*see, e.g.*, lines 5.23 and 14.14, which merely reference "PFAS-containing" products but do not mention intentional presence).

- In line 7.4, confirm that MPCA expects manufacturers to report the sum total concentration of all PFAS (as opposed to the total of each individual reportable PFAS intentionally present).

III. CONCLUSION

SEMI and SIA are committed to meeting the complex challenge of balancing the need for environmental protection and the sustainability of semiconductor manufacturing operations and the end products where semiconductor devices are used. SEMI and SIA welcome the opportunity to engage with the MPCA to further explain the critical, currently unavoidable, and well-documented role that certain PFAS have in the semiconductor manufacturing process and the end products where semiconductor devices are used.

SEMI and SIA are grateful for the opportunity to engage in the MPCA's rulemaking process and are available to meet at your convenience to further elaborate on the issues discussed in these comments. If you have any questions or would like to discuss our positions, please do not hesitate to contact Ben Kallen (bkallen@semi.org) or Alex Gordon (agordon@semiconductors.org).

Sincerely,

Ben Kallen
Senior Manager, Public Policy & Advocacy
SEMI

Alex Gordon,
Manager, Government Affairs
Semiconductor Industry Association (SIA)

RECEIVED
By: OAH on 5/21/2025
Michael Michaud Attachment

HYDRAULIC INSTITUTE

May 21, 2025

The Honorable Jim Mortenson
Minnesota Office of Administrative Hearings
600 North Robert Street
PO Box 64620
St. Paul, Minnesota 55164-0620

Submitted Electronically

RE: Minnesota Pollution Control Agency's Notice of Intent to Adopt New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per-and Polyfluoroalkyl Substances (PFAS, Revisor's ID number R-4828, OAJ Docket Number 5-9003-40420)

Dear Judge Mortenson:

Thank you for the opportunity to submit these comments on behalf of the Hydraulic Institute (HI) to the Minnesota Pollution Control Agency (MPCA) regarding the Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees (proposed rule).

Founded in 1917, the Hydraulic Institute spent much of the past century playing a leading role in development and implementation of pump standards. As the nationally and internationally recognized representative of the US pump industry, HI has members that manufacture, distribute, service and provide materials for pumps and pumping systems that are manufactured in the United States and sold globally.

The U.S. pump industry employs more than 100,000 Americans who play an integral role in supporting the production of products essential to improving the quality of daily life of the public and protecting the planet. Pumping is a critical function in numerous processes and many industries, most notably water and wastewater; commercial buildings and HVAC; groundwater and irrigation, oil and gas; chemical production; power generation (traditional and new energy sources); mining; pharmaceutical; pulp and paper and food & beverage.

When present in the products manufactured by our member companies, fluoroelastomers and fluoropolymers are used due to their unique properties that provide for effective sealing, creating barriers for emissions, reducing energy use, and performance in highly corrosive or high temperature environments. Fluoroelastomers and fluoropolymers provide highly reliable performance which is particularly important when access to the production system is difficult and dangerous, and they provide a safe and reliable production process. Additionally, fluoroelastomers and fluoropolymers allow products to meet detailed specifications required by accepted standards and regulations designed to protect health, safety, the environment, and

efficient operations. In many cases, failure of these products can result in catastrophic consequences.

The HI has the following concerns with the PFAS in Products Reporting and Fee Rule: implementation and waiver timelines, due diligence requirements, the complexity of the rule and lack of clarity on some definitions, reporting PFAS concentration levels, and reporting responsibilities and fees. Without modifications, the rule would impose a significant reporting and fee burden on manufacturers in the pump industry.

Implementation, Extension, and Waiver Timelines: The current reporting and fee rule deadline is unreasonable, given that the reporting platform has to be released and there is no clarity on the information that will be required to report. For companies with complex supply chains such as our members, gathering information will take significant time in order to be sure that it is accurate and useful to the state of Minnesota.

Recommendation: The initial reporting deadline should be set for 6 (six) months after the reporting system is finalized and open.

Waiver Requests – 7026.0050, Subpart 4B: If a waiver request is denied, there needs to be sufficient time for companies to collect accurate information throughout their supply chain.

Recommendation: Reports should be required to be submitted no sooner than 90 days after a denial of a waiver request.

Extensions – 70026.0060 – Subpart 3 C - If an extension request is denied, there needs to be sufficient time for companies to collect accurate information throughout their supply chain.

Recommendation: Reports should be required to be submitted no sooner than 90 days after an extension notification is granted.

Due Diligence – 7026.0080, Subpart 2: As written, the requirement to request detailed disclosure information "until all required information is known" is unrealistic and imposes a significant burden on reporters. Many different parts can be used in the assembly of industrial valves, coming from many different suppliers located globally. Because of the complexity of managing global supply chains, products may be purchased and stored for months or years. When asking for information, suppliers can be reluctant to share their sensitive trade data, or suppliers may no longer be in business.

Crucially, this language is not aligned with other similar reporting requirements. In particular, VMA members and reporters in other industry sectors currently are collecting data to provide reports (due in 2026) under the U.S. EPA's extensive TSCA PFAS reporting program (TSCASection 8(a)(7). Given the effort expended over the last number of months to collect data under that reporting rule, MPCA's due diligence standard should mirror that of U.S. EPA. Under the U.S. EPA program, submitters are required to report information to the extent that it is "known to or reasonably ascertainable by" the company. The term "known to or reasonably ascertainable by" ("KRA") is defined in 40 C.F.R. §705.3 to mean "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know."

Recommendation: MPCA should adopt the KRA due diligence standard as defined in the U.S. EPA TSCA PFAS reporting program.

Reporting of PFAS concentration -7026.0030, Subpart 1C: High molecular weight fluoroelastomers and fluoropolymers are used in the manufacture of gaskets, seals, pumps, coatings, chemical piping and industrial valves, all of which are integral to the production of products core to maintaining modern life. These are solid, molded products with negligible potential for worker or consumer exposure or other safety concerns while handling the product. There is not a cost-effective, reliable, common way to test these products to understand the specific PFAS concentration, and if there were it would be very burdensome. Because of the different (chemical and toxicological) properties of fluoropolymers and fluoroelastomers compared to other types of PFAS, trying to determine an appropriate concentration of this subset of PFAS in such products provides information with little value to the state of Minnesota, while creating frustration and expense to companies.

Recommendation: In lieu of specific PFAS concentration information for fluoropolymers and fluoroelastomers, we recommend **that MCPA provide a checkbox to indicate that the product is a fluoropolymer or fluoroelastomer.** MCPA could assign a common concentration level for those products if desired.

Report: Required Information 7026.0030, Subpart 1: There are two reporting scenarios outlined, one beginning January 1, 2026, and one for new products not yet reported. Both scenarios note that a report must be submitted for each product "sold, offered for sale, or distributed in the state".

This does not clearly define how to determine what products should be included in the reports, or what the time period is that should be included. For example, product catalogs can contain hundreds, thousands and tens of thousands of products, but those products may not be sold into the state. Additionally, quotes may be offered for products, but a sale may not be made so those products are never sold into the state. Requiring reports on all of these products that never enter the state is extremely burdensome to companies, and would provide a gross overestimate of the amount of PFAS in the state of MN. It would also provide so much data that any conclusions drawn from the data would be meaningless.

Recommendation: For the first report currently due on January 1, 2026, only products projected to be sold into the state of Minnesota or manufactured in the state from January 1, 2026 – January 1, 2027 should be included.

Further, we suggest that the definition of "Distribute for sale" in 7026.0020, Subpart 9, be modified to "means to ship or otherwise transport a product with the intent or understanding that the product will be sold or offered for sale in the state of Minnesota by a receiving party after the product is delivered."

Trade Secret – 7026.0070: Companies may choose to use a fluoropolymer or fluoroelastomer in order to meet the requirements of a particular use application or function, which can provide a competitive advantage to the company**.**
Recommendation: We suggest adding "function" for trade secret protection as well.

Reporting Responsibility and Fees:

Both the proposed definition of "manufacturer" as well as the reporting scope do not consider complex supply chains or final products that have numerous component parts. Additionally, clarity is needed to clearly identify the entity ("manufacturer") who has primary compliance responsibility.

Recommendation: We suggest the following definition of "Manufacturer:" The person that creates or produces a product, that has a product created or produced, or whose brand name is legally affixed to the product, **whichever is first to sell, offer for sale, or distribute for sale the product in the state**. In the case of a product that is imported into the United States when the person that created or produced the product or whose brand name is affixed to the product does not have a presence in the United States, manufacturer means either the importer or **the first** domestic distributor of the product, whichever is first to sell, offer for sale, or distribute for sale the product in the state.

In addition, under 7026.0020, Subpart 1 and 2, we suggest that this be modified to allow a parent company to submit one report that covers the final products, component parts, brand names and subsidiaries. Payment of fees, if required, should be similarly modified to align with the reporting.

* * * * *

Thank you again for the opportunity to submit comments. We welcome further discussion or any questions you may have.

Sincerely,
/s/

Michael Michaud
Hydraulic Institute

RECEIVED
By: OAH on 5/21/2025

May 21, 2025

https://www.pca.state.mn.us/sites/default/files/c-pfas-rule1-06.pdf

IDEXX Laboratories Inc. Response to Proposed Permanent Rules Relating to PFAS in Products, Revisor's ID Number R-4828

Thank you for the opportunity to provide comments on R-4828, Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees.

By way of background, IDEXX manufactures human, animal (pet and livestock), dairy, and water diagnostic products, including complex electronic instruments, primarily in Maine. Our products test for, among other things, infectious diseases that can be zoonotic (spreadable from animals to humans, such as SARS CoV2) or cause significant impact to the food supply (such as African Swine Fever and Mad Cow Disease). A significant number of these products are under the jurisdiction of and/or regulated by authorities including the U.S. Food & Drug Administration and the U.S. Department of Agriculture. IDEXX's diagnostic products help enable the health and well-being of people, livestock, and pets, and help ensure the safety of milk and water, here in Minnesota, throughout the United States, and in more than 175 countries globally.

Our water testing products (including testing solutions for drinking water, wastewater monitoring, and recreational water) are relied on throughout Minnesota, including by the Minnesota Departments of Health and Agriculture, water utilities of Minneapolis and St. Paul, and more than 150 local public health laboratories, water utilities and wastewater treatment plants across the state. Additionally, more than 2.5 billion people worldwide rely on our test to ensure safe drinking water.

IDEXX offers not only diagnostic solutions to most of the animal production chain but also provides services that, for example, help animal producers manage vaccination more efficiently, reduce the use of antibiotics, re-introduce animals in herds after treatments, optimize reproduction cycles, and ensure early and definitive identification of highly contagious and life-threatening diseases that threaten human and animal populations.

Our focus on human and animal health diagnostic products allies us with the Program's environmental protection goals. Indeed, reduction of harmful environmental contaminants is at the core of our business. However, it is crucial that that essential products such as IDEXX's remain available and continue to be of the same high quality and performance as required in our heavily regulated environment.

Minnesota is the only state that has enacted a broad PFAS reporting requirement that does not exempt animal health products. In HF 2310, the legislature gave the MPCA broad leeway to provide flexibility and clarity through rulemaking.

First, we recommend that the fee structure be capped in section 7026.0100. Animal and human health diagnostics often use identical platforms having different diagnostic targets (different form and function). For example, many diagnostic companies offer tests on their proprietary platform or device. These devices only vary in that different biological molecules (or antigens) may be included to provide specific test results for the targeted analyte, or disease

marker. Since biological molecules do not contain PFAS, requiring separate applications for each product when the platform or device is identical will lead to a lack of availability for life saving tests in Minnesota and a substantial increase in workload for the Department without any reduction of PFAS compounds entering Minnesota.

By requiring fees to be paid by every unique product, the cost to sell products in Minnesota will impact veterinarians seeking to ensure that pets are healthy, farmers seeking to ensure food safety, and municipalities seeking to provide safe drinking water, by making the cost of reporting far outweigh the cost to manufacture. Notably, the cost to file either extensions or notifications for more than 1000 unique products could be as high as $1 Million, and $500,000 per year, each year after. Alternatively, we suggest 7026.0030 Subp. 1, A (1) (a) (iv) could be removed. It is sufficient to bundle similar products that contain the same PFAS chemicals, with the same function, within the same reporting range. If the products themselves have slightly different formulations of non-PFAS materials, this should have no bearing on PFAS data collection.

Additionally, while we appreciate the allowance to file an extension while we continue to investigate our supply chain, paying $300 fee per extension request is an additional cost for products that may not contain PFAS. IDEXX has been investigating our supply chain for the past 7 years for regulated chemicals, including PFAS, and have partnered with Claigan Environmental to better understand the use of PFAS in the electronics sector and still have limited success in gathering comprehensive data for our most complex materials. Additionally, some of our veterinary medical devices contain more than 1000 complex electrical components, including PCB (printed circuit boards) and other complex electrical and mechanical assemblies. These are purchased parts made by manufacturers often multiple tiers down in our supply chain. We are prepared to report on what is known and continue to investigate our supply chain, but it is economically unfeasible to only grant 90-day extensions and pay $300 for each extension fee. Instead, an extension should be granted for good faith efforts with no penalty fee. Alternatively, we suggest capping the extension fee to a reasonable one-time fee and/or lengthening the extensions granted to 12 months or the annual recertification window.

In conclusion, any human or veterinary diagnostics or water quality testing approved to restore or protect the health and welfare of animals and people and the processes used to produce the products should be considered as necessary for health and therefore the costs to notify and investigate supply chains should not be disproportionate to providing these critical products to Minnesota veterinarians, health care providers, municipalities and public health laboratories. We respectfully request that you take these comments into account when publishing the rule.

Diana Rondeau

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RECEIVED
By: OAH on 5/21/2025
Kiera Callahan Attachment

May 21, 2025

Minnesota PFAS in Products Reporting and Fee Rule
OAH Docket No. 5-9003-40410

Subject: PFAS in Products Reporting and Fee Rule

Dear colleagues,

BP Polymers, LLC ("BPP") is writing to you in support of Minnesota's PFAS in Products program and the associated reporting and fees rules. BPP offers a unique, proprietary resin, Kortrax®, that can be added to high-density polyethylene ("HDPE") to create various types of packaging imbued with barrier properties. As an active part of the packaging industry, we have seen the negative effects of fluorinated polyethylene and PFAS contamination. Unlike surface modification barrier treatments such as fluorination, Kortrax® is free of PFAS contamination and the adjoining environmental and public health effects. BP Polymers Kortrax® can be found in a wide variety of industries, including flavorings, and BPP provides proven technologies that benefit users and consumers every day.

Fluorination plays a prominent role in the packaging industry and its advocates consider it to be a critical process to create a successful barrier against the leakage of aggressive substances. Yet, the most utilized types of fluorination create PFAS.[1] Proponents of fluorination argue that the PFAS formed as part of the barrier process is negligible and does not affect the contents housed within fluorinated HDPE containers. However, the presence of PFAS in fluorinated HDPE is not a novel issue and has been demonstrated as far back as 2011.[2] Furthermore, studies indicate that there is a high rate of transferability of the PFAS generated by the fluorination process into the contents of fluorinated HDPE containers, including food products.[3]

The PFAS associated with fluorination processes comes with alarming environmental and public health effects. PFAS has a significant negative impact on an assortment of bodily systems, and the most hazardous types, including PFOA and PFOS, are bioaccumulative and almost impossible to remove.[4] Additionally, as we now know, these chemicals are everywhere – in our water, packaging, clothes, food, and more.[5] When you consider the breadth of exposure to PFAS on a daily basis, it is alarming to say the least. Looking at the scale of this issue, the American public has been robbed of their autonomy to decide

[1] US EPA, O. (2022, March). https://www.epa.gov/system/files/documents/2022-03/letter-to-fluorinated-hdpe-industry_03-16-22_signed.pdf
[2] Rand, A. A., & Mabury, S. A. (2011). Perfluorinated Carboxylic Acids in Directly Fluorinated High-Density Polyethylene Material. *Environmental Science & Technology*, *45*(19), 8053–8059. https://doi.org/10.1021/es1043968.
[3] US EPA, O. (2022, September 12). *EPA Releases Data on Leaching of PFAS in Fluorinated Packaging*. Www.epa.gov. https://www.epa.gov/pesticides/epa-releases-data-leaching-pfas-fluorinated-packaging.
Whitehead, H. D., & Peaslee, G. F. (2023). Directly Fluorinated Containers as a Source of Perfluoroalkyl Carboxylic Acids. *Environmental Science & Technology Letters*. https://doi.org/10.1021/acs.estlett.3c00083.
[4] Fenton, S. E., Ducatman, A., Boobis, A., DeWitt, J. C., Lau, C., Ng, C., Smith, J. S., & Roberts, S. M. (2020). Per- and Polyfluoroalkyl Substance Toxicity and Human Health Review: Current State of Knowledge and Strategies for Informing Future Research. *Environmental Toxicology and Chemistry*, *40*(3), 606–630. https://doi.org/10.1002/etc.4890.
Brunn, H., Arnold, G., Körner, W., Rippen, G., Steinhäuser, K. G., & Valentin, I. (2023). PFAS: forever chemicals—persistent, bioaccumulative and mobile. Reviewing the status and the need for their phase out and remediation of contaminated sites. *Environmental Sciences Europe*, *35*(1). https://doi.org/10.1186/s12302-023-00721-8.
[5] Jeffrey Kluger (2023, May 19). *All The Stuff in Your Home That Might Contain PFAS 'Forever Chemicals.'* TIME. https://time.com/6281242/pfas-forever-chemicals-home-beauty-body-products/.

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for themselves the dose of this constant poison that they are exposed to. Fluorination is just one piece of the puzzle but an important one.

Proponents of fluorination often challenge state PFAS bans by asserting that fluorination is not an intentional use of PFAS. Yet, it is indisputable that most forms of fluorination create PFAS. And, it can be argued that this resultant PFAS is what makes fluorination so successful as a barrier method. Hence, the importance of crafting PFAS legislation with definitions of "intentionally added" that are inclusive of fluorination and the chemical processes that generate PFAS. BPP urges the Minnesota Pollution Control Agency ("MPCA") to adopt an expansive definition of "intentionally added" that includes fluorination and similar processes that create PFAS as part of the formation of a barrier.

In addition, manufacturers have hidden their PFAS production behind reporting exemptions and trade secret protections. Nowhere is this more present in a recent federal case whereby it is alleged that the EPA has failed to disclose information about a popular fluorination company's PFAS generation via Freedom of Information Act ("FOIA") requests due to the company claiming confidential business information ("CBI") protection. Notably, the information sought by the FOIA request is not typical of a confidential business information claim and which the Toxic Substances Control Act mandates ("TSCA") to be publicly disclosed.[6] Therefore, although trade secret and confidential business information protection is critical, the MPCA should be aware of how companies attempt to utilize these exemptions to obfuscate their PFAS generation.

In conclusion, statewide efforts to ban fluorinated HDPE and its role in packaging are critical. The federal response to PFAS contamination has been scattered and disjointed; hence, statewide responses are urgently needed to encourage a change in the market and protect consumers. BP Polymers, LLC supports Minnesota's PFAS in Products: Reporting and Fees Rules and applauds the MPCA's ongoing efforts to eliminate PFAS in the state. As part of the adoption of the new PFAS rules, BPP proposes a more expansive definition of "intentionally added" with more stringent standards for manufacturers. Additionally, with companies attempting to avoid PFAS enforcement, we encourage the MPCA to limit trade secret protection and exemptions to those situations in which it is absolutely necessary.

Should you have any questions or wish to further discuss this letter and the information contained therein, please do not hesitate to reach out.

Sincerely,

Kevin J. Callahan

Kevin J. Callahan
COO of BP Polymers, LLC
Kevin@bppolymers.com

[6] Pat Rizzuto (2024, February 15). *Data on PFAS in Some Plastics Concealed by EPA, Lawsuit Alleges*. Bloomberg Law News. https://www.bloomberglaw.com/bloomberglawnews/environment-and-energy/XCQB2E34000000#jcite ; *Public Employees for Environmental Responsibility v Environmental Protection Agency*, (D.D.C. Feb 15, 2024).

May 21, 2025

The Honorable Jim Mortenson
Administrative Law Judge
Minnesota Pollution Control Agency
Office of Administrative Hearings
600 North Robert Street
P.O. Box 64620
St. Paul, MN 55164

Submitted electronically to https://minnesotaoah.granicusideas.com/discussions/40410-pollution-control-agency-notice-of-hearing-on-pfas-in-products-reporting-and-fee-rule

Re: Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees; Revisor's ID Number R-4828, OAH Docket Number 5-9003-40410

Dear Judge Mortenson:

ASC appreciates the opportunity to comment on the Minnesota Pollution Control Agency's (MPCA's) proposed reporting and fee rule for products containing intentionally added per-and-polyfluoroalkyl substances (PFAS).

The Adhesive and Sealant Council (ASC) is a trade association representing the North American adhesive and sealant value chain. The Council is comprised of 117 adhesive and sealant manufacturers, raw material and equipment suppliers and distributors, and industry consultants, representing more than 75 percent of the U.S. industry. Offering education, legislative advocacy, professional networking, and business growth solutions to its members, the ASC is the center of knowledge and a catalyst for industry growth on a global basis for manufacturers, suppliers, and end-users. Our members who sell and distribute products in the state of Minnesota are impacted by this proposed rule.

Minnesota's PFAS in products law, Amara's Law,[1] remains the most stringent and expansive law regulating PFAS in products in the United States. The only other state with similar requirements, Maine, significantly scaled back its reporting requirements in 2024 to only require reporting of "currently unavoidable uses" of PFAS and added necessary exemptions from its sales prohibition to ensure that critical uses of PFAS and uses of PFAS already regulated by

[1] Minn. Stat. § 116.943.

federal law will not be impacted.[2] Maine also extended the deadline for its reporting requirement. Minnesota has not.

Minnesota's law broadly applies to *any* product, including industrial and commercial products, or product component sold or distributed in the state which contains *any* amount of intentionally-added PFAS, no matter how miniscule and regardless of the likelihood of exposure of PFAS to an individual. The law imposes reporting requirements on manufacturers, fee obligations, and product phase outs. Minnesota adopted the broad definition of PFAS to mean "a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom," deviating from the federal U.S. Environmental Protection Agency (EPA) more narrow definition of PFAS.[3] This definition captures potentially thousands of substances. The law's prohibitions and reporting requirements exempt very few types of products.

Against this framework, the agency now proposes a rule that further expands and complicates its reporting requirements. Our members must be prepared to provide detailed information about PFAS in their products in satisfaction of these requirements by January 1, 2026, when this reporting rule has only now been proposed and will not be finalized until soon before the reporting deadline. Importantly, the rule implicates every company in the supply chain who provides materials and components for these products. The proposed rule does not account for the reality of product supply chains. Our members manufacture large portfolios of complex products that consist of numerous components sourced from numerous suppliers for each product. Our members will face significant challenges gathering detailed composition data from all of their suppliers. The process of data collection alone to comply with the January 1, 2026 deadline will significantly disrupt to our members' businesses as they incur added costs and have to dedicate extensive resources to comply with the rule.

The proposed rule would also impose a strict reporting standard unlike any other state or even federal PFAS reporting law[4]: "A manufacturer or group of manufacturers must request detailed disclosure of information…from their supply chain **until all required information is known**." This standard is unreasonable. It is infeasible to guarantee that a manufacturer will receive all of the detailed data required under the rule from all suppliers of every product component. Suppliers may not know the composition of a product component and would be forced to inquire with their own upstream suppliers. For complex products, the inquiries could go up a dozen tiers and the data still may not be available, particularly for trace amounts of PFAS. Suppliers also may have limited information or may not be able to share information due to concerns about protecting confidential business information. The requirement to survey suppliers "until all information is known" would effectively force companies to have to test products for PFAS content just to ensure the information becomes "known," which is inconsistent with the statute. Manufacturers need flexibility in the reporting standard to conduct and document *reasonable*, realistic due diligence efforts.

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[2] https://www.maine.gov/dep/spills/topics/pfas/PFAS-products/.
[3] 40 C.F.R. § 705.3.
[4] EPA's TSCA PFAS Reporting Rule requires that a manufacturer report information to the extent that it is "known to or reasonably ascertainable by" them, meaning information already in the manufacturer's possession or control, and information a similarly situated manufacturer would be expected to know. 40 C.F.R. § 705.15. Maine has adopted this reporting standard as well.

Overall, as drafted, the proposed rule does not promote compliance, is overly burdensome to manufacturers subject to reporting, and will likely result in the agency receiving an overload of data that is duplicative or not necessary, relevant, or useful for MPCA to understand the PFAS exposures of greatest concern. We recommend that MPCA consider the following changes to ensure that compliance is achievable by impacted manufacturers and that MPCA receives useful information on PFAS in products:

1) Implement a *de minimis* threshold (such as PFAS at or below 1% concentration in the product) for reporting so that trace amounts of intentionally-added PFAS are not required to be reported. Having a *de minimis* threshold will provide much needed clarity and improve compliance.

2) Extend the January 1, 2026 compliance deadline to provide manufacturers adequate time to review the final reporting rule and gather information to comply with the reporting requirements. We recommend an extension of two years.

3) Reduce the amount of data to be reported to only report information that is statutorily required, which is:

- a brief description of the product, including a universal product code (UPC), stock keeping unit (SKU), or other numeric code assigned to the product;

- the purpose for which PFAS are used in the product, including in any product components;

- the amount of each PFAS, identified by its chemical abstracts service registry number, in the product, reported as an exact quantity determined using commercially available analytical methods or as falling within a range approved for reporting purposes by the commissioner;

- the name and address of the manufacturer and the name, address, and phone number of a contact person for the manufacturer.

4) Eliminate the annual re-certification requirement (and associated fee), as it is unnecessary and will only add to compliance burdens for manufacturers. Manufacturers are already obligated by statute to report to MPCA if a significant change was made to the product.

5) Allow for grouping of similar products in the same report. This will reduce the number of reports that must be submitted and thus reduce unnecessary administrative burdens for manufacturers as well as MPCA staff reviewing the reports.

6) Remove the standard of diligence in the proposed rule and adopt the TSCA PFAS Reporting rule and Maine PFAS reporting rule “known to or reasonably ascertainable by” standard of diligence.

Thank you for the opportunity to provide comments on this important rulemaking. Please contact me if you have any additional questions.

Sincerely,

William E. Allmond, IV
President
The Adhesive and Sealant Council
510 King Street, Suite 418
Alexandria, VA 22314

RECEIVED
By: OAH on 5/21/2025
Javaneh Tarter Attachment 2

May 21, 2025

The Honorable Jim Mortenson
Administrative Law Judge
Minnesota Pollution Control Agency
Office of Administrative Hearings
600 North Robert Street
P.O. Box 64620
St. Paul, MN 55164

Submitted electronically to https://minnesotaoah.granicusideas.com/discussions/40410-pollution-control-agency-notice-of-hearing-on-pfas-in-products-reporting-and-fee-rule

Re: Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees; Revisor's ID Number R-4828, OAH Docket Number 5-9003-40410

Dear Judge Mortenson:

The Color Pigments Manufacturers Association (CPMA) and the Society of Chemical Manufacturers and Affiliates (SOCMA) appreciate the opportunity to comment on the Minnesota Pollution Control Agency's (MPCA's) proposed reporting and fee rule for products containing intentionally added per-and-polyfluoroalkyl substances (PFAS).

CPMA is the national trade association representing the color pigments industry. CPMA represents companies in the value chain that are engaged in the manufacture, processing or selling of color pigments in North America. Color pigments are important components in a wide range of applications, including printing inks, paints and coatings, plastics, building materials, cosmetics, personal care products, pharmaceuticals and agricultural products. Formed in 1925, CPMA provides programs to enhance regulatory compliance and support the manufacture and use of color pigments.

SOCMA is the national trade association dedicated to the specialty and fine chemical industry. Founded in 1921, SOCMA represents a diverse membership of chemical companies who batch manufacture new and innovative chemistries used in a wide range of commercial, industrial, and consumer products. SOCMA maintains a strong record of member service through programs that maximize commercial opportunities, enhance regulatory and legal compliance, and promote

industry stewardship. SOCMA's members also implement ChemStewards®, an EHS&S performance improvement program that is a mandatory component of membership.

Our members who sell and distribute products in the state of Minnesota are impacted by this proposed rule.

Minnesota's PFAS in products law, Amara's Law,[1] remains the most stringent and expansive law regulating PFAS in products in the United States. The only other state with similar requirements, Maine, significantly scaled back its reporting requirements in 2024 to only require reporting of "currently unavoidable uses" of PFAS and added necessary exemptions from its sales prohibition to ensure that critical uses of PFAS and uses of PFAS already regulated by federal law will not be impacted.[2] Maine also extended the deadline for its reporting requirement. Minnesota has not.

Minnesota's law broadly applies to *any* product, including industrial and commercial products, or product component sold or distributed in the state which contains *any* amount of intentionally-added PFAS, no matter how miniscule and regardless of the likelihood of exposure of PFAS to an individual. The law imposes reporting requirements on manufacturers, fee obligations, and product phase outs. Minnesota adopted the broad definition of PFAS to mean "a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom," deviating from the federal U.S. Environmental Protection Agency (EPA) more narrow definition of PFAS.[3] This definition captures potentially thousands of substances. The law's prohibitions and reporting requirements exempt very few types of products.

Against this framework, the agency now proposes a rule that further expands and complicates its reporting requirements. Our members must be prepared to provide detailed information about PFAS in their products in satisfaction of these requirements by January 1, 2026, when this reporting rule has only now been proposed and will not be finalized until soon before the reporting deadline. Importantly, the rule implicates every company in the supply chain who provides materials and components for these products. The proposed rule does not account for the reality of product supply chains. Our members manufacture large portfolios of complex products that consist of numerous components sourced from numerous suppliers for each product. Our members will face significant challenges gathering detailed composition data from all of their suppliers. The process of data collection alone to comply with the January 1, 2026 deadline will significantly disrupt to our members' businesses as they incur added costs and have to dedicate extensive resources to comply with the rule.

The proposed rule would also impose a strict reporting standard unlike any other state or even federal PFAS reporting law[4]: "A manufacturer or group of manufacturers must request detailed disclosure of information…from their supply chain **until all required information is known**."

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[1] Minn. Stat. § 116.943.
[2] https://www.maine.gov/dep/spills/topics/pfas/PFAS-products/.
[3] 40 C.F.R. § 705.3.
[4] EPA's TSCA PFAS Reporting Rule requires that a manufacturer report information to the extent that it is "known to or reasonably ascertainable by" them, meaning information already in the manufacturer's possession or control, and information a similarly situated manufacturer would be expected to know. 40 C.F.R. § 705.15. Maine has adopted this reporting standard as well.

This standard is unreasonable. It is infeasible to guarantee that a manufacturer will receive all of the detailed data required under the rule from all suppliers of every product component. Suppliers may not know the composition of a product component and would be forced to inquire with their own upstream suppliers. For complex products, the inquiries could go up a dozen tiers and the data still may not be available, particularly for trace amounts of PFAS. Suppliers also may have limited information or may not be able to share information due to concerns about protecting confidential business information. The requirement to survey suppliers "until all information is known" would effectively force companies to have to test products for PFAS content just to ensure the information becomes "known," which is inconsistent with the statute. Manufacturers need flexibility in the reporting standard to conduct and document *reasonable*, realistic due diligence efforts.

Overall, as drafted, the proposed rule does not promote compliance, is overly burdensome to manufacturers subject to reporting, and will likely result in the agency receiving an overload of data that is duplicative or not necessary, relevant, or useful for MPCA to understand the PFAS exposures of greatest concern. We recommend that MPCA consider the following changes to ensure that compliance is achievable by impacted manufacturers and that MPCA receives useful information on PFAS in products:

1) Implement a *de minimis* threshold (such as PFAS at or below 1% concentration in the product) for reporting so that trace amounts of intentionally-added PFAS are not required to be reported. Having a *de minimis* threshold will provide much needed clarity and improve compliance.

2) Extend the January 1, 2026 compliance deadline to provide manufacturers adequate time to review the final reporting rule and gather information to comply with the reporting requirements. We recommend an extension of two years.

3) Reduce the amount of data to be reported to only report information that is statutorily required, which is:

- a brief description of the product, including a universal product code (UPC), stock keeping unit (SKU), or other numeric code assigned to the product;

- the purpose for which PFAS are used in the product, including in any product components;

- the amount of each PFAS, identified by its chemical abstracts service registry number, in the product, reported as an exact quantity determined using commercially available analytical methods or as falling within a range approved for reporting purposes by the commissioner;

- the name and address of the manufacturer and the name, address, and phone number of a contact person for the manufacturer.

4) Eliminate the annual re-certification requirement (and associated fee), as it is unnecessary and will only add to compliance burdens for manufacturers. Manufacturers are already obligated by statute to report to MPCA if a significant change was made to the product.

5) Allow for grouping of similar products in the same report. This will reduce the number of reports that must be submitted and thus reduce unnecessary administrative burdens for manufacturers as well as MPCA staff reviewing the reports.

6) Remove the standard of diligence in the proposed rule and adopt the TSCA PFAS Reporting rule and Maine PFAS reporting rule "known to or reasonably ascertainable by" standard of diligence.

Thank you for the opportunity to provide comments on this important rulemaking. Please contact us if you have any additional questions.

Sincerely,

David Wawer
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RECEIVED
By: OAH on 5/21/2025

Heather Rhoderick Attachment

VALVE MANUFACTURERS ASSOCIATION

May 21, 2025

The Honorable James Mortenson
Minnesota Office of Administrative Hearings (OAH)
600 North Robert Street
PO Box 64620
St. Paul, Minnesota 55164-0620

Submitted Electronically via Office of Administrative Hearings (OAH) Rulemaking eComments Website

RE: Notice of Intent to Adopt New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per- and polyfluoroalkyl substances (PFAS), Revisor's ID Number R-4828, OAH docket number 5-9003-40410

Dear Judge Mortenson:

Thank you for the opportunity to submit these comments on behalf of the Valve Manufacturers Association (VMA) to the Minnesota Pollution Control Agency (MPCA) regarding the Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees (proposed rule).

VMA is the trade association for the industrial valve and flow control industry, comprised of members who are industry leaders. VMA members manufacture, distribute, service and provide materials for high quality and trusted valves, actuators, and controls that are manufactured in the United States and sold globally.

The industrial valve industry is vibrant, innovative and responsible. The U.S. valve industry employs more than 50,000 Americans who play an integral role in supporting the production of products essential to improving the quality of daily life of the public and protecting the planet. Industrial valves are relied on to serve critical applications in many industries, most notably water and wastewater; oil and gas; chemical; construction; power generation (traditional and new energy sources); mining; pharmaceutical; pulp and paper and food & beverage.

When present in the products manufactured by our member companies, fluoroelastomers and fluoropolymers are used due to their unique properties that provide for effective sealing, create barriers for emissions, reduce energy use, and enhance performance in highly corrosive or high temperature environments. Fluoroelastomers and fluoropolymers provide highly reliable performance which is particularly important when access to the production system is difficult

and dangerous, and they provide a safe and reliable production process. Additionally, fluoroelastomers and fluoropolymers allow products to meet detailed specifications required by accepted standards and regulations designed to protect health, safety, the environment, and efficient operations – of paramount importance when failure of these products could result in catastrophic consequences.

The VMA has the following concerns with the PFAS in Products Reporting and Fee Rule: implementation and waiver timelines, due diligence requirements, the complexity of the rule and lack of clarity on some definitions, reporting PFAS concentration levels, and reporting responsibilities and fees. Without modifications, the rule would impose a significant reporting and fee burden on manufacturers in the industrial valve industry.

Implementation Timelines

The current reporting and fee rule deadline is unreasonable, given that the reporting platform has to be released and there is no clarity on the information that will be required to report. For companies with complex supply chains such as our members, gathering information will take significant time in order to be sure that it is accurate and useful to the state of Minnesota.

Recommendation: Can the initial reporting deadline should be set for 6 (six) months after the reporting system is finalized and open?

Reporting of PFAS concentration -7026.0030, Subpart 1C

High molecular weight fluoroelastomers and fluoropolymers are used in the manufacture of gaskets, seals, pumps, coatings, chemical piping and industrial valves, all of which are integral to the production of products core to maintaining modern life. These are solid, molded products with negligible potential for worker or consumer exposure or other safety concerns while handling the product. There is not a cost-effective, reliable, common way to test these products to understand the specific PFAS concentration, and if there were it would be very burdensome. Because of the different (chemical and toxicological) properties of fluoropolymers and fluoroelastomers compared to other types of PFAS, trying to determine an appropriate concentration of this subset of PFAS in such products provides information with little value to the state of Minnesota, while creating frustration and expense to companies.

Recommendation: In lieu of specific PFAS concentration information for fluoropolymers and fluoroelastomers, we recommend that MCPA provide a checkbox to indicate that the product is a fluoropolymer or fluoroelastomer. MCPA could assign a common concentration level for those products if desired. Can the MCPA provide this type of check box?

Report: Required Information 7026.0030, Subpart 1

There are two reporting scenarios outlined, one beginning January 1, 2026, and one for new products not yet reported. Both scenarios note that a report must be submitted for each product "sold, offered for sale, or distributed in the state".

This does not clearly define how to determine what products should be included in the reports, or what the time period is that should be included. For example, product catalogs can contain hundreds, thousands and tens of thousands of products, but those products may not be sold into

the state. Additionally, quotes may be offered for products, but a sale may not be made so those products are never sold into the state. Requiring reports on all these products that never enter the state is extremely burdensome to companies, and would provide a gross overestimate of the amount of PFAS in the state of Minnesota. It would also provide so much inaccurate data that any conclusions drawn from the data would be meaningless.

Recommendation: For the first report currently due on January 1, 2026, only products projected to be sold into the state of Minnesota or manufactured in the state from January 1, 2026 – January 1, 2027 should be included. Can the MCPA make this clarification?

Further, we suggest that the definition of "Distribute for sale" in 7026.0020, Subpart 9, be modified to "means to ship or otherwise transport a product with the intent or understanding that the product will be sold or offered for sale <u>in the state of Minnesota</u> by a receiving party after the product is delivered."

Waiver Requests – 7026.0050, Subpart 4B

If a waiver request is denied, there needs to be sufficient time for companies to collect accurate information throughout their supply chain.

Recommendation: Require reports to be submitted no sooner than 90 days after a denial of a waiver request.

Extensions – 70026.0060 – Subpart 3 C

If an extension request is denied or granted, there needs to be sufficient time for companies to collect accurate information throughout their supply chain.

Recommendation: Require reports to be submitted no sooner than 90 days after an extension notification is denied or granted.

Trade Secret – 7026.0070

Companies may choose to use a fluoropolymer or fluoroelastomer in order to meet the requirements of a particular use application or function, which can provide a competitive advantage to the company**.**

Recommendation: Add "function" for trade secret protection.

Due Diligence – 7026.0080, Subpart 2

As written, the requirement to request detailed disclosure information "until all required information is known" is unrealistic and imposes a significant burden on reporters. Many different parts can be used in the assembly of industrial valves, coming from many different suppliers located globally. Because of the complexity of managing global supply chains, products may be purchased and stored for months or years. When asking for information, suppliers can be reluctant to share their sensitive trade data, or suppliers may no longer be in business.

Crucially, this language is not aligned with other similar reporting requirements. In particular, VMA members and reporters in other industry sectors currently are collecting data to provide

reports (due in 2026) under the U.S. EPA's extensive TSCA PFAS reporting program TSCA Section 8(a)(7). Given the effort expended over the last number of months to collect data under that reporting rule, MPCA's due diligence standard should mirror that of U.S. EPA. Under the U.S. EPA program, submitters are required to report information to the extent that it is "known to or reasonably ascertainable by" the company. The term "known to or reasonably ascertainable by" ("KRA") is defined in 40 C.F.R. §705.3 to mean "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know."

Recommendation: Can the MPCA adopt the KRA due diligence standard as defined in the U.S. EPA TSCA PFAS reporting program?

Reporting Responsibility and Fees

Both the proposed definition of "manufacturer" as well as the reporting scope do not consider complex supply chains or final products that have numerous component parts. Additionally, clarity is needed to clearly identify the entity ("manufacturer") who has primary compliance responsibility.

Recommendation: We suggest the following definition of "Manufacturer:" The person that creates or produces a product, that has a product created or produced, or whose brand name is legally affixed to the product, whichever is first to sell, offer for sale, or distribute for sale the product in the state. In the case of a product that is imported into the United States when the person that created or produced the product or whose brand name is affixed to the product does not have a presence in the United States, manufacturer means either the importer or the first domestic distributor of the product, whichever is first to sell, offer for sale, or distribute for sale the product in the state.

In addition, under 7026.0020, Subpart 1 and 2, can this be modified to allow a parent company to submit one report and pay one fee that covers the final products, component parts, brand names and subsidiaries? This would allow only one fee to be payable and reduce duplicate reporting.

* * * * *

Thank you again for the opportunity to submit comments. We welcome further discussion or any questions you may have. These can be directed to Heather Rhoderick at hrhoderick@vma.org.

Sincerely,

Heather Rhoderick
President
Valve Manufacturers Association

ALLIANCE FOR AUTOMOTIVE INNOVATION

Office of Administrative Hearings
Attn: William Moore, OAH
600 North Robert Street
P.O. Box 64620
St. Paul, MN 55164-0620

May 21, 2025

Re: Comments of the Alliance for Automotive Innovation on Notice of Intent to Adopt New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS), Revisor's ID Number R-4828, OAH docket number 5-9003-40410

To the Office of Administrative Hearings:

The Alliance for Automotive Innovation (Auto Innovators)[1] appreciates the opportunity to provide comments on the Minnesota Pollution Control Agency's Notice of Intent to Adopt New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS), or the PFAS in Products: Reporting and Fees Rule.[2] Auto Innovators has been actively engaged with PCA staff since rule development began and, as is noted in the Statement of Need and Reasonableness (SONAR), has provided comment in response to the previous Requests for Comments published with respect to this rulemaking, and also participated in PCA's informal check-in group, as well as holding an individual meeting with PCA. We hereby affirm and incorporate comments made during these previous engagements.

Because of the significant impact this rulemaking will have on the automotive sector, Auto Innovators has a strong interest in the implementation of Amara's Law. Auto Innovators represents the full automotive industry, including the manufacturers producing over 90% of vehicles sold in the United States, as well as equipment suppliers, battery producers, semiconductor makers, technology companies, and autonomous vehicle developers.

I. Introduction to the Automotive Industry and Its Products

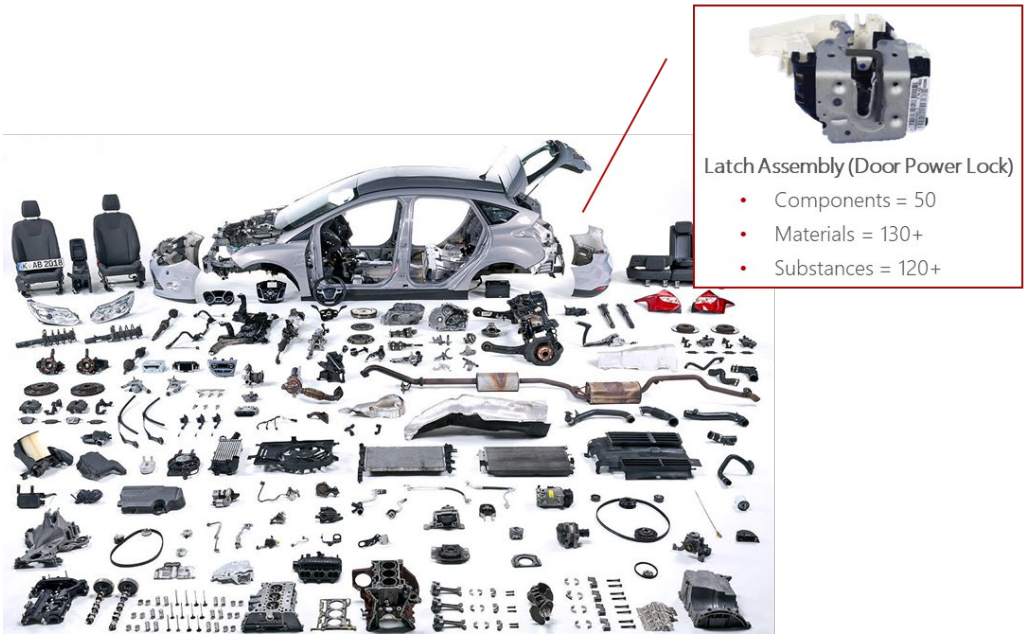
Before digging into Auto Innovators' policy and regulatory recommendations on the PFAS in Products: Reporting and Fees Rule, we think an introduction to the automotive industry and its products is important to fully understand our concerns and the anticipated impacts on the industry from the proposed PFAS reporting and fees structure. Unlike some sectors, the automotive industry has a complex international supply chain, and produces a product that may consist of 30,000

[1] Auto Innovators represents the full automotive industry, including the manufacturers producing most vehicles sold in the U.S., equipment suppliers, battery producers, semiconductor makers, technology companies, and autonomous vehicle developers. Our mission is to work with policymakers to realize a cleaner, safer, and smarter transportation future and to ensure a healthy and competitive automotive industry that supports U.S. economic and national security. Representing approximately 5 percent of the country's GDP, responsible for supporting nearly 10 million jobs, and driving $1 trillion in annual economic activity, the automotive industry is the nation's largest manufacturing sector. www.autosinnovate.org.
[2] https://www.pca.state.mn.us/get-engaged/pfas-in-products-reporting-and-fees.

individual parts at the lowest component level, encompassing various systems. Managing the manufacture of a vehicle with such a large variety of parts, including distribution and sourcing of those parts, involves a multifaceted supply chain network. This process encompasses the entire journey from raw material procurement to the final delivery of vehicles and spare parts to customers. A substantial number of the parts used in the manufacture of an automobile are imported, and may be subject to confidential business information treatment. Auto Innovators provides this background to ask PCA staff to consider the intricate engineering and management involved in the manufacture of a vehicle and the impacts and challenges posed by requiring information that may not be available to potential reporters.

A. *Complexity of Autos as a Product*

Vehicles are considered a "complex durable good." The average age of a car on the road today is over 12 years old; vehicles are built and manufactured to last for many years, and their components must be durable and deliver performance. Vehicles at their lowest component level are made up of as many as 30,000 individual parts that are built into assembles and sub-assemblies, with vehicles having around 3,000 to 7,000 end-item assemblies. We ask that PCA staff consider the time and cost implications for both PCA and the automotive sector of identifying and submitting data on each individual part for all vehicles sold in Minnesota as the agency moves forward with the scope, level of detail and required due diligence for this reporting system.



In order to keep vehicles safe and functional for consumers as long as possible, the automotive industry doesn't just build and sell vehicles; it also builds, stores, and sells a surplus of automotive parts and components to serve as service and replacement parts to keep those vehicles safely operating. Many times service and replacement parts are manufactured at the same time as the original vehicle, and are held in storage—often for years—until they are placed into service. Federal

safety statutes effectively require automakers to have parts on hand to service a vehicle for a period of 15 years after its sale.

Motor vehicles are required by law to meet a litany of rigorous state and federal performance standards, including Federal Motor Vehicle Safety Standards and fuel economy standards set by the National Highway Traffic Safety Administration; greenhouse gas and criteria pollution emissions standards set by both the Environmental Protection Agency and the California Air Resources Board; and more. These standards require both certification and testing before sale, as well as in-use compliance testing to ensure continued compliance.

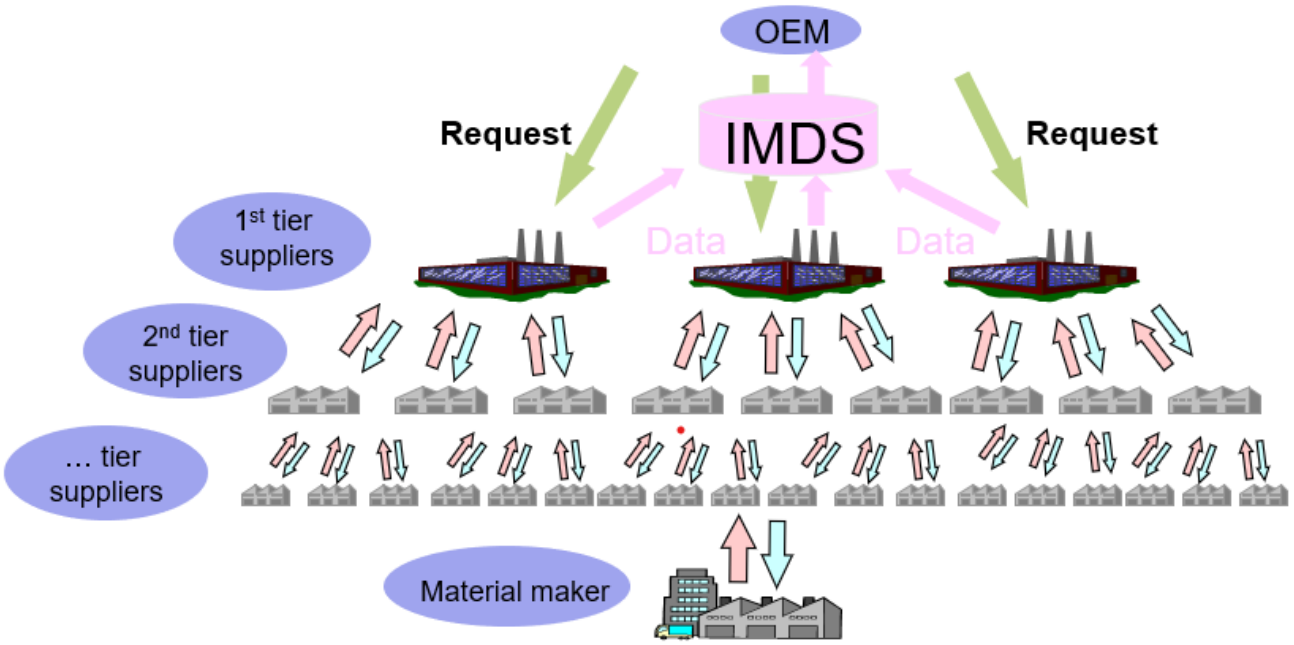
Auto companies sell many different models of vehicles, with a plethora of variants to meet all the different preferences that consumers desire. Vehicles have long development and manufacturing timeframes, with the design process beginning seven or more years prior to the anticipated time of sale of the vehicles. Following design, there is supply and sourcing of the parts, machining and build-out of manufacturing lines for the actual manufacturing phase, plus certification and testing of the vehicles to ensure they meet the above-mentioned standards. Because of the complexity of this process, a single model line is only refreshed once every several years, and an original equipment manufacturer (OEM) will alternate refreshes for model lines over time to manage the burden of this process. Importantly, major technological improvements, including such things as a motor vehicle air conditioning system redesign that implements a new refrigerant substance, mostly occur during a redesign cycle only, and are not included as part of year-to-year minor model updates. This complexity substantially contributes to the burden of PFAS reporting and the requirement to report updated information, which will effectively be annual, as further discussed below.

B. *Complexity of Supply Chain*

When considering the complex manufacture of vehicles, and in particular inquiries that must be made down the supply chain regarding the presence of PFAS chemicals in products or components, it is critical that PCA staff understand the complexity of the automotive supply chain. Our supply chain can have as many as 10 tiers of suppliers providing component substances and parts all the way up to the OEM that assembles the vehicle. Additionally, automotive suppliers are located across the globe.

The International Materials Data System (IMDS) is the global automotive industry's material data system, facilitating the collection, recording, and tracking of substance and material information throughout the complex supply chain. IMDS empowers the automotive industry to conduct

compliance verification by analyzing the substances present in vehicles and vehicle parts. Suppliers proactively send declaration of material content forward through the supply chain. IMDS is an incredibly useful, robust tool, as it can provide a primary glimpse into where various substances are located in an automobile. However, it does have limitations, especially in light of the scope PCA is considering for reporting. IMDS is reliant on the accuracy of the information that is input by the supply chain, in part due to the many tiers involved in manufacture. Because of the strict due diligence standard proposed for the PFAS in Products: Reporting and Fees Rule, further discussed below, OEMs would be required to expend substantial time and resources attempting to track the required information throughout the supply chain, and ultimately still may not be able to satisfy the proposed requirements. This is one of many reasons why PCA should reconsider them.



C. *PFAS Use in Automobiles*

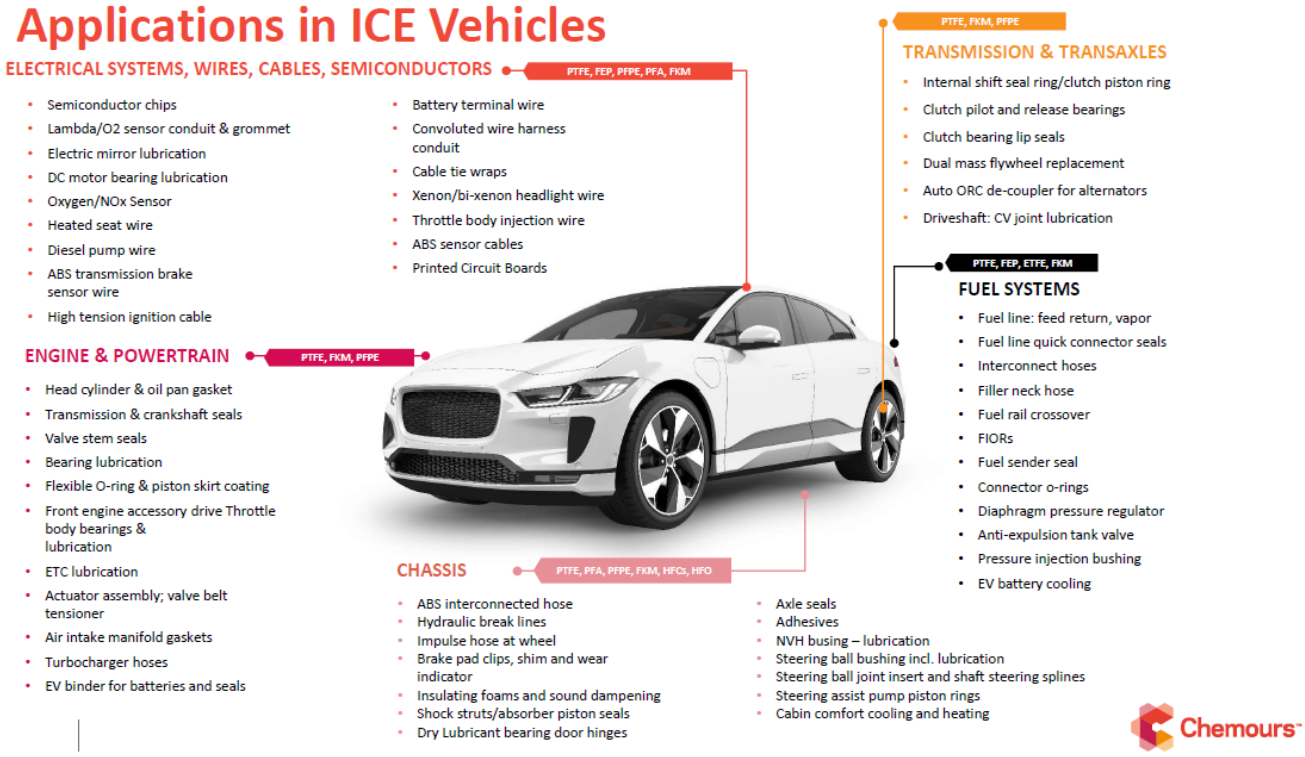
PFAS are used in vehicles in many critical applications;[3] it is impossible to build today's vehicle without PFAS, and it is highly unlikely that the automotive industry will be able to eliminate all uses of PFAS in vehicles by 2032. Automakers and their suppliers take the potential impacts of chemicals used to build today's vehicles very seriously and are always looking for substitute compounds that can perform the same function with a lower environmental impact. The industry has recognized areas where it can reduce the use of PFAS chemicals in specific applications and eliminated use of PFOA and PFOS in new vehicles. Despite this, there are some uses that cannot yet be replicated by

[3] Several automotive interest organizations and companies commented on the European Chemicals Agency's proposed Restriction on the Manufacture, Placing on the Market and Use of PFAS to provide information on automotive uses of PFAS. Those comments can be found at https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term, and Auto Innovators can provide a list of those comments for PCA if desired.

any other known chemical. Although the industry is beginning efforts to identify alternative technologies and formulas that do not use PFAS, once those are identified it could take many years of testing and validation to prove their safety and performance. Then, those alternatives must be implemented in vehicle design and production.

PFAS are critical to the functioning of motor vehicles and their parts in many different ways and are found throughout the vehicle. One non-exhaustive inventory of just the fluoropolymers used in the automotive industry identified more than 250 types of parts that are comprised entirely of fluoropolymers, including seals, tubes, and gaskets—half of which are located in the engine. A non-exhaustive list of places where PFAS are used in vehicles includes refrigerants for air conditioning systems (some of which are separately regulated and/or incentivized by other government regulations), semiconductors, electric vehicle batteries, fuel lines, on-board diagnostic (OBD) system sensors, emissions reduction seals, wiring, anti-lock braking systems, radar and proximity sensors for blind spot detection and automatic braking, power steering, head gaskets, shock absorber piston seals, and coated weather stripping. Data from the automotive industry's IMDS with information on current production and replacement/legacy parts found nearly 8 million auto parts that contain PFAS, with more than 5 million of those containing fluoropolymers. Current data is showing that available information on PFAS in vehicles indicates between 500 and 1,500 components that contain PFAS; we expect that as OEMs continue to identify PFAS within their component supply chain, that number will exceed 1,500 and could get as high as 3,000. Multiply those roughly 1,500 parts known to contain PFAS by an estimated 15 vehicle reports, by the approximately 15 OEMs selling new light-duty vehicles in the state of Minnesota, and OEMs would be reporting as many as 337,500 lines of data in accordance with PCA's proposed reporting requirements and structure. This data would just cover the sale of new vehicles. This is an estimate of the amount of data OEMs could be reporting, and we anticipate the number to actually be higher if PCA finalizes the reporting requirements and structure that it has proposed.

PFAS are used in automotive applications because of their temperature resistance, low flammability, flexibility, resistance to fluids, lightweight nature, and more. The water-resistant properties of PFAS makes them key for the lubricants and greases used in vehicle suspension systems. The heat resistance qualities of PFAS allow flexible fuel lines to safely deliver gasoline into a hot engine without causing a fire. Similarly, heat resistance – along with protection from water intrusion – protects the integrity of wire looms and sensors on a vehicle that allow today's advanced safety systems to function. Further, brake fluids are hygroscopic, which means they absorb moisture from the atmosphere under normal humidity levels. PFAS coatings on brake lines keep brake systems operating at peak performance levels for extended periods. Reduction of vehicle emissions comes in part due to the chemical and heat-resistant protections that PFAS provide to gaskets and O-rings, which keep engines tightly sealed. PFAS coatings on cylinder heads and hoses increase fuel efficiency and reduce fugitive gasoline vapor emissions. It is not an exaggeration to say that nearly every automotive system depends on certain types of PFAS chemicals to provide a safe, durable, and reliable product to consumers.



II. Comments on Draft Rules Governing PFAS Reporting and Fees

In this section Auto Innovators provides comments on the text of the draft PFAS in Products: Reporting and Fees Rule.

A. *Proposed Criteria for Aggregating Products for Reporting Are Too Strict*

The draft PFAS in Products: Reporting and Fees Rule proposes that products could be grouped together for reporting:

> The manufacturer may group together similar products comprised of homogenous materials if the products meet the following criteria:
>
> i. the PFAS chemical composition in the products are the same;
>
> ii. the PFAS chemicals in the products fall into the same reporting concentration ranges;
>
> iii. the PFAS chemicals in the products provide the same function in each product; and
>
> iv. the products have the same basic form and function and only differ in size, color, or other superficial qualities that do not impact the composition of the intentionally added PFAS.[4]

[4] Proposed Minnesota Rules, part 7026.0030, subpart 1, item A.(1)(a).

Auto Innovators recommends that PCA provide looser criteria for the grouping of products. Automakers produce vehicle lines with many vehicle variants, an issue that has been discussed in previous PCA workshops and stakeholder meetings. The requirements for the PFAS chemical composition to be exactly the same and within the same narrow concentration ranges will quite possibly restrict OEMs' abilities to group product variants together. PCA should instead consider setting a threshold for "substantially similar" products that would allow for greater grouping of products for reporting.

B. *Component-Level Reporting as Proposed Will Be Burdensome for the Automotive Industry, and Will Result in Data of Minimal Utility for Minnesotans*

1. Issues with Draft Regulatory Text and Component-Level Reporting

The draft PFAS in Products: Reporting and Fees Rule proposes that PFAS must be reported at the component level for products.

> If the product consists of multiple PFAS-containing components, the manufacturer must report each component under the product name provided in the brief description of the product.[5]

It additionally proposes that components and products can be aggregated together for reporting, but only if they meet very specific conditions.

> The manufacturer may group similar components listed within a product if the components meet the following criteria:
>
> i. the PFAS chemical composition in the components are the same;
> ii. the PFAS chemicals in the components fall into the same reporting concentration ranges;
> iii. the PFAS chemicals in the components provide the same function in each product component; and
> iv. the components have the same basic form and function in the final product and only differ in size, color, or other superficial qualities that do not impact the composition of the intentionally added PFAS[.][6]

Auto Innovators is concerned about how this will impact the automotive industry's reporting. As discussed above, each vehicle is estimated to have 1,500 or more components containing PFAS that could need to be individually reported and detailed as "components" of the products reported.[7] Additionally, because of the strict criteria for aggregation, Auto Innovators expects that very few vehicle components will contain the exact same PFAS, in the exact same concentration ranges, providing the same function. Therefore, industry will not gain substantially from the ability to group components, and would be expected to report a lot of these components individually.

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[5] Proposed Minnesota Rules, part 7026.0030, subpart 1, item A.(1)(b).
[6] Proposed Minnesota Rules, part 7026.0030, subpart 1, item A.(1)(1).
[7] This estimate was developed from data available in IMDS and, as discussed above, that data is likely not as comprehensive as the proposed regulations would require.

As proposed, information gathering and reporting will be very burdensome for the automotive industry, and will inundate PCA's database, and Minnesotan consumers, with massive volumes of reports containing minimally useful data. Companies will have to dedicate a substantial amount of time to inputting data for all of those lines of information for each of those component parts. That volume of data and information input also has to be multiplied by each of the individual vehicle classes reported as a "product" by an OEM, multiplied by all of the different OEMs selling vehicles in Minnesota. As discussed above in our section on PFAS in vehicles, this could mean as many as 337,500 lines of data just from the OEMs, if not more.

This is also likely to lead to confusion for any Minnesotan trying to review the data. First, there is the risk of duplication of reporting—what if a very small component, like a gasket, is individually reported but then also potentially reported as part of its sub-assembly unit, like an engine? What if a supplier has already submitted information on that part? Additionally, OEMs will quite possibly report their components with some differences in labeling, naming, and parts/assembly division, based on the way they view and report those elements internally. That is likely to make it difficult for Minnesota consumers to accurately comprehend the amount of PFAS in their own vehicle and/or compare data on vehicles and does not align with the PCA's goals of consumer awareness and education.

Auto Innovators recommends that MPCA revise its proposed requirements for component reporting and expand its criteria for the grouping of products and product components, in order to better facilitate reporting by entities and provide more useful information to Minnesotans. In this vein, below Auto Innovators details its proposal for vehicle reporting that would rely on such revisions to the proposed reporting requirements.

2. Reporting the Function of the PFAS by Component Will Be Highly Burdensome

PCA proposes that in component-level reporting, OEMs will have to report "the function that each PFAS chemical provides to the product or its components[.]"[8] Auto Innovators strongly prefers to report the function of PFAS with respect to the overall product, as reporting the purpose at the component level for as many as 30,000 individual parts will be highly burdensome. Information on the purpose of each PFAS is not provided in IMDS. For this reason, it is preferable to report on PFAS at the vehicle level. This would be further supported under our proposal for reporting, described below.

3. Auto Innovators Proposal for Vehicle Reporting

Each auto manufacturer has multiple vehicle models, and a single vehicle has tens of thousands of individual parts at the lowest component level built into sub-assemblies and assemblies. Reporting on each one of those individual components will not only overwhelm the data management system, it will also place an unreasonable burden on automobile manufacturers. All other sectors that provide complex durable goods to consumers will have the same issue—hundreds if not thousands of individual parts in the finished product. Investigating tens of thousands of parts in the automotive industry would be costly and would result in fragmented and duplicated information that may overwhelm the database while providing little value to Minnesota consumers, who are likely to be

[8] Proposed Minnesota Rules, part 7026.0030, subpart 1, item D.

purchasing a whole vehicle (and concerned about the risks in that whole vehicle) as opposed to any individual component.

The automotive industry, through Auto Innovators, has developed an alternative proposal for PFAS reporting that we believe will provide information that is useful to Minnesota consumers about PFAS present in various parts of the vehicle without placing unnecessarily burdensome obligations on reporting entities.

Auto Innovators believes that reporting the total amount of PFAS in a vehicle family (the product), plus the higher-level locations of those PFAS present in various parts of the vehicle, would be clearer for Minnesotans browsing the data than digging through thousands of lines of redundant small component parts reporting data.

Here is an image of what reporting would look like using our proposed template:

OEM #2, Vehicle #4 - Truck (ICE)		
PFAS Substance + Vehicle Location	PFAS Total (	% of Vehicle Weight
PTFE (CAS# 9002-84-0)	**357.2214332**	**0.014%**
Body	100.6141809	0.004%
Chassis	188.6539344	0.007%
Electrical	1.375517334	0.00005%
Interior	1.806957768	0.00007%
Powertrain	64.75952085	0.003%
Unassigned	0.011322	0.0000004%
Polyvinylidene fluoride (CAS# 24937-79-9)	**300.7629512**	**0.012%**
Body	0.00079422	0.00000003%
Chassis	0.000046	0.000000002%
Electrical	300.759003	0.012%
Unassigned	0.003108	0.0000001%
Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene (CAS# 9011-17-0)	**80.11281319**	**0.003%**
Body	0.204705882	0.00001%
Chassis	0.352891665	0.00001%
Powertrain	79.55521565	0.003%
Ethene, tetrafluoro-, homopolymer (CAS# 9002-84-0)	**62.1533528**	**0.002%**
Body	5.932395461	0.00023%
Chassis	9.370032304	0.00037%
Electrical	1.061819626	0.00004%
Interior	2.113240514	0.00008%
Powertrain	43.67586489	0.002%
1-Propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethene ... (CAS# 25190-89-0)	**29.55318309**	**0.001%**
Body	0.11261904	0.000004%
Chassis	0.000833125	0.00000003%
Interior	0.011489362	0.0000005%
Powertrain	29.42824157	0.001%

This proposed reporting looks at a vehicle, looks at the various PFAS chemicals that are present in the vehicle, and then organizes them by larger comprehensible systems/areas: Body, Chassis, Electrical, Interior (which would likely be of particular interest for consumers), Powertrain, or Unassigned. This reporting also uses the classification breakdown that our IMDS reporting system has, so that data would be more comparable across automakers. In that way, a consumer can see

what PFAS chemicals are present in the interior of a vehicle they are considering without having to discern or aggregate all of the individual product components that might make up the interior passenger cabin.

We would be happy to discuss this reporting proposal with PCA in greater detail. But, as currently proposed, we do not have a clear indication that the PFAS in Products: Reporting and Fees Rule would allow reporting in this manner, for the reasons discussed above.

4. Combine Two Lowest Reporting Ranges for a Bottom Tier that Covers *De Minimis* Level

PCA proposed reporting ranges for the concentration of a PFAS in a product or component, a concept that Auto Innovators generally supports. Reporting the amount of PFAS within a range at the finished product level would simplify the information needed to fulfill the requirements of the law, as reporting at the vehicle level would give an excellent and understandable measure of each car's PFAS content. The PFAS in Products: Reporting and Fees Rule proposes that:

> A manufacturer must report the concentration of PFAS chemicals as identified in subitem (1) or (2):
>
> (1) within the following ranges:
>
> (a) practical detection limit to <100 parts per million (ppm);
> (b) 100 ppm to <1,000 ppm (0.1 percent);
> (c) 1,000 ppm to <10,000 ppm (one percent);
> (d) 10,000 ppm to <150,000 ppm (15 percent);
> (e) 150,000 ppm to <300,000 ppm (30 percent);
> (f) 300,000 ppm to <600,000 ppm (60 percent);
> (g) 600,000 ppm to <900,000 ppm (90 percent);
> (h) 90 to 100 percent; or
> (i) present but the amount or concentration range is unknown;[9]

Auto Innovators recommends that PCA combine the reporting ranges currently listed as (1)(a) practical detection limit to <100 parts per million (ppm) and (b) 100 ppm to <1,000 ppm (0.1 percent) to a range that just covers from the practical detection limit to <1,000 ppm (0.1 percent). We recommend this because in a number of other chemical regulations, there is a *de minimis* value of 0.1 percent,[10] and so it makes more sense to have the range spread from the practical detection limit to that point. Notably, the automotive IMDS system utilizes a 0.1 percent *de minimis* threshold for most of the chemicals that it tracks, and information existing in the system may not be updated simply because a new chemical regulation comes into effect with a different threshold.

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[9] Proposed Minnesota Rules, part 7026.0030, subpart 1, item C.

[10] For example, the European Union's European Chemicals Agency (ECHA) maintains a list of substances of very high concern (SVHCs), and if an article contains an SVHC above a *de minimis* concentration value of 0.1%, notification to ECHA is required. https://echa.europa.eu/substances-of-very-high-concern-identification-explained.

Combining reporting ranges would also bring Minnesota's concentration ranges closer to the ranges that EPA plans to utilize for reporting.[11] Those are:

TABLE 6 TO PARAGRAPH (c)(8)—CODES FOR REPORTING MAXIMUM CONCENTRATION OF CHEMICAL SUBSTANCE

Code	Concentration range (% weight)
M1	Less than 1% by weight.
M2	At least 1 but less than 30% by weight.
M3	At least 30 but less than 60% by weight.
M4	At least 60 but less than 90% by weight.
M5	At least 90% by weight.

5. Total Fluorine Analysis

Beyond those reporting ranges, PCA also proposes to allow reporting of the total organic fluorine (TOF): "(2) the total organic fluorine, determined using commercially available analytical methods, if the amount of each PFAS is not known within applicable due diligence standards under part 7026.0080[.]"[12] Auto Innovators' experience is that scientific testing to determine the amount of PFAS in a hard consumer product, especially one like a vehicle, is difficult at best.[13] That being said, the automotive industry has expressed support for ASTM International Standard F3700-25, Standard Guide for Selecting and Applying Analytical Methods to Evaluate PFAS in Consumer and Related Products.[14] F3700-25 "provides an overview of analytical methods, techniques, and procedures that may be used when determining the presence of PFAS in consumer and related products [, but] does not specify which analytical methods, sample preparation techniques, or procedures apply to any given product." It may be worth PCA review.

C. *The Due Diligence Standard of "Until All Required Information is Known" is Burdensome and Does Not Comport with Reporting Deadlines*

The draft PFAS in Products: Reporting and Fees Rule proposes regarding supply chain information requests that "[a] manufacturer or group of manufacturers must request detailed disclosure of information required in part 7026.0030 from their supply chain until all required information is

[11] 88 Fed. Reg. 70,516, 70,553 (Oct. 11, 2023).
[12] Proposed Minnesota Rules, part 7026.0030, subpart 1, item C(2).
[13] See also the Government Accountability Office's analysis of this issue at GAO. 2022. Technology Assessment. Persistent Chemicals. Technologies for PFAS Assessment, Detection, and Treatment. GAO-22-105088, https://www.gao.gov/products/gao-22-105088.
[14] https://store.astm.org/f3700-25.html.

known."[15] Auto Innovators finds this to be an impracticable and unreasonable due diligence threshold and recommends that PCA reconsider. PCA explains this choice in the SONAR:

> Subpart 1 is proposed to make clear that a manufacturer must assume responsibility for reporting unless notification has been received from a manufacturer in the supply chain in accordance with part 7026.0020, subpart 2, confirming that the reporting requirements have been fulfilled…. By ensuring that manufacturers trace PFAS usage through multiple tiers of manufacturers in the supply chain, the MPCA can gather comprehensive and accurate data on PFAS in products, thereby preventing gaps in reporting that could undermine the rule's effectiveness. This thorough approach ensures that all relevant PFAS data is captured, regardless of where in the supply chain the chemicals were introduced, promoting transparency and accountability across the entire manufacturing process. It also helps mitigate the risk of non-compliance, ensuring that no stage of the production process is overlooked and that the ultimate responsibility for accurate reporting is fulfilled.[16]

Manufacturers of products subject to the notification requirement should be able to rely solely on documents or information provided by suppliers and the supply chain to determine whether such products or product components contain intentionally added PFAS. If a supplier informs the manufacturer that the components they purchase that are incorporated into their end products do not contain PFAS, a manufacturer should be able to rely on that information in the absence of contrary evidence. The notification requirement should make clear that a manufacturer's inquiry regarding PFAS content with respect to any supplier ends with the existing information provided to a manufacturer by that supplier.

It would be unreasonable for the PFAS in Products: Reporting and Fees Rule to require manufacturers to mount a burdensome due diligence effort essentially to prove what they already believe, namely the absence of PFAS in parts and components that go into their end products. Most manufacturers have had little or no reason to collect information from their foreign suppliers about the presence of PFAS in the components they use. End product manufacturers typically have complex global supply chains, and each end product can have thousands of individual parts and components sourced from a variety of suppliers. For example, a side mirror alone can contain over 30 individual parts.

The approach proposed by PCA is clear overreach. Amara's Law does not authorize investigation of a manufacturer's supply chain. PCA should not use a reporting requirement for products to get data that is beyond the scope of the statute and to force manufacturers to investigate the entire global supply chain. As previously explained, many suppliers may be outside of the scope of Amara's Law and may not be legally obligated to report their information to PCA.

As discussed above, both our products and our supply chain are highly complex. The automotive industry will struggle to get information "until it is known," and we expect that to get information potentially 10 tiers down through the supply chain will take several months at best. That due diligence standard does not comport with the reporting deadline of January 1, 2026—less than eight

[15] Proposed Minnesota Rules, part 7026.0080, subpart 2 (emphasis added).
[16] SONAR at 37.

months from now. Additionally, the requirement to keep pursuing information "until it is known" will mean substantial expenditures of reporting company staff time and resources; if OEMs cannot determine the information or the supply chain will not provide it in that time, then presumably OEMs would not be permitted to sell vehicles, which would be an unreasonable outcome.

We recommend that PCA adopt the due diligence threshold that EPA set for its similar Toxic Substances Control Act Section 8(a)(7) PFAS reporting rule, where EPA acknowledged the complexity and burden required by gathering such data. That requirement is for obligated entities to report required information "to the extent known to or reasonably ascertainable by them[.]"[17] In turn, "known to or reasonably ascertainable by" is defined as "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know."[18] This requirement is more tempered and does not require reporters to search to the ends of the earth to find information, as is currently the case under this draft. Even EPA itself recognized that "it may not be within the scope of 'reasonably ascertainable' to survey all articles and products, especially for article importers."[19] EPA also notes that "if particular information cannot be derived or reasonably estimated without conducting further customer surveys (i.e., without sending a comprehensive set of identical questions to multiple customers), it would not be 'reasonably ascertainable' to the submitter. Thus, there is not a need to conduct new surveys for purposes of this rule."[20] This makes clear how much more burdensome Minnesota's standard is beyond what the EPA found in 2023 to be an appropriate level of due diligence. PCA already referenced the TSCA 8(a)(7) rule when proposing a definition for the term "publicly available" as stated in the SONAR.

Maine, the only other state with a PFAS reporting requirement that comes close to being as extensive as the one proposed by Minnesota, also uses EPA's "known to or reasonably ascertainable by" standard.[21]

D. *The Requirements Regarding Updated Filings are Unrealistic*

The draft PFAS in Products: Reporting and Fees Rule proposes that:

> By February 1 each year, a manufacturer or group of manufacturers must submit an update to the report submitted under part 7026.0030 if during the previous 12 months:
> (1) a significant change was made to a product;
> (2) new product information was provided to a manufacturer; or
> (3) a new product was sold, offered for sale, or distributed in or into the state.[22]

In turn, the draft rule defines a "significant change" as:

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[17] 40 C.F.R. § 705.15.
[18] 40 C.F.R. § 705.3.
[19] 88 Fed. Reg. 70,516, 70,538 (Oct. 11, 2023).
[20] 88 Fed. Reg. at 70,521.
[21] See 06-096 C.M.R. ch. 90, § 3(A) (2025), *available at* https://www.maine.gov/sos/sites/maine.gov.sos/files/inline-files/096c090.docx.
[22] Proposed Minnesota Rules, part 7026.0040, subpart 1, item A.

> [A] change in the composition of a product that results in the addition of a specific PFAS not previously reported in a product or component or a measurable change in the amount of a specific PFAS from the initial amount reported that would move the product into a different concentration range listed under part 7026.0030, subpart 1, item C.[23]

For the automotive industry, the combination of these two provisions is likely to mean that auto manufacturers would be resubmitting vehicle PFAS information every year, which would essentially be the same information. Auto manufacturers release new model years of several vehicles every year, but more times than not those new models involve only minor changes, possibly the substitution or adjustment of a few parts, and no major redesigns. However, when a "significant change" can include the addition of a specific PFAS not previously reported in a component or a measurable change in the amount that would move the product into a different concentration range, that threshold is likely to be triggered and would result in reporting all vehicle data every year. In addition, the terms "new product information" and "new product" are not defined—would new product information include a company name change or new address? Auto Innovators recommends that PCA consider a less strict and more straightforward threshold for updated reporting.

E. *Provisions on Reporting on Behalf of Other Manufacturers Raise Additional Considerations*

The draft PFAS in Products: Reporting and Fees Rule lays out provisions for reporting on behalf of other manufacturers, which raise several additional considerations for the automotive industry.

The automotive industry has over 3,500 tier 1 suppliers, and this figure does not include the further tiers 2 to roughly 10 of upstream suppliers. Auto Innovators believes that working out reporting on behalf of other manufacturers in the automotive supply chain within the next eight months before the reporting deadline at the start of 2026 will be incredibly difficult and unreasonable to establish and manage.

It also isn't clear how Minnesota will keep track of which suppliers have reported and what data they have received. Similarly, Auto Innovators has concerns about how Minnesota will keep track of the fees paid and which reports they are intended to cover. This greatly increases the possibility of PCA receiving many redundant component reports.

Finally, the automotive industry's issues regarding the reporting of spare parts, covered below, raise questions about whether manufacturers of those parts will be required to report. If spare parts are addressed as Auto Innovators proposes below, it would resolve the issue of reporting on behalf of other manufacturers with respect to those parts.

III. Additional Concerns

Auto Innovators wishes to address a number of additional concerns regarding the PFAS in Products: Reporting and Fees Rule that don't relate directly to the actual proposed text.

[23] Proposed Minnesota Rules, part 7026.0010, subpart 18.

A. *How to Address Spare and Replacement Parts*

As discussed above, the automotive industry sells substantial volumes of spare parts in order to keep vehicles safely functioning, often parts that were manufactured at the same time as the vehicle and have been held in storage until they are needed in the market. It is also noteworthy that those parts have little purpose unless they are installed in the vehicles they are intended to service. Whether and how to consider those parts with respect to reporting is a critical question for the automotive industry, and Auto Innovators makes the following recommendations.

As mentioned above, Auto Innovators expects that there could be as many as 8 million service and replacements parts available in the market for vehicles that may contain PFAS. Therefore, Auto Innovators suggests interpretations below that seek to limit the reporting burden for the automotive industry regarding these spare and replacement parts while ensuring that needed information on PFAS in vehicles is available. Finally, if spare and replacement parts are required to be separately reported as products, Auto Innovators will need guidance on what numeric product codes would be required.

1. Spare and Replacement Parts for Reported New Production Vehicles

One class of spare and replacement parts that PCA should consider are those for new production vehicles that will be reported as products under this program. Because PCA is requiring reporting at the component level, Auto Innovators recommends that spare and replacement parts for vehicles be considered reported through the vehicle report. This is sensible because that PFAS content is factored into the whole vehicle and component reporting, and because those spare and replacement parts will be intended to take the place of a part that has already been factored into reporting.

In fact, PCA appears to have already agreed to this approach. In the Questions and Answers document PCA released in conjunction with its July 18, 2024 webinar on rulemaking toward the implementation of Amara's Law,[24] PCA included the following question: "Do service parts need to be reported separately if they contain intentionally added PFAS and are already reported as a component of a finished product SKU?" PCA answered that "If service parts contain intentionally added PFAS and are already reported as part of a finished product SKU, separate reporting for the service parts is generally not required. The key point is that the PFAS content in the service parts is included in the overall reporting of the finished product." Auto Innovators hopes PCA retains this finding.

Auto Innovators makes one final note that OEMs may deliver cars for sale to dealers in Minnesota, and those dealers may install additional parts to make the vehicles attractive for sale or because they were requested by the customer. OEMs should not be responsible for reporting those components because they were not installed by the OEM.

2. Spare and Replacement Parts for Legacy Vehicles

A second class of spare and replacement parts that PCA should consider are those for legacy vehicles—vehicles that have already been sold into the state and are not currently being sold as new

[24] https://www.pca.state.mn.us/sites/default/files/c-pfas-rule1-00.pdf.

complete vehicles. Those complete vehicles that are already in-use should be considered "used products" consistent with the law and draft regulation. Auto Innovators recommends that spare and replacement parts for legacy vehicles be considered component parts of "used products," and thus considered not subject to reporting requirements. It would be prohibitive for the automotive industry to determine the PFAS content of these parts, which may have been developed and manufactured years ago, to meet newly introduced regulatory requirements. If the automotive industry was required to report these parts, the estimate of 337,500 lines of data from OEMs would exponentially increase.

B. *Automotive Model Years and Vehicles for Sale*

Autos as a product have several peculiarities that create some confusion for PFAS reporting. For the majority of calendar year 2025, the United States will be in model years (MY) 2025 and 2026 and will at various times in the year be selling vehicles from both MYs as new to consumers. If vehicles are placed in Minnesota prior to January 1, 2026, such as being sent to a dealer, but could be sold to a customer after that date, are they subject to reporting? If so, how far back in time would OEMs have to report on vehicles previously placed in the state but sold after the January 1, 2026 reporting deadline? Additionally, as discussed above, it is unclear whether new model years of a product constitute a new product for reporting purposes.

Auto Innovators suggests that for the automotive industry, we instead report annually by model year the vehicles for sale in Minnesota. This would greatly simplify and clarify obligations for our industry.

C. *The PCA Underestimates Costs*

In the SONAR, PCA states that "[m]anufacturers are anticipated to bear minimal costs to comply with the reporting rule."[25] Auto Innovators disagrees with this characterization, and expects that the costs manufacturers will have to undertake will be substantial, as already somewhat described above.

To conclude that manufacturers will have minimal costs while the state estimates its own implementation cost to be just over $6 million is disingenuous.[26] Companies with compliance obligations will have multiple staff members, for example both technical and legal staff, reviewing the PCA's final rule and associated documentation in order to best understand the regulatory requirements and the agency's expectations for compliance. Just as PCA will have to build data systems to collect data, manufacturers will need to build IT systems to collect and report the extensive data required. Previous surveys of our membership have anticipated that OEMs may spend about 30 hours on rule familiarization, and suppliers may spend closer to 80 hours on the same. For EPA's TSCA 8(a)(7) PFAS reporting rule, Auto Innovators estimated that OEMs may spend around 50 hours searching the IMDS system to obtain information on the presence of PFAS in products.[27] We also anticipated that OEMs could spend around 120 hours to search production, service parts, and purchasing records in order to identify suppliers they would need to contact in order to obtain PFAS content information. Auto Innovators expects that further follow-up with all of

[25] SONAR at 42.
[26] SONAR at 42.
[27] Our previous assessment of compliance costs for EPA's TSCA 8(a)(7) PFAS reporting rule can be found in our July 2021 comments, available at https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0549-0030.

the suppliers for a product like a vehicle could be as many as a few thousand hours. From just this information it is clear that the burden to reporters should not be expected to be "minimal." It is difficult to more exactly pinpoint expected costs for the industry without more substantive details about how reporting will actually take place and what the system will look like.

PCA should look at cost estimates for similar regulatory efforts to better inform its own cost estimate for the proposed PFAS in Products: Reporting and Fees Rule. For example, PCA should consider the estimates of the reporting burden developed by the EPA for its TSCA 8(a)(7) rule which, although low, recognizes that there are substantial costs for industry to collect and report data. Auto Innovators expects that the process for compliance with Amara's Law will be very similar to the process for compliance with the TSCA 8(a)(7) rule. PCA should also review comments in that docket and revise its costs.[28]

D. *The Timelines for Finalization of a Rule, A Reporting System, and Submission*

Auto Innovators is concerned that the timeline that PCA is anticipating, with a final rule issued a few months from now and a reporting system available late in 2025, does not allow obligated entities to sufficiently prepare to make all reports as required by January 1, 2026. At a minimum, the reporting deadline should be delayed until PCA has successfully beta tested the reporting system.

Auto Innovators estimates that it will take our industry at least 6 months to a year to collect available data on PFAS in production vehicles and spare parts. We also estimate that it will take an additional 6 or more months to get PFAS data on OEM-branded items that are not manufactured by the OEM, such as jackets, travel mugs, or other merchandise products.

1. Little Information is Currently Available on <u>How</u> to Report

Although the draft PFAS in Products: Reporting and Fees Rule gives an indication about what will be required from reporting, it gives little direction about *how* manufacturers will be required to report, and an understanding of this is truly critical for regulated entities to understand the actions required and to comprehend the resources that will be needed to execute those tasks. Auto Innovators believes these issues have implications for the reporting on behalf of other manufacturers concept as well. Auto Innovators would prefer to share information with PCA via an Excel file upload, which we believe will be the least burdensome for industry. However, we do understand that PCA is in the process of developing an online reporting system. Auto Innovators is interested in information on the reporting system as soon as it is available. Furthermore, Auto Innovators volunteers to help PCA beta test the reporting system and help provide feedback as complex durable goods manufacturers. Auto Innovators expects that the automotive industry will be one of the largest submitting industries with potentially very high volumes of data, and we believe our input will be critical. We agreed to help EPA beta test their TSCA 8(a)(7) reporting system as well, until that beta testing period was recently canceled by the agency.

[28] See 86 Fed. Reg. 14,904 (March 19, 2021); and Comment submitted by Alliance for Automotive Innovation, EPA-HQ-OPPT-2020-0616-0007, https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0616-0007.

2. Extensions of the Reporting Deadline

We note that both under the law[29] and under the draft PFAS in Products: Reporting and Fees Rule,[30] PCA has the authority to extend the deadline for the submission of information if the commissioner determines that more time is needed for compliance. Auto Innovators recommends that PCA begin work on an extension of the deadline, given the timelines discussed above. The sooner that an extension can be confirmed for reporting entities, the more time it gives for planning and inventory management. There is precedent for extensions in other states; Maine, for example, granted waivers of the reporting requirements as it continued to work through implementation issues in its program. Auto Innovators notes that manufacturers can also request extensions, but those provisions operate with application and approval timelines and appear to only effectively last for 90 days.[31] Action on the initiative of PCA itself instead is highly preferable. Auto Innovators recommends that PCA delay the reporting deadline until at least 6 months after the completion of beta testing of the data collection system.

E. *MPCA's Goal of a Public Database*

Auto Innovators understands that part of PCA's goal with respect to PFAS reporting is to develop a public database on PFAS in products that can be used by Minnesota consumers. However, as mentioned above, PCA must be very thoughtful in developing its standards for reporting to ensure the data populated i is legible and useful for consumers. As discussed above, we think reporting at a low component level will create confusion, and that consumers would best benefit from a higher-level overview of the presence of PFAS in automotive systems and areas. Auto companies' major product is a complete vehicle, not the litany of parts it contains.

In addition, in creating a public database, PCA must be mindful of protecting confidential business information (CBI). Reporters may have contractual agreements with their suppliers to keep certain information confidential. PCA needs to provide additional information on how to submit CBI claims for data, and information on how the database manager will also dedicate themselves to maintaining the CBI status of that data.

F. *The Messages the SONAR is Communicating on PFAS*

Auto Innovators has concerns about the way the SONAR communicates about PFAS. PCA notes that "[m]any PFAS have been proven to be toxic, associated with adverse health outcomes such as altered immune and thyroid function, liver disease, kidney disease, adverse reproductive and developmental outcomes, and cancer[,]"[32] but Amara's Law's broad scope covers many more PFAS chemicals that do not have scientific evidence regarding the risks and harms of those substances.

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[29] "The commissioner may extend the deadline for submission by a manufacturer of the information required under subdivision 2 if the commissioner determines that more time is needed by the manufacturer to comply with the submission requirement." Minn. Stat. Ann. § 116.943 subd. 3(d).
[30] "The commissioner must extend the deadline for submitting information under part 7026.0030 if the commissioner determines that more time is justified by the manufacturer or group of manufacturers to comply with the reporting requirements." Proposed Minnesota Rules, part 7026.0060, subpart 1.
[31] Proposed Minnesota Rules, part 7026.0060, subparts 2-3.
[32] SONAR at 8.

Additionally, the SONAR discusses a broad brush illustration of potential pollution risks from cradle to grave of products, but it should be noted for consumers that this high-level explanation misses the actual risks and realities for various products. For example, the end-of-life management of vehicles as a product is much different from many other products, as there is a vibrant parts recovery and resale market, and around 86% of a vehicle is recycled or reused at end-of-life.

G. *Exempt Packaging Reporting – We Do Not Collect This Information*

Auto Innovators argues that packaging reporting should not be required as part of this program, because companies do not collect this information and have it readily available in our IMDS tracking system.

H. *Fees Appear Disproportional to Amount of Funding Needed for PFAS Program*

Auto Innovators questions whether the fees charged for reporting, when the scope of reporting is considered, are well-tailored to the amount of funding needed by PCA to administer the PFAS program. Although the fees per report appear generally reasonable for manufacturers, Auto Innovators notes that suppliers throughout the supply chain are also obligated to ensure they are covered by reporting, since business-to-business transactions are in scope, which really multiplies the number of fees collected. There are potentially hundreds of suppliers that sell to one OEM, multiplied by all of the different OEMs selling vehicles into Minnesota, and the supplier obligations with respect to fees could be substantial—which OEMs cannot be responsible for. PCA should consider this when it comes to fee payment obligations, and ensure that their fee collection structure is tailored toward meeting the financial needs of the reporting program.

I. *Upcoming Currently Avoidable Use Rulemaking*

Auto Innovators is also interested in further information on PCA's upcoming currently unavoidable use rulemaking, as members of the automotive industry will be applying for currently unavoidable use status for PFAS used in vehicles. We hope that PCA will be issuing that rulemaking soon, as the sooner that it is finalized and the automotive industry can apply for a currently unavoidable use finding, the sooner it will provide certainty for the automotive industry, which could use this sort of information given its long development and production timelines.

Auto Innovators wonders whether reporting is required if a manufacturer receives a currently unavoidable use exemption grant, and whether the answer to that question changes after 2032 when the complete phase-out takes effect. We recommend that manufacturers that receive a currently unavoidable use exemption should not be required to report, as this will lessen the reporting burden on those uses.

J. *Corporate Structures and Reporting*

In the draft PFAS in Products: Reporting and Fees Rule, PCA provides little guidance regarding who the reporting entity should be in situations where corporate structures are complex, for example automakers who may have one corporate headquarters entity in their home global region but may have U.S. subsidiaries or affiliates for the United States. EPA, on the other hand, did provide such guidance for TSCA 8(a)(7) PFAS reporting. Absent further guidance from PCA, Auto Innovators'

understanding is that PCA does not have a position on which entity relative to a company's corporate structure submits the reporting.

K. *Limiting Innovation*

The draft PFAS in Products: Reporting and Fees Rule's requirements are so complex they will stop or delay implementation of new vehicle technologies. Extensive reporting for emerging technologies (e.g., safety, fuel efficiency, batteries, or hydrogen fuel cells) will stifle entry to market and application of those technologies at a time when the industry is working to further reduce emissions. The reporting system must be available and easy to use if technology developers will be required to make notification prior to selling new products and related components in the state.

Conclusion

Thank you for your consideration of our comments. Depending on how they are designed, the PFAS reporting requirements under the PFAS in Products: Reporting and Fees Rule in combination with the actual data reporting system have the potential to place highly substantial burdens upon the automotive industry. If that burden is too great, some automakers may choose to leave the state altogether instead of expending resources to comply with the requirements. It should additionally be noted that any such decision by automakers could possibly come under consideration in the fall of 2025 in order to give companies sufficient time and opportunity to halt necessary processes before January 1, 2026. This further element should be considered as PCA continues its work and develops its timelines for operation of the PFAS reporting program.

Please feel free to reach out to me if you need any further information or would like additional discussion.

Sincerely,

Catherine Palin
Alliance for Automotive Innovation

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May 21, 2025

The Honorable Jim Mortenson
Minnesota Office of Administrative Hearings
600 North Robert Street
PO Box 64620
St. Paul, Minnesota 55164-0620

Re: Minnesota Pollution Control Agency's Notice of Intent to Adopt New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS), Revisor's ID Number R-4828, OAH Docket Number 5-9003-40410

Dear Judge Mortenson:

On behalf of the Consumer Technology Association (CTA), we respectfully submit these comments on MPCA's Notice of Intent to Adopt New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing PFAS (Proposed Rule). CTA is North America's largest technology trade association. Our members are the world's leading innovators – from startups to global brands – helping support more than 18 million American jobs. We appreciate the opportunity to provide these comments and welcome continued dialogue with MPCA as the Agency implements the 2023 Products Containing PFAS Law.[1]

7026.0030 Report; Required Information
Grouping Products in Reporting: The Proposed Rule in 7026.0030(1) allows manufacturers to report by product group, but only if the PFAS composition in the products are the same, the PFAS fall into the same reporting concentration ranges, the PFAS provide the same function, and the products have the same basic form and function. This method of grouping products is so exacting that it would be impractical for many manufacturers of complex articles to use.

Reporting by broader product grouping is essential for complex articles. For example, electronic products can be modular with many component parts. This can lead to thousands of possible permutations for a single "product" and therefore could lead to thousands of notifications per manufacturer. Various PFAS substances may be present in products within the same product category and at different concentrations. The Proposed Rule should allow manufacturers to group different versions of the same product that have variations in the number and concentration of PFAS.

[1] Minn. Stat. § 116.943

Reporting at the Product Level: The Proposed Rule requires manufacturers to report individual components if a product consists of multiple PFAS-containing components. For complex articles like electronics, there are products which contain hundreds or thousands of components. A more workable requirement would be to allow manufacturers to report at the product level. We recommend allowing an option similar to the Canadian PFAS reporting guidance which says that "If information is not reasonably accessible for components, calculate the concentration for the entire manufactured item."[2]

New Products: 7026.0030(1) states that "a manufacturer or group of manufacturers of a new product with intentionally added PFAS after January 1, 2026, must submit a report before the product can be sold, offered for sale, or distributed in the state." However, later in the Proposed Rule 7026.0040(1)(A)(3) outlines how reporting updates must be made for when a "new product was sold, offered for sale, or distributed into the state" by February 1 of each year. These two seemingly contradict. The statute requires that a report be submitted whenever a new product is sold in the state. The statute does not require submission of a report *before* the product can be sold (as it says in 7026.0030(1)). A requirement to report before the sale of a product might breach a company's confidentiality requirements or put companies at a disadvantage. We recommend that the sentence on lines 5.5-5.7 be removed and instead refer to the requirement in 7026.0040 where new products must be reported by February 1 of each year.

Discontinued Products and Repair/Replacement Parts: The Proposed Rule outlines reporting which is required for products that are currently being sold in the state as well as future products to be sold. However, manufacturers may have products that are now discontinued but may still be in stock in some retailer's location. Product manufacturers do not have control over when their products are on all retailers' shelves and may not know when all discontinued products are fully sold. The Proposed Rule should clarify how manufacturers should address discontinued products, if at all. Additionally, to allow for ease of repair, we ask that repair and replacement parts be exempt from the reporting requirement.

Reporting Concentrations and de minimis: The reporting ranges in 7026.0030(C) require reporting the presence of any PFAS in a product at an unclear "practical detection limit." MPCA should establish a clear de minimis reporting threshold for the information required under 7026.0030. The statute is focused on the notification and prohibition of intentionally added PFAS, and the Proposed Rule should avoid unnecessary reporting of byproducts and impurities in products. We respectfully ask that MPCA include in their Proposed Rule a threshold consistent with other jurisdictions' chemical reporting and restrictions requirements. Ideally, MPCA should align with minimum threshold limits established by EU REACH and Canada PFAS regulations. Such minimum limits promote the safe use of substances of high concern without overly burdening the supply chain by requiring excessive and destructive testing to determine whether trace amounts of these substances are present in articles. It would also help reduce the Agency's workload by minimizing the number of reports related to parts and components that contain only negligible amounts of PFAS.

[2] https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/pfas-s71-guidance-manual.html

Clarify No Testing Required: We also ask that MPCA clarify that no testing is required as part of the reporting requirements. We would like to emphasize that there are currently no standardized testing methods to detect PFAS in complex articles. Under 7026.0030(C), the Proposed Rule allows reporting PFAS via given ranges, as "present but the amount or concentration range is unknown," or via total organic fluorine. As we write below, we recommend incorporating a "known or reasonably ascertainable" standard for reporting. With a "known or reasonably ascertainable" standard, 7026.0030 suggests that testing is not required. The Agency should make this clear in the Proposed Rule. Not requiring reporting would be consistent with EPA's TSCA Reporting and Recordkeeping Requirements for PFAS.[3]

7026.0040 Reporting Updates

7026.0040(2) requires annual recertification for manufacturers not required to update under 7026.0040(1). This is an unreasonable requirement and is not suitably justified by the Agency. Recertification every five years would be preferable. The Agency should also clarify what information is required for any recertification.

7026.0060 Extensions

Electronic devices are manufactured through a complex global supply chain, and companies require sufficient lead time to implement any notification requirements. A single electronic product can have thousands of components which are sourced from multiple suppliers from which manufacturers will need to facilitate information requests, create databases to generate necessary reports, validate and clarify any information received, and then link all received information to products sold. Given these factors, it is likely that electronics manufacturers will submit extension requests. However, a 90-day extension is not sufficient for this process. We believe that the commissioner should be able to grant 180-day or 1-year extension requests. The commissioner's extensions should also be renewable if the commissioner deems renewal justified.[4]

7026.0070 Trade Secret Data Request

Subpart 2 of 7026.0070 explains that if a chemical identity is claimed as a trade secret, manufacturers must submit a chemical subclass to designate as public data. However, the Proposed Rule or the SONAR do not offer any guidance on how manufacturers must select this chemical subclass. MPCA should indicate in the Proposed Rule that this process be conducted in line with EPA guidance on creating generic chemical names under TSCA.[5] Alignment with EPA allows for regulatory certainty, ease of compliance for industry, and does not require MPCA to develop its own guidance.

7026.0080 Due Diligence

Reporting requirements should be based on a "reasonably ascertainable" information standard. Due to the complexity of the supply chain for the electronics sector, the data standard outlined in the Proposed Rule is incredibly high and difficult to meet. We recommend that the Agency adopt

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[3] https://www.govinfo.gov/content/pkg/FR-2023-10-11/pdf/2023-22094.pdf page 70522 "this rule is not a product testing requirement…" and page 70535 "In other words, this reporting standard is not a testing requirement…"

[4] https://www.epa.gov/chemicals-under-tsca/epa-extends-reporting-period-pfas-manufacturers

[5] https://www.epa.gov/tsca-inventory/guidance-creating-generic-names-confidential-chemical-substance-identity-reporting

the approach used by US EPA for its quadrennial Chemical Data Reporting rule[6] as well as the standard EPA is using for its own PFAS Reporting and Recordkeeping Rule under TSCA.[7] This standard is more practical, feasible, and consistent with other reporting requirements for manufacturers. The requirement to submit data "known to or reasonably ascertainable by" a manufacturer is also the standard set by the Maine PFAS in Products law.[8]

7026.0100 Fees

We respectfully ask that the Proposed Rule establish more clarity around the reporting fees. The Proposed Rule outlines that manufacturers or groups of manufacturers may submit reports, and a report must be submitted for each product or component that contains intentionally added PFAS. This could result in a number of report combinations or arrangements, and the Agency should create clear guidance with examples on how fees would be assessed. With that said, we request that fees be based on a per manufacturer basis.

Additional Guidance

The reporting timeline in the Proposed Rule is coming up quickly and manufacturers still do not have much practical guidance on how to report data to the Agency. We ask that MPCA provide detailed guidance documents, examples, templates, in-scope CASRNs, and other information to assist manufacturers with their reporting. The sooner this information is available, the better, since companies need significant time to plan their reports. Additionally, we encourage the Agency to harmonize the reporting process wherever possible with other jurisdictions. The Agency should particularly consider the procedures required by U.S. EPA, Canada, and Maine which have disclosure requirements on products containing intentionally-added PFAS.

Conclusion

Thank you again for the opportunity to provide these comments on the Proposed Rule. If you have any questions about our comments, please do not hesitate to reach out to me at dmoyer@cta.tech.

Sincerely,
Dan Moyer
Sr. Manager, Environmental Law & Policy
Consumer Technology Association

[6] Federal definition of "known to or reasonably ascertainable by" https://www.law.cornell.edu/cfr/text/40/704.3
[7] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-8a7-reporting-and-recordkeeping
[8] https://www.maine.gov/dep/spills/topics/pfas/PFAS-products/

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FREUDENBERG-NOK

May 21, 2025

Statement on Minnesota's Proposed Reporting Rule Regarding Products Containing Per- and Polyfluoroalkyl Substances (PFAS)

Content

1. Introduction

Freudenberg Sealing Technologies (FST) is a leading supplier of advanced sealing products for customers in the automotive and general industry. In researching, developing, and introducing innovative products and process solutions, the company benefits from more than 170 years of engineering and materials experience. The focus has always been on the technological demands and requirements of our customers.

With the world's largest range of seals, FST offers sealing products for everything from dental drills and filling lines to wind turbines, aircraft, and automotive transmissions. Seals are often small components, usually invisible but essential for the smooth functioning and long service life of the system in which they are installed. In all application areas and industries, the company's unique material expertise and continuous innovation create the basis for continued customer satisfaction. The company operates at 60 locations worldwide with approximately 15,000 employees. Sales in 2022 amounted to $2.756 million. In the state of Minnesota alone, FST develops, stocks, and supports our customers with over 42,000 fluoropolymer-containing seals to meet the performance demands of our local customer base at our facility in Shakopee, MN which employs over 40 associates.

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FST fully supports the goals of the Minnesota Pollution Control Agency (MPCA) to improve protection of human health and the environment from risks posed by chemicals. Preventative health care, environmental protection, occupational safety, the safety of machines, production lines and processes, and product safety as well as good corporate citizenship are of great importance at FST.

FST aims to continuously reduce its environmental impact throughout the entire value chain to the extent feasible and commensurate with risk. While developing new products and technologies, safe and environmentally sound manufacturing, utilization, and disposal practices are adopted. In addition to this, FST is constantly focusing its efforts on reducing environmental impact by using natural resources more efficiently, lowering emissions, saving energy, water, and other operating materials, as well as optimizing transportation processes. Waste is handled in accordance with the principle that prevention is better than recycling, which in turn is better than disposal. Residual substances that can neither be avoided nor recycled are disposed of in a responsible manner and in accordance with applicable laws and regulations. FST's management systems comply with internationally recognized standards such as the environmental protection standard ISO 14001 and the EU Eco-management guidelines.

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2. Commentary

a. Provide an exemption for fluoropolymers in the reporting rule and at the very least in the MPCA's upcoming currently unavoidable use rule.

As outlined in this statement and in figure 1 below, fluoropolymers, especially the fluorinated elastomers FKM and FFKM, the fluorinated silicones FVMQ as well as polytetrafluoroethylene (PTFE) have unique properties as base materials for gaskets and seals, most importantly high temperature stability and media resistance (e.g. against fuels, acids, bases, high performance lubricants such as motor and gear box oils, hydraulic fluids), excellent wear resistance and low friction properties, corrosion resistance and permeation tightness.

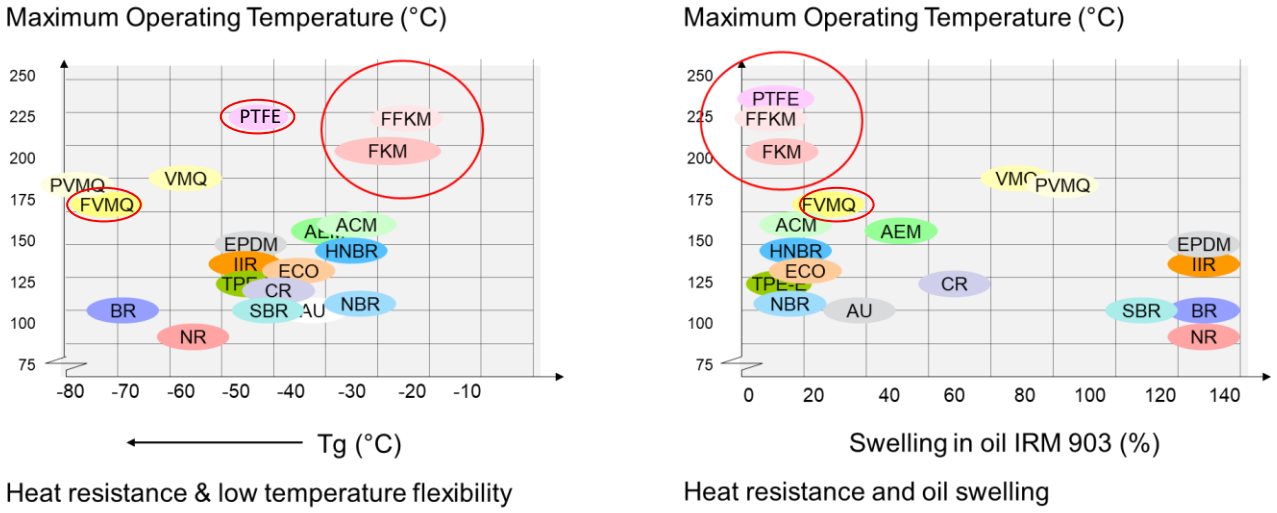

Figure 1: *Classification of elastomer materials according to ASTM D2000 / SAE J200*

Due to their unique property profile, fluoroelastomers and PTFE are used in high-performance sealing materials in wide-spread applications from transportation, general industry, process industry, food and beverage, as well as in advanced technologies like fuel cells or batteries. Replacing fluoroelastomers or PTFE in sealing applications with other polymer classes always comes with a considerable loss of performance resulting in reduced lifetime of the respective component or system. This loss of functionality leads to premature failure of the seal, which

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can cause leakage, leading to emissions of the respective fluids to the environment and associated safety issues and result in major damage or complete destruction of the entire system (e.g., damage to a valve, engine, gearbox, hydraulic system).

Seals used in dynamic applications which avoid the use of fluoroelastomers and PTFE are subject to premature wear due to higher abrasion and cause increased fuel/energy consumption due to increased friction.

To avoid unexpected leakage and major damages, seals made from polymers other than fluoroelastomers or PTFE would have to be replaced frequently and preventively, necessitating costly down times and expensive maintenance intervals. In many applications a premature and unplanned replacement of a seal is not possible at all (e.g., in offshore wind turbines or ship engines).

It is important to note that fluoroelastomers and PTFE-based materials are expensive and show a significant price gap to other classes of elastomers. These two materials are therefore primarily used when no other polymer class provides the necessary performance and customer specifications cannot be met with other materials.

The majority of fluoropolymers also meet the criteria to be designated as “polymers of low concern” by the OECD (Organization for Economic Co-operation and Development). Environment and Climate Change Canada has also recognized the inherent differences between fluoropolymers and other types of PFAS by excluding fluoropolymers from the agency’s proposed Risk Management Approach for PFAS.[1] This exclusion was based on Environment and Climate Change Canada’s State of PFAS Report which found that “there is evidence to suggest that fluoropolymers may have significantly different exposure and hazard profiles when compared with other PFAS in the class.”[2] Other regulators are also starting to

[1] Environment and Climate Change Canada, Risk management approach for PFAS, excluding fluoropolymers (Mar. 2025), https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/risk-management-approach-per-polyfluoroalkyl-substances.html.

[2] Environment and Climate Change Canada, State of PFAS report (Mar. 2025), https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/state-per-polyfluoroalkyl-substances-report.html.

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acknowledge the low-risk properties of fluoropolymers, including in New Mexico where a new state PFAS in products law contains an exclusion for fluoropolymers.[3]

Fluoropolymers should be exempt from the MPCA's reporting rule and at the very least from the upcoming 2032 ban as a currently unavoidable use of PFAS since there are no equivalent performing materials and such long chain, large molecules do not pose meaningful environmental and health risks. Excluding only certain applications of fluoropolymers would not reflect reality as all applications which require fluoropolymers in gaskets and seals are using these substances due to an inability to substitute with another material of similar or equivalent performance.

b. The Reporting Rule should incorporate the federal "known to or reasonably ascertainable by" (KRA) reporting standard.

FST has over 100,000 unique products which are available to our local customer base and distributed by our facility in Shakopee, Minnesota, of which over 42,000 are fluoropolymer containing. Many of the articles which FST provides are manufactured by third parties in which the fluoropolymer content is unknown, a trade secret, and/or difficult to obtain from a complex supply chain. FST recommends that the MPCA changes the language and requirements in its reporting proposal regarding due diligence so that Minnesota's standard is consistent with standards used in PFAS reporting programs in other jurisdictions. The MPCA proposal states that "manufacturers must request detailed disclosure of [reportable information] from their supply chain until all required information is known." This due diligence standard is unrealistic, especially for a company such as FST that is supported by a complex, global supply chain.

Instead, the MPCA should employ the KRA due diligence standard used by the U.S. Environmental Protection Agency (EPA) for the Toxic Substances Control Act Section 8(a)(7) PFAS reporting rule.[4] Use of the KRA standard in the MPCA's rule will help "ensure that due diligence efforts are reasonable and feasible for manufacturers," as the MPCA mentioned in a

[3] New Mexico House Bill 212.
[4] 40 C.F.R. Part 705.

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Q&A on this rulemaking from last year.[5] Moreover, use of the KRA standard will help harmonize the MPCA's rule with not just EPA's rule, but also with PFAS reporting programs in other jurisdictions that employ a similar reporting standard, including Environment and Climate Change Canada's PFAS reporting requirements[6] and Maine's PFAS in products law.[7]

c. Clarify the testing provision of the law to help ensure companies can comply with MPCA requests for test results.

Subdivision 4 of Minn. St. § 116.943 gives the MPCA the authority to require manufacturers to provide test results to the agency within 30 days if the MPCA has reason to believe a product in the state contains intentionally added PFAS. The equipment and instrumentation required to test for PFAS content is very sophisticated, expensive, and is often outside the capability of most analytical laboratories. PFAS is also ubiquitous and often detected at very low levels as a background contaminant. For these reasons, FST recommends that in the event of suspected intentionally added PFAS, that the company in question be allowed to demonstrate compliance with the testing provision of subdivision 4 of the statute with evidence such as statements from suppliers and/or compositional information from safety data sheets (SDS). Also, FST recommends that the required time to reply to a testing demand be extended from 30 to 90 days. In the event that testing is required, it is not uncommon for test facilities to have backlogs which can sometimes delay testing for weeks or months. Setting the response deadline to 90 days will also allow time for the company to obtain necessary materials, data from the supply chain, as well as any other pertinent information.

d. Remove the requirement that manufacturers submit an annual recertification, or at least remove the requirement to pay a fee for this annual recertification.

We understand that MPCA is proposing a $1000 flat fee per manufacturer for submission of the initial report. FST supports a flat fee model as opposed to a fee based on individual product submissions.

[5] MPCA, Progress on PFAS Rule Development Webinar: Questions and Answers (Sept. 2024), https://www.pca.state.mn.us/sites/default/files/c-pfas-rule1-00.pdf.
[6] Canada Gazette, Part I, Volume 158, Number 30: Supplement, Notice with respect to certain per- and polyfluoroalkyl substances *July 27, 2024).
[7] 38 M.R.S. § 1614.

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The MPCA is also proposing that, by February 1 of each year, manufacturers must submit an annual update for certain changes to reported information or an annual recertification if there are no such changes. Manufacturers would also be required to pay a $500 flat fee for this annual update or recertification. FST is consistently updating its product portfolio to reflect the needs of its customers and this type of annual reporting requirement would require a significant amount of operational resources, especially for the annual recertification since in this situation there would be no changes to the previously reported information warranting an update. We therefore recommend that the requirement to submit an annual recertification be removed from the proposed reporting rule, or at the very least the requirement to pay a fee for this annual recertification should be removed.

e. Delay the reporting deadline by at least one year.

As the MPCA has not designated the format, required information, and a final methodology for submission, it is unreasonable to expect manufacturers to report by the current January 1, 2026 reporting deadline. FST therefore recommends that the MPCA delay the reporting deadline by at least a year from when the reporting rule is finalized.

Thank you for your attention to this communication.

Sincerely,

Ryan Fleming
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Product Stewardship
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Robert Martell
Vice President – Global Sourcing

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May 21, 2025

The Honorable James Mortenson
Minnesota Office of Administrative Hearings (OAH)
600 North Robert Street
PO Box 64620
St. Paul, Minnesota 55164

Submitted via rulemaking portal

Re: Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees

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Dear Judge Mortenson,

These comments are submitted by the Air-Conditioning, Heating, and Refrigeration Institute (AHRI) regarding the Minnesota Pollution Control Agency's (MPCA) *Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees*, as required by Minn. Stat. § 116.943 ("Amara's Law").

AHRI represents more than 330 manufacturers of heating, ventilation, air conditioning, refrigeration (HVACR) and water heating equipment. It is an internationally recognized advocate for the HVACR and water heating industry and certifies the performance of many of the products manufactured by its members. In North America, the annual economic activity resulting from the HVACR and water heating industry is more than $211 billion. In the United States alone, AHRI member companies, along with distributors, contractors, and technicians employ more than 700,000 people.

HVACR and water heating equipment provide essential services to society by providing life-saving climate control and ventilation in most buildings, notably homes, hospitals, schools, and elder care facilities. The cold chains for both food and medicines depend on transportation and storage provided by transport and commercial refrigeration equipment manufactured by our members.

AHRI supports the intent of Amara's Law and acknowledges that the reporting timelines and certain definitions are set in statute but urges MPCA to recognize that six months is not enough time to have reporting requirements that are more stringent than parallel federal regulations. This rule will require laboratory testing of thousands of components within complex products, if complex equipment manufacturers cannot receive all required information from their suppliers. Merely identifying the use of chemicals in complex, multinational supply chains is an exceptionally challenging and often unsuccessful task for manufacturers of complex systems, due to the general lack of transparency around component composition and the number of chemicals (approximately 9,000) included in the broad definition of PFAS the State of Minnesota uses. This is exacerbated by confidentiality claims from component manufacturers

and suppliers and the extremely short timeline of the proposed regulations from publication to implementation.

AHRI requests MPCA review the statutory authority and reasonableness of fees for reporting

Statutory Authority

AHRI has concerns with MPCA's proposal to implement a flat fee structure for all filings by manufacturers, to include initial filing, update, waivers, and extension requests. Under Minnesota Statute 116.943, subdivision 6, the law provides for the agency to adopt a fee structure for manufacturers to pay when submitting the data that is required and enumerated under the law.

> *Subdivision 6. Fees. The commissioner may establish by rule a fee payable by a manufacturer to the commissioner upon submission of the information required under subdivision 2*[1] *to cover the agency's reasonable costs to implement this section. Fees collected under this subdivision must be deposited in an account in the environmental fund.*[2]

However, it is unclear from the statute whether the agency has authority to assess fees to manufacturers for submission of filings that do not appear to include the data listed under subdivision 2. As noted above, the statute refers to the commissioner having the ability to establish rules for fees for the *submission of the information required under subdivision 2*. The provisions under subdivision 3 of the statute dictate the waiver and extension requests. However, subdivision 3 does not appear to *require* the submission of the data that is listed in subdivision 2. Additionally, it appears that all of the listed information is not required in the proposed rule for

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[1] Subd. 2. Information required.
(a) On or before January 1, 2026, a manufacturer of a product sold, offered for sale, or distributed in the state that contains intentionally added PFAS must submit to the commissioner information that includes:
(1) a brief description of the product, including a universal product code (UPC), stock keeping unit (SKU), or other numeric code assigned to the product;
(2) the purpose for which PFAS are used in the product, including in any product components;
(3) the amount of each PFAS, identified by its chemical abstracts service registry number, in the product, reported as an exact quantity determined using commercially available analytical methods or as falling within a range approved for reporting purposes by the commissioner;
(4) the name and address of the manufacturer and the name, address, and phone number of a contact person for the manufacturer; and
(5) any additional information requested by the commissioner as necessary to implement the requirements of this section.
(b) With the approval of the commissioner, a manufacturer may supply the information required in paragraph (a) for a category or type of product rather than for each individual product.
(c) A manufacturer must submit the information required under this subdivision whenever a new product that contains intentionally added PFAS is sold, offered for sale, or distributed in the state and update and revise the information whenever there is significant change in the information or when requested to do so by the commissioner.
(d) A person may not sell, offer for sale, or distribute for sale in the state a product containing intentionally added PFAS if the manufacturer has failed to provide the information required under this subdivision and the person has received notification under subdivision 4. *116.943 PRODUCTS CONTAINING PFAS. Subdivision 2.*
[2] 116.943 PRODUCTS CONTAINING PFAS. Subdivision 6.

waivers and extension requests; and therefore, AHRI requests that MPCA reconsider the fees noted in the proposed rule.

AHRI acknowledges that there is a catch-all provision in the law that allows for the commissioner to take any action that it deems necessary to carry out the law.[3] However, the law specifically provides a provision for the collection of fees by the commissioner and as noted above, the provision only pertains to submissions with the information listed in subdivision 2.

AHRI respectfully requests the agency reconsider the fees noted in the proposed rule, particularly for waiver and extension requests.

Reasonableness

AHRI requests that the agency reconsider the reasonableness and fairness of the fees proposed in the rule.

The Minnesota Administrative Procedures Act (APA) requires that an agency prepare a statement of need and reasonableness (SONAR) for proposed rules that demonstrate evidence and arguments that the agency plans to use to support the proposed rules.[4] The SONAR must assess the cost justification, describe alternative methods for achieving the purposes of the rule, and assess the probable costs of compliance with the proposed rule.[5]

The SONAR does not contain sufficient cost data to demonstrate how the MPCA made determination regarding costs, as it relates to the waiver requests and extension requests proposed by the rule. A mere assertion that the proposed fees are reasonable is not enough to meet the burden under Minnesota statute.[6]

The Minnesota APA requires agencies to consider the reasonableness and fairness of the regulatory burden imposed.[7] Manufacturers may face undue burdens in terms of allocation of resources needed to comply with the Minnesota PFAS reporting requirements as they will need to expend resources to gather information from their supply chains that they otherwise do not have access to or be required to test products.

AHRI recommends for the agency to reconsider the reasonableness of the proposed fees and provide a supplement to the SONAR with additional cost justifications.

AHRI urges Minnesota to focus its efforts on the regulation of persistent, bioaccumulative, and toxic (PBT) chemicals in high-exposure products.

Minnesota's broad definition of PFAS includes approximately 9,000 known chemicals. Although the focus of Minnesota's legislation is PBT PFAS chemicals that pose a risk to human health and

[3] Minn. Stat. §§ 116.943 Subdivision 9.
[4] Minn. Stat. §§ 14.131 and 14.23.
[5] *Id,*
[6] *Id.*
[7] *Id*.

the environment, Minnesota's definition of PFAS includes many chemicals that do not all share these three critical properties. For example, most low global warming refrigerants (A2Ls) used in HVACR and water heating systems are proven to have low levels of toxicity.[8] The U.S. Environmental Protection Agency (EPA) Significant New Alternatives Policy (SNAP) criteria for evaluating alternatives for acceptable use conditions includes assessments of the potential exposure risks, toxicity and environmental impact of the refrigerant.[9] The EPA SNAP approval process has determined that the chemical makeup of A2L refrigerants presents minimal risk to humans and the environment. Moreover, HVACR and water heating products are hermetically sealed and tend to have a useful life over 15 years, which means Minnesotan consumers will rarely – if ever – come into contact with refrigerants or fluoropolymers present in HVACR and water heating equipment. Additionally, certain polymers that meet Minnesota's definition of PFAS (i.e., fluoropolymers such as polytetrafluoroethylene (PTFE)) are used in a wide variety of consumer products with unlikely potential for human or environmental release or exposure during use of the product and are predominantly not water soluble, therefore, presenting minimal risk associated with the actual product itself.

AHRI is concerned that Minnesota is at risk of being overwhelmed by incomplete datasets for the millions of unique products and components in the scope of this rule. AHRI's Directory of Certified Product Performance[10] alone lists over 4 million unique products with over 9 million new products sold and installed annually in homes and businesses. AHRI members must parse through tens of thousands of stock-keeping units (SKUs), each having hundreds of associated components and spare parts, to better understand whether their products will be affected by this proposed regulation. This introduces hundreds of millions of potential chances for any given product or component to contain one of the thousands of PFAS included in Minnesota's PFAS definition.

Reporting requirements are overly stringent and unattainable in the given timeframe

AHRI requests MPCA move to a risk-based, reasonably ascertainable reporting framework

AHRI reiterates that January 1, 2026, is not a feasible deadline for the intensity of the reporting program proposed by MPCA. MPCA is an outlier in the intensity of its reporting requirements. MPCA proposes that manufacturers' due diligence consists of manufacturers requesting detailed disclosure information from their supply chain "until all information is known."[11] The reporting standard that EPA specifies in its Toxic Substances Control Act (TSCA) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances Regulation under TSCA section 8(a)7, requires manufacturers to report "information known to or reasonably ascertainable by the manufacturer." This standard is also used in other TSCA section 8 rules, including the TSCA section 8(a) Chemical Data Reporting (CDR) rule.[12] While manufacturers

[8] ANSI/ASHRAE Standard 34-2022
[9] EPA Significant New Alternatives Policy- Criteria for Evaluating Alternatives, https://www.epa.gov/snap/about-snap-review#criteria. (Last accessed on January 28, 2025).
[10] AHRI's Directory of Certified Product Performance, https://www.ahridirectory.org/. (Last accessed on January 27, 2025).
[11] *Proposed Permanent Rules Relating to PFAS in Products; Reporting and Fees*; Minnesota Pollution Control Agency. Published April 21, 2025
[12] 40 CFR 711.15

prepare to report the required PFAS information to meet the federal EPA TSCA obligations by January 11, 2026, more stringent state-level reporting standards create burdensome requirements for manufacturers to achieve in parallel.

AHRI asks that the MPCA change this proposed rule to allow manufacturers to submit PFAS information for their products that is known or reasonably ascertainable. AHRI questions if there is sufficient laboratory capacity to handle the testing requirements proposed by MPCA to allow manufacturers to comply by January 1, 2026. AHRI also requests that the function of the PFAS is removed from the reporting requirements to be consistent with other federal and state requirements. The function of the PFAS is potentially proprietary and requesting this information could lead to additional hurdles acquiring the information. In addition, if samples are tested and PFAS chemicals are identified, it may not be possible to know the function of the PFAS.

Finally, AHRI requests a defined reporting pathway. This could be achieved through the development of an online reporting platform or the provision of a standardized template, ensuring all stakeholders have a clear and efficient means of compliance.

Those manufacturers that cannot produce all the required information to report to MPCA – by surveying their supply chain and/or testing all components within their products to identify which of the 9,000+ compounds that meet MPCA's definition of PFAS are present in their products and equipment – will be prohibited from selling into Minnesota.

AHRI requests MPCA identify the PFAS compounds by Chemical Abstract Services Registry Number (CASRN) to facilitate reporting compliance

AHRI acknowledges the complexity of defining PFAS compounds, but highlights that Minnesota elected to use the broadest definition, encompassing over 9,000+ potential compounds. AHRI requests that the MPCA release a list of the compounds that meet the MPCA's interpretation of PFAS to facilitate the supply chain surveys undertaken by manufacturers. For example, Environment and Climate Change Canada (ECCC) provided a list of chemicals by CASRN that met their definition of PFAS to be included in Canada's PFAS reporting program.

AHRI raises concerns with reporting on behalf of other manufacturers

AHRI is concerned that the group reporting option will not enable streamlined reporting provisions as intended. As the due diligence provisions do not allow for reasonably ascertainable information to be reported to MPCA, manufacturers will not be able to provide the information required for a single manufacturer, let alone an industry coalition.

The proposed rule's vagueness creates uncertainty regarding required agreements with suppliers, which entity is obligated to report for replacement parts and components, and which entity retains the liability for reporting along the supply chain. AHRI requests specific guidance on necessary documentation and reporting responsibilities and obligations in these scenarios to ensure effective compliance.

AHRI Requests MPCA align with other states

AHRI requests that the MPCA align its reporting requirements with those of other states. For example, Maine delayed the reporting and phaseout requirements for SNAP-approved refrigerants and HVACR equipment until 2040. In addition, New Mexico's 2025 PFAS law wholly exempted SNAP-approved refrigerants and HVACR equipment. These exemptions demonstrate that PFAS in this equipment presents minimal risk and highlights the essential functions that HVACR and water heating equipment play in modern society.

Products or components containing *de minimis* levels and for Research and Development should be exempt from the regulation.

PFAS in electrical and other components are difficult for manufacturers to track. Manufacturers of HVACR and water heating equipment have limited visibility and control over complex, multi-tiered, global electronics supply chains. Manufacturers of HVACR and water heating equipment must rely on the accuracy of reporting from every supplier throughout their entire supply chain on trace amounts of a chemical, even those that are present unintentionally. AHRI notes there are common components in use by the HVACR and water heating industries that could be manufactured at the same facilities producing components for industries that may contain PFAS, according to the proposed rule. This could result in unintentional cross-contamination and the continued presence of *de minimis* quantities of PFAS in components used in HVACR and water heating equipment. AHRI continues to urge MPCA to exempt articles that contain only *de minimis* quantities of PBT or non-PBT PFAS of 0.1% by weight or less, which will allow for a practicable regulation that is reasonably implementable. Not having a *de minimis* exemption puts an unreasonable burden on manufacturers, and therefore, MPCA should provide permanent regulatory relief.

AHRI also asks that MPCA exempt products intended for research and development from the reporting and fees requirements. EPA provides exemptions for research and development in both SNAP and TSCA. Under this proposed rule, a manufacturer would have to report and pay fees to the state for prototype systems and components that may not enter Minnesota's stream of commerce as a commercial product.

Reporting exemptions for products for which federal law governs the presence of PFAS

AHRI requests further clarification regarding the scope of reporting exemptions, particularly in relation to products already subject to federal regulations. Specifically, AHRI seeks clarity on whether the proposed rule intends to include refrigerants managed under the Environmental Protection Agency's Significant New Alternatives Policy (SNAP) program within its reporting requirements for intentionally added PFAS.

The EPA SNAP program already evaluates and lists acceptable substitutes for refrigerants, taking into account environmental and health considerations.

To avoid duplicative reporting burdens and potential inconsistencies, AHRI respectfully requests that the MPCA clarify how the state's PFAS reporting requirements will interact with the federal oversight provided by the SNAP program. Specifically, AHRI asks MPCA to consider whether refrigerants approved under the EPA SNAP program will be subject to the full reporting requirements of this rule.

AHRI requests increases to extension and denial periods

AHRI notes that the "Authority" clause within the proposed rule lacks sufficient specificity, particularly regarding the process and timelines for manufacturers to request extensions for reporting requirements. Additionally, AHRI requests that the period granted for extensions be increased from 3 months (90 days) to 9 months and the waiver denial period be increased from 30 days to 180 days. This timeline for extensions and waiver denials will align MPCA with ECCC's PFAS reporting requirements.

AHRI asks that the MPCA eliminate the extension request fee. MPCA does not have a final reporting rule for a reporting deadline that is a mere 6 months away. This short timeline and the high standards for reporting will force many manufacturers to request extensions to no fault of their own.

Definitions

Definitional clarity is required for several term and phrases in MPCA's proposed rule.

AHRI notes that the MPCA has not defined what constitutes "intentionally added" and requests that the rule be amended to clarify the definition of this phrase.

AHRI requests clarity on the term "packaging" within the definition of "component." As written, it would appear that a packaging of a product, though not intended to be the sale product, would be included in this rule.

In this proposed rule, the term "Manufacturer" includes the entity that manufactures a product or whose brand name is legally affixed to the product. However, there are numerous circumstances when two different entities meet that definition: one may manufacture the product and the other may legally affix their name to the product. In such circumstances, it is not clear who the "manufacturer" is, and therefore, which entity has the obligation to fulfill MPCA's reporting requirement.

Conclusion

AHRI thanks MPCA for the opportunity to provide feedback on this rule. AHRI maintains that there is minimal opportunity for exposure to the chemicals used in HVACR and water heating equipment. HVACR and water heating equipment are maintained and serviced by qualified professionals and the chemicals used in HVACR and water heating equipment and components are not generally accessed by the public. The requirements within this proposed rule would be

impossible or nearly impossible for manufacturers of HVACR and water heating equipment with which to comply.

We look forward to discussing this important matter with you at your earliest convenience.

Sincerely,

Hayley Davis
Manager, State Government Affairs

RECEIVED
By: OAH on 5/21/2025

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t. 212.675.1141 • e. info@toyassociation.org

May 21, 2025

Ms. Katrina Kessler, P.E.
Commissioner
Minnesota Pollution Control Agency
Submitted Electronically

RE: MPCA Draft Rule – PFAS and Fee Rules

Dear Commissioner Kessler,

Thank you for the opportunity to submit comments regarding the draft Proposed Rules for New Chapter 7026; Revisor ID R-4828, relating to PFAS in Products; Reporting and Fees by the Minnesota Pollution Control Agency (MPCA). These comments are provided on behalf of The Toy Association and its 900+ members, representing manufacturers, importers, designers, retailers, inventors, and toy safety testing labs, all working to ensure safe and fun play for children and families in Minnesota and across the country and world.

Toy safety is the number one priority for the toy industry. The Toy Association and its members have been global leaders in advancing toy safety, both physical and chemical, for over nine (9) decades. The industry is well aware of the concerns re: the use of PFAS in manufacturing products and many companies are voluntarily phasing out PFAS usage in all aspects of their product line. Unfortunately, the MPCA rules, as currently drafted, set unreasonable, accelerated timelines and reporting requirements that will make it nearly impossible for toy manufacturers to comply.

While the MPCA notes in the *Statement of Need and Reasonableness* (SONAR) dated April 2025 that the proposed rule is "expected to clarify some of the definitions"[1], there remain many unanswered questions surrounding the definitions and unfortunately some of the new rule language has created additional questions and some confusion among manufacturers. As detailed below in our comments, the accelerated and unreasonable timeframe for compliance, high administrative costs, and the breadth of covered products represent our top concerns with the proposed Rules, as currently drafted.

1. **Timeframe: The current highly accelerated and unreasonable reporting and compliance timeframes and deadlines do not provide sufficient time for manufacturer preparedness, which unavoidably lead to involuntary non-compliance, despite best efforts.**

   First, there are serious concerns with the timing requirements set forth in the proposed rules. The proposed, accelerated timeframe (first reporting due in six months (6), i.e., Jan

[1] MPCA Statement in Need of Reasonableness: In the Matter of Proposed Minnesota Rules New Chapter 7026; Revisor ID No. RD-4828 April 2025 Page 10

1, 2026, and annually thereafter) is unrealistic and unachievable, especially given that the necessary framework and required details are not in place as of today. Typical state reporting requirements recognize the need to allow manufacturers ample time to staff up and familiarize themselves with new regulations and rules.

The level of investigation and preparation required for companies to be able to prepare for upcoming compliance with the proposed rule presents a significant, overly onerous administrative burden on affected companies, across the toy industry, other industries, and complex supply chains, even without considering the aspects that are as-yet undefined, ambiguous or unclear.

Without an extended and realistic period for manufacturer preparation, beginning *after* the implementation date of the rule, it will not be possible for companies with even the simplest product ranges or supply chains to complete the necessary investigations in time, effectively causing unavoidable non-compliance.

The proposed rule's shared responsibility structure (§7026.0020) is novel and does not have an equivalent or comparable requirement in any other state or federal regulation. This model will require time both for the identification and determination of other potential reporting entities, and for the negotiation for assumption of responsibility for each product report. Both elements, even when there is a clear picture of the respective applications, will take more time for assessment, determination and outreach *for just one product, never mind for* the entire reporting structure (which is then repeated annually thereafter). For entities with multiple product ranges and/or supply chains, this becomes exponentially more complicated and unachievable.

The proposed rule states that coverage applies to "…product sold, offered for sale, or distributed in the state…" (§ 7026.0020). This does not consider that manufacturers may, and do in most cases, offer a product for sale in a different timeframe from when it may eventually be sold or distributed in the state by retailers or other entities – and manufacturers do not have any means of determining movements in the supply chain subsequent to the original direct sale or procurement into the U.S. market as a whole. Unless the manufacturer is the entity selling directly to consumers, retailers and third-party agents are the business entities that determine whether and when products are sold in which U.S. state.

Further, the SONAR's assumption that the proposed deadline for implementation, January 1, 2026, is 'reasonable'[2] because it is the date listed in statute does not consider, as mentioned above, the real-world application of compiling needed data in a global supply chain. At the same time, MPCA assumes that there will be a "potential large amount of extension requests"[3], which is likely an acknowledgement of the unworkable timeframe.

Request:

- **Once the reporting framework has been developed and proven, we request a more realistic and representative implementation timeline for reporting and compliance be implemented to ensure sufficient time for company preparedness and to reduce unnecessary administrative burdens.**

[2] MPCA Statement in Need of Reasonableness: In the Matter of Proposed Minnesota Rules New Chapter 7026; Revisor ID No. RD-4828 April 2025 Page 28
[3] MPCA Statement in Need of Reasonableness: In the Matter of Proposed Minnesota Rules New Chapter 7026; Revisor ID No. RD-4828 April 2025 Page 28

2. **Covered products and components: The rule does not adequately define 'PFAS' nor 'intentionally added PFAS' nor does it establish de minimis levels acceptable in manufacturing, failing to take into account the complexity of sourcing and supply chains**

   The proposed rule is unnecessarily broad and onerous as it provides no definition for what is considered to be 'PFAS" nor what constitutes 'intentionally added PFAS'..

   While the definition for 'function' (§ 7026.0010) indirectly addresses 'intentional' by referring to a PFAS that is "…intentionally incorporated at any stage *in the process* of preparing a product or its constituent components…" (emphasis added), the sentence directs attention to the process, not the product. In reality, one or more PFAS may be incorporated (in the manufacturing process) but not be present or part of the product or component subsequently produced, but this is not taken into account in the phrasing of the proposed rule.

   The proposed rule does not provide consideration for a minimum level of reportable PFAS, especially considering that the definition of 'function' addresses potential presence of PFAS in the manufacturing process that can, and often will, have no presence or intended function in the finished product or component.

   As a real-world function of the supply chain, in many cases products contain components that are sourced from open-market providers and designed or manufactured for other markets. In these cases, downstream manufacturers have neither the visibility nor the ability to determine the data points required in the proposed rule. A common example of open-market components are (internal) electronic components that are purchased for inclusion in consumer products; the manufacturer of the final product does not have the supply chain reach to design and manufacture these components, and instead purchases the necessary components from existing (multiple) sources.

   The due diligence requirements listed in § 7026.0080 impose an unachievable requirement by stating that "A manufacturer or group of manufacturers must request detailed disclosure of information […] from their supply chain *until all required information is known*." (emphasis added). Even taking into consideration the reality that such requests take time to identify, contact and compile (beyond the timeframe currently being considered) and the associated administrative and financial burdens, as is demonstrated in this document, due to many factors it will not be possible for manufacturers to attain *all* of the required information.

   The Toy Association recommends that MPCA aligns the due diligence requirements in the proposed rule with the existing application of the 'reasonably ascertainable' definition under the Environmental Protection Agency's (EPA) Toxic Substance Control Act (TSCA) [4], which includes a due-diligence allowance framework for instances where PFAS presence or level may not be reasonable to ascertain[5].

[4] 40 CFR 704.3, TSCA Section 8(a)(2) "Known to or reasonably ascertainable by" is defined as to include "all information in a person's possession or control, plus all information that a reasonable person might be expected to possess, control or know"
[5] Federal Register Vol. 88, No. 195, p 70520 'C. What is the reporting standard of this rule?'

Request:

- **Reassess the scope and coverage in the proposed rule to provide the applicability parameters necessary for compliance consideration.**
- **Provide for a *de minimis* reporting threshold and include a definition that identifies 'intended function' as relating to the intention for presence in the finished product.**
- **Revise the proposed rule to provide achievable requirements.**

3. **Administrative Fees and Cost Structure: The per-product cost structure proposed by Minnesota is excessively high and will be crippling for business; it is certain that businesses will be unable to absorb these proposed fees or do business in Minnesota, especially for the small businesses that comprise 96% of the US toy industry; it will force companies not to sell their products in Minnesota, to avoid exorbitant fees, or it will encourage non-reporting.**

   The draft rule proposes that each product must be presented under its own report, unless it meets a very restrictive set of grouping permissions (§7026.0030). As such, the same component containing one or more 'intentionally added PFAS' for each identifiable product offering, even when the reportable component(s) may be identical in type or PFAS presence for more than one product type, will require manufacturers to meet a duplicative and excessively onerous administrative requirement (separate reports for each distinct product type) in addition to a concurrent, duplicative and onerous fiscal burden imposed for each new product type. As an example, a manufacturer with 100 separate product types would be forced to pay a fee of $100,000 (one hundred thousand dollars) for the first reporting of any new product offerings introduced per annum. Many industries, including the toy industry, are innovation-driven and a significant proportion of new product introductions occur each year as a necessary function of the market in which they operate, leading to significant new report obligations for each year. For larger companies, the number of new product types introduced each year can exceed 1,000, leading to costs of over $1,000,000 (one million dollars) each year for the fees alone, even without considering the administrative and resource burdens. Even though the proposed rule states that the annual update/re-certification fees are a flat fee of $500, this annualized cost does not take into account the logistical costs associated with managing and reviewing these requirements across even a small number of product types. Each of these considerations conflicts with MPCA's belief that "manufacturers are anticipated to bear minimal costs to comply with the reporting rule"[6]. We urge MPCA to carefully consider cost structure and reduce fees, if any, to minimal amounts.

   Additionally, the proposed rule does not consider the additional excessive and onerous cost burdens being imposed on manufacturers by (a) the fact that most PFAS do not have associated recognized test methodologies (and even where there are defined tests, these are largely associated with testing for water which is not applicable to testing of solid materials), (b) the testing timeframes and costs associated with assessing all covered products across a manufacturer's product offerings just to demonstrate compliance would render any such product economically unviable to bring to market even before the product is introduced into the market but after all of the necessary development and production costs have already been borne, and (c) testing for Total

[6] MPCA Statement in Need of Reasonableness: In the Matter of Proposed Minnesota Rules New Chapter 7026; Revisor ID No. RD-4828 April 2025 Page 42

Organic Fluorine (ToF) screen testing will introduce false positive reporting instances since the screen itself identifies the presence of an element that *might* be PFAS and would trigger reporting (plus the associated ongoing reporting burden and fees detailed later in this document) without providing a reliable or representative level of accuracy as to whether or not PFAS are actually present.

The proposed fees rule states that, even though there is a recognition that while a product or its components may relate to more than one manufacturer, reporting obligations (including associated fees) can be addressed by one entity, but then introduces a requirement that each and every entity must pay an unnecessarily onerous and burdensome fee of $1,000 per product report and this requirement applies separately for each associated manufacturer.

Request:

- **MPCA itself, in the SONAR, acknowledged that excessive fees "would deter manufacturers from reporting"[7] and we respectfully request that the fee structure be reevaluated given the information provided above.**
- **Reporting fees should be reduced to bare minimal levels, on a per product basis, not a function of how many companies in the manufacturing stream may be associated with that product.**
- **Provide for a volume discount structure for businesses reporting multiple products**

Conclusion

Thank you for the opportunity to submit comments on this important MCPA rulemaking. The Toy Association is committed to open and constructive dialogue regarding PFAS policy and we look forward to continuing and productive work with MPCA on this issue. If you have any questions, please do not hesitate to contact me.

Sincerely,

Jos Huxley
Senior Vice President of Technical Affairs
The Toy Association
jhuxley@toyassociation.org

CC: Charlotte B. Hickcox, Director, State Government Affairs, The Toy Association

[7] MPCA Statement in Need of Reasonableness: In the Matter of Proposed Minnesota Rules New Chapter 7026; Revisor ID No. RD-4828 April 2025 Page 40

About The Toy Association and the toy industry:

The Toy Association is the North America-based trade association; our membership includes more than 900 businesses, from inventors and designers of toys to toy manufacturers and importers, retailers and safety testing labs, and all members are involved in bringing safe & fun toys and games to children. The toy sector is a global industry of more than US $90 billion worldwide annually, and our members account for more than half of this amount.

Toy safety is the top priority for The Toy Association and its members. Since the 1930s, we have served as leaders in global toy safety efforts; in the 1970s we helped to create the first comprehensive toy safety standard, which was later adopted under the auspices of ASTM International as ASTM F963. The ASTM F963 Toy Safety Standard has been recognized in the United States and internationally as an effective safety standard that has been adopted as a mandatory toy safety standard for all toys sold in the U.S. under the Consumer Product Safety Improvement Act (CPSIA) in 2008. It also serves as a model for other countries looking to protect the health and safety of their citizens with protective standards for children. The 2023 revision to ASTM F963 was accepted by the Commission and came into force in April 2024. The Toy Association continues to work with medical experts, government, consumers and industry to provide technical input to ensure that toy safety standards keep pace with innovation and potential emerging issues.

The Toy Association is committed to working with legislators and regulators around the world to reduce barriers to trade and to achieve the international alignment and harmonization of risk-based standards that will provide a high level of confidence that toys from any source can be trusted as safe for use by children. Standards alignment assures open markets between nations to maximize product availability and choice.

RECEIVED
By: OAH on 5/21/2025
Ben Wagner Attachment

MedicalAlley

May 21, 2025

Minnesota Pollution Control Agency
520 Lafayette Road
St. Paul, MN 55155

RE: Response to Request for Comments Related to Proposed New Rules Governing Reporting and Fees by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS), Revisor's ID Number R-4828

To Whom It May Concern,

Medical Alley represents a global network of more than 800 leading health technology and care organizations including representation from all corners of the state of Minnesota. Our mission is to activate and amplify healthcare transformation.

On behalf of our partners, we respectfully submit these comments in response to the Minnesota Pollution Control Agency's (MPCA) Request for Comment on the Proposed Permanent Rules Relating to PFAS in Products: Reporting and Fees (c-pfas-rule1-06) and the Statement of Need and Reasonableness (SONAR) (c-pfas-rule1-07), pursuant to Minn. Stat. § 116.943.

While Medical Alley and our network supports responsible environmental regulation in the interest of public health, we are deeply concerned that this proposed rule—if implemented in its current form—will impose excessive, impractical, and potentially unworkable burdens on Minnesota's healthcare innovation sector, particularly medical device manufacturers, without delivering corresponding environmental benefits.

We respectfully urge the MPCA to consider the following issues and implement the recommended changes.

Reporting Exemption for FDA-Regulated Medical Devices

Statutory Reference: Minn. Stat. § 116.943, subd. 4(b)

"Subdivisions 4 and 5 do not apply to a prosthetic or orthotic device or to any product that is a medical device or drug or that is otherwise used in a medical setting or in medical applications regulated by the United States Food and Drug Administration."

While the statute explicitly exempts FDA-regulated medical devices and related health products from Minnesota's PFAS product ban, the proposed rule does not extend this exemption to the reporting and fee requirements under Subdivision 2.

As a result, manufacturers of FDA-regulated products—already subject to federal oversight and exempt from Minnesota's PFAS prohibitions—would nonetheless face ongoing reporting and fee obligations, creating a misalignment within the rule that imposes unnecessary regulatory and financial burdens.

Recommendation:
Amend (7026.0020) and (7026.0090) to include the following exemption:

"Any product that is a medical device or drug or that is otherwise used in a medical setting or in medical applications regulated by the United States Food and Drug Administration."

Reporting Deadline Flexibility and Extensions

Statutory Reference: Minn. Stat. § 116.943, subd. 2(b)

"The agency may extend the deadline for submission of the required information for one or more specified products upon request by a manufacturer..."

The proposed rule allows for 90-day extensions; however, this does not reflect the full magnitude of the effort required to identify PFAS in highly complex, multi-tiered global supply chains. For many medical device manufacturers, components may be sourced through eight or more supply chain layers, often involving proprietary materials shielded by intellectual property protections. In such cases, manufacturers may not even have visibility into the materials, let alone the PFAS content.

The FDA has established processes to receive sensitive materials data directly from suppliers while protecting trade secrets. However, such supplier-to-regulator channels do not exist under the MPCA's framework. Without a similar mechanism, manufacturers are often unable to compel or access the information necessary for timely PFAS reporting.

Further complicating compliance, identifying regulated PFAS in products is a resource-intensive process that can span years. Many manufacturers are already more than a year into their internal supply chain evaluations, with no clear end in sight, simply to locate potential PFAS use. Even with this effort, conclusive answers may not be possible due to analytical limitations.

According to the European Chemicals Agency, chemical standards exist for approximately 40 PFAS compounds—out of the more than 10,000 PFAS that may exist. Currently, less than 1% of PFAS have commercially available analytical reference standards (CAARS).

Without a CAARS, it is not feasible to quantify the presence of a given PFAS, making comprehensive testing impossible in practice.

Advanced analytical techniques such as high-resolution mass spectrometry may result in false positives when evaluating unknowns, in part due to fluorine's monoisotopic nature and algorithmic bias toward fluorinated formulas. Moreover, such methods are limited to detecting extractable substances, not PFAS that may be bound within solid-state materials.

Recommendation:
Considering these real-world challenges, we recommend that MPCA:

- Adopt at minimum a one-year reporting delay to provide manufacturers adequate time to gather complex supply chain data, especially where suppliers are reluctant or unable to disclose PFAS content.
- Enable agency-initiated and manufacturer-initiated waivers, particularly for FDA-regulated products or sectors with low exposure risk.
- Recognize that testing is not a feasible alternative to supplier disclosure in many cases and avoid defaulting to test-based enforcement where no commercial method exists.

These measures would allow MPCA to maintain the intent of the statute while enabling compliance that reflects the technological, logistical, and legal realities of complex manufacturing ecosystems.

Clarify the Reporting Fee

The rule requires manufacturers to pay a $1,000 fee per "report" submitted under the reporting requirements. However, the term "report" is not clearly defined. It remains unclear whether this fee applies per manufacturer, per product line, per individual product, or per submission.

This ambiguity has created significant concern among manufacturers—particularly those with extensive product portfolios—who may interpret the rule to require thousands of separate reports and corresponding fees. Such a reading would result in an excessive administrative and financial burden with no proportional environmental or public health benefit.

Recommendation:
We request that MPCA clarify the definition of "report" for purposes of the reporting fee. Clear guidance is essential to ensure consistent interpretation across industries and to help manufacturers prepare for compliance in a predictable and efficient manner.

Use Statutory Definition of "Intentionally Added"

The term "intentionally added" is used in the statute and rule but remains ambiguous in practice. Manufacturers need guidance on how this applies to:

- PFAS present as background impurities or processing residuals,
- PFAS that were not knowingly added by the manufacturer,
- Trace PFAS levels below detection thresholds.

Without clarification, there is risk of overreporting or inconsistent application.

Recommendation:
We request that MPCA provide clear guidance on what constitutes "intentionally added" PFAS, including thresholds, trace amounts, and how intent is assessed when PFAS is introduced by a third party in the supply chain.

Additional Comments

As the MPCA is aware, PFAS encompass a broad class of over 10,000 substances with widely varying chemical, physical, and toxicological properties. Within this group, fluoropolymers—commonly used in medical devices—are chemically stable, non-mobile, non-bioavailable, and have not been shown to present the same environmental or human health risks as lower molecular weight PFAS.

Fluoropolymers play essential roles in the performance and safety of many FDA-regulated medical devices due to their dielectric properties, chemical inertness, and durability. Their presence is often critical to the function and biocompatibility of devices such as catheters, implantables, and inhalers.

Conclusion

We strongly encourage MPCA to revise the proposed rule to reflect the statute's limits and provide clarity in its implementation, reduce disproportionate burdens on essential healthcare technologies, and provide manufacturers with the flexibility and clarity needed for compliance.

Regulation of PFAS is critical, but it must be balanced with public health and innovation needs. The Medical Alley community is committed to supporting responsible reform, but

we urge the MPCA to adopt more reasonable timelines, clearer definitions, exemptions for FDA-regulated products, and more pragmatic implementation mechanisms.

Thank you for your attention and commitment to thoughtful environmental stewardship.

Please reach out to Medical Alley Associate Director of Communications Ben Wagner (bwagner@medicalalley.org) with any questions.

Sincerely,

Roberta Antoine Dressen
President and CEO, Medical Alley

AMERIPEN
The power of packaging in balance™

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Phone: +1 413-686-9198

May 20, 2025

Submitted via portal: Office of Administrative Hearings Comments On Rules

Minnesota Pollution Control Agency
520 Lafayette Road N
St. Paul, MN 55155-4194

RE: PFAS in products: Reporting and fees rulemaking – Comments

Dear Minnesota Pollution Control Agency,

AMERIPEN – the American Institute for Packaging and the Environment – appreciates the opportunity provided by the Minnesota Pollution Control Agency ("MPCA") to submit written comments regarding the draft rules for the reporting and fees rulemaking under the PFAS in Products law (also known as "Amara's Law"). AMERIPEN respectfully submits this comment letter for MPCA's consideration when developing the final reporting and fee rules as part of the law.

AMERIPEN is a trade association dedicated to improving packaging and the environment. We are the only material-inclusive packaging association in the United States representing the entire packaging supply chain. This includes materials suppliers, packaging producers, consumer packaged goods companies, retailers, and end-of-life materials managers. Our membership also includes a robust array of industry, material, and product-specific trade associations who are essential to the AMERIPEN fabric. We focus on science and data to define and support our public policy positions, and our advocacy and policy engagement is based on rigorous research rooted in our commitment to achieve sustainable packaging policies. We have several major, brand name, member companies headquartered in Minnesota, many who have a presence in the state, and more many who import packaging materials and products into the state. The packaging industry in Minnesota supports more than 40,000 jobs and accounts for more than $12.2 billion in total economic output.

The below written comments and clarifying questions from AMERIPEN, organized by draft rule section, speak to the contents of the draft rules MPCA released on April 21, 2025. They are offered after having consulted the accompanying Statement of Need and Reasonableness.

Section 7026.0010 – DEFINITIONS.

Subpart (7) defines "component" to include "packaging only when the packaging is inseparable or integral to the final product's containment, dispensing, or preservation." AMERIPEN is extremely concerned with this provision, as it expands the scope of the law beyond its statutory design. Under Amara's Law, "product" is defined as "an item manufactured, assembled, packaged, or otherwise prepared for sale to consumers, including but not limited to its product

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components, sold or distributed for personal, residential, commercial, or industrial use, including for use in making other products."[1] Given that definition, a product is an item that can be packaged but is not packaging itself, and can include the subsidiary components intrinsic to that item. While the law also explicitly exempts food packaging,[2] it does so because there is an existing law that specifically regulates PFAS in food packaging[3] and it does not affect the interpretation of "product." Given the clear definition of the law, AMERIPEN requests that the last sentence in paragraph (7) be stricken and replaced with the following: "Component does not include packaging."

AMERIPEN appreciates the language in subpart (18) adding clarity as to what qualifies as a "significant change" that would trigger an updated report obligation.

AMERIPEN also appreciates the last sentence in subpart (19), regarding "substantially equivalent information," which will help limit redundant and unnecessary reporting for products or components offered for sale under multiple brands.

Section 7026.0020 – PARTIES RESPONSIBLE FOR REPORTING.

Clause (A) of subpart 2, which governs reporting agreements between producers, specifies that the condition it contains only pertains to parties to the reporting agreement. However, no such limitation is provided in clauses (B), (C), or (D). AMERIPEN requests a minor amendment to add a phrase to each of these clauses to address this inconsistency, reading as follows: "…all manufacturers **that are a party to a reporting responsibility agreement**…".

SECTION 7026.0030 – REPORT; REQUIRED INFORMATION.

AMERIPEN appreciates the provisions in subparagraphs (A)(1)(a) and (A)(1)(b) of subpart 1 that allow manufacturers to group together similar products comprised of homogenous materials, as it will help reduce reporting burdens. However, there is not a clear rationale for why grouped products have to have PFAS chemicals that provide the same function, as required in each subunit (iii). AMERIPEN suggests striking this unnecessary condition or else providing justification for it.

It is further unclear why the manufacturer reporting of PFAS concentrations in components is qualified as being for components "made up of homogenous material" in subparagraph (C) of subpart 1. AMERIPEN seeks the rationale for this approach as well.

7026.0040 – REPORTING UPDATES.

AMERIPEN supports the approach in paragraph (A) of subpart 1 to provide up to 12 months for a manufacturer to report significant or certain other changes. However, subparagraph (2) requires

[1] Minnesota Statutes 2024, section 116.943, subdivision 1, paragraph (q).
[2] Minnesota Statutes 2024, section 116.943, subdivision 8, subparagraph (a)(2).
[3] Minnesota Statutes 2024, section 325F.075.

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such updated reporting if "new product information was provided to a manufacturer." This condition is written very broadly and can be readily interpreted to apply to any information whatsoever, even if it bears no relevance to the PFAS content in a product. AMERIPEN requests a minor clarification to this clause to read as follows: "new product information **pertaining to a product's categorization or PFAS content** was provided to a manufacturer." Similarly, subparagraph (3) should be constrained to apply only to new products that contain intentionally added PFAS, to read as follows: "a new product **that contains intentionally added PFAS** was sold, offered for sale, or distributed in or into the state."

Subpart 2 requires manufacturers to annually recertify their reporting, subjecting them to annual recertification fees and requiring MPCA to devote additional resources to the administration of Amara's Law. AMERIPEN objects to this provision for several reasons. First, it is entirely unnecessary, as manufacturers are already required to report significant changes to MPCA on annually basis when a relevant update occurs. Second, it creates additional costs and personnel demands for the manufacturers and the state alike. Finally, annual recertification is not contemplated or called for in the underlying statute. AMERIPEN requests removal of this subpart and any other provisions related to annual recertification.

Section 7026.0060 – EXTENSIONS.

Paragraph (B) of subpart 3 requires the MPCA Commissioner to grant a 90-day extension of the reporting deadline for justified requests. While AMERIPEN appreciates this provision, it is possible to provide additional flexibility for MPCA and manufacturers alike. Amara's Law does not specify a default extension time, so AMERIPEN suggests that manufacturers be authorized to request up to 180 days instead. As the law is implemented and manufacturer experience matures, it is likely that this timeframe can be reduced in future rulemakings.

Section 7026.0080 – DUE DILIGENCE.

Subpart 2 requires manufacturers to request their suppliers to provide the information required under the proposed regulations "until all required information is known." However, a manufacturer cannot guarantee another entity will comply despite its best efforts to obtain the information. As such, and in the spirit of incentivizing due diligence, AMERIPEN requests the addition of a final sentence in subpart 2 stating: "**Notwithstanding the rest of this subpart, a manufacturer that cannot obtain all required information is deemed compliant with this subpart if it demonstrates a good faith effort in attempting to obtain it."**

Section 7026.0100 – FEES.

The fees provided in the draft rules are flat fees. While those are easier for MPCA to implement, they are not necessarily tied to or reflective of the actual costs of performing regulatory work under Amara's Law. Moreover, the statute limits any reporting fees to an amount "to cover the

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agency's reasonable costs to implement" the law.[4] AMERIPEN therefore requests language that would cap these fees to the actual and reasonable costs that MPCA incurs in implementing Amara's Law.

# # #

AMERIPEN strives to offer a good-faith and proactive approach. We continue to focus on strategies that develop and/or strengthen policies to progress the "reduce, reuse, recycle" strategies, while at the same time, enhancing the value of packaging. Our members are driving innovation, designing better environmental performance to evolve the recycling infrastructure and to create a more circular economy for all packaging. In our efforts to reduce environmental impact by increasing the circularity of packaging, our members continue to recognize the value of collaboration and the importance of working across the packaging value chain. We remain committed to supporting progressive, proactive, and evidence-based strategies for sustainable packaging policies and programs.

AMERIPEN thanks MPCA for this opportunity to provide written comments regarding the draft rules and appreciates MPCA staff's efforts during this process. Please feel free to contact me by email (GMelkonian@serlinhaley.com) with any questions on AMERIPEN's positions.

Sincerely,

Gregory Melkonian
Regulatory and Government Affairs Associate

[4] Minnesota Statutes 2024, section 116.943, subdivision 6.

JP4EE Appendix 2 - List of GPC Brick Codes covering EEE using PFAS

Note: this list is prepared based on our best knowledge and non-exhaustive.

Brick Code covering EEE	Brick Title covering EEE
10001686	Airbrushes (Powered)
10001742	Burning/Engraving Craft Tools (Powered)
10001694	Kilns (Powered)
10001732	Melter (Powered)
10001695	Pottery Wheels (Powered)
10001749	Printing Press (Powered)
10001693	Sculptors Tools (Powered)
10001707	Sewing/Knitting Tools (Powered)
10001754	Spinning/Weaving Tools (Powered)
10005726	Analogue/Digital Converters
10001467	Audio Headsets
10001483	Audio Visual Accessories - Replacement Parts
10001484	Audio Visual Accessories Other
10001482	Audio Visual Accessories Variety Packs
10005744	Audio Visual Labelling Systems
10001475	Converter Cassettes
10005204	Megaphones
10001476	Microphones
10005747	MP3 Docking Stations
10001468	Signal Boosters
10005809	Sound-active Effect Lighting
10001472	Switch-boxes
10001479	Television Internet Packs
10001470	Universal Remote Controls
10005735	Visual Distribution Amplifiers
10001469	Wireless Television Links
10001485	Audio Visual Equipment Variety Packs
10001429	Home Audio Amplifiers/Preamplifiers
10001432	Home Audio Cassette Decks
10001433	Home Audio CD Decks
10001443	Home Audio Effects Equipment
10001447	Home Audio Equipment - Replacement Parts/Accessories
10001448	Home Audio Equipment Other
10001446	Home Audio Equipment Variety Packs
10001440	Home Audio Jukeboxes
10001441	Home Audio Karaoke Systems
10001434	Home Audio MD Decks
10001437	Home Audio Receivers/Tuners/Radios
10001436	Home Audio Speaker Systems
10001435	Home Audio Speakers - Individual

10001442	Home Audio/Visual Mixers
10001430	Home Stereo Systems
10001431	Home Theatre Systems
10001444	Turntables - CD
10001439	Turntables - Vinyl
10001424	Clock Radios
10001425	Dictation Machines
10001419	Portable Audio Cassette Players
10001427	Portable Audio/Video - Replacement Parts/Accessories
10001428	Portable Audio/Video Other
10001426	Portable Audio/Video Variety Packs
10001416	Portable CD Players
10001421	Portable Digital Video Players
10001420	Portable DVD Players
10005765	Portable FM (Frequency Modulation) Transmitters
10001417	Portable MD Players
10001418	Portable MP3 Players
10005807	Portable PA (Public Address) Music Systems
10001423	Portable Radio-recorders
10001422	Portable Radios
10005710	Portable Speakers
10001401	Television Combinations
10001400	Televisions
10001402	Televisions - Hand-held
10001404	Televisions - Replacement Parts/Accessories
10001405	Televisions Other
10001403	Televisions Variety Packs
10001411	Aerials
10005841	Audio/Visual Receivers
10005736	Low-noise Block (LNB) Converters
10005760	Satellite Reception Accessories
10005829	Satellite/Terrestrial Antenna Systems
10001409	Set-top Boxes
10005739	Video Receiving/Installation Variety Packs
10005808	Audiograms
10001406	Camcorders
10001408	Combination Players/Recorders
10001407	DVD Players/Recorders
10005748	Memory Card Recorders
10001412	Video Cassette Players/Recorders
10001410	Video Hard Disc Recorders
10001414	Video Recording/Playback - Replacement Parts/Accessories
10001413	Video Recording/Playback Variety Packs
10006240	Audio (Non-Music) - Digital
10001464	Audio Cassettes - Pre-recorded
10001459	CD/MD - Pre-recorded
10003718	Dual Discs - Pre-recorded
10001460	DVD - Pre-recorded
10001466	Pre-recorded Media Other
10001465	Pre-recorded Media Variety Packs

10001463	Video Cassettes - Pre-recorded
10001449	Audio Cassettes - Recordable
10001450	CD/MD - Recordable
10001451	DVD - Recordable
10001456	Floppy Discs
10001452	Memory Cards
10001458	Recordable Media Other
10001457	Recordable Media Variety Packs
10006398	USB Flash Drives/Thumb Drives
10001455	Video Cassettes - Recordable
10003777	Audio Visual/Photography Variety Packs
10001533	Car Audio - Replacement Parts/Accessories
10001531	Car Audio Aerials
10001530	Car Audio Amplifiers
10005205	Car Audio Cassette Players/Changers
10001527	Car Audio CD Players/Changers
10001525	Car Audio Head Units
10001528	Car Audio MD Players/Changers
10001534	Car Audio Other
10001529	Car Audio Speakers
10005828	Car Audio Subwoofers
10001526	Car Audio Tuners/Receivers
10001532	Car Audio Variety Packs
10001519	Car DVD Players
10005749	Car GPS Antennae
10001517	Car Navigation Equipment
10005728	Car Radar Detectors
10001520	Car Video Cassette Players
10001518	Car Video Monitors
10001521	Car Video Receiving Equipment
10001523	Car Video/Navigation - Replacement Parts/Accessories
10001524	Car Video/Navigation Other
10001522	Car Video/Navigation Variety Packs
10003685	In-car Electronics Variety Packs
10001499	Binoculars
10001502	Microscopes
10001501	Monoculars/Telescopes
10001505	Optics - Replacement Parts/Accessories
10001506	Optics Other
10001504	Optics Variety Packs
10001486	Analogue Cameras
10005750	Camera Flash Accessories
10001489	Camera Flashes
10001487	Digital Cameras
10005700	Digital Photo Frames
10001491	Interchangeable Lenses
10005842	Mobile Photo Storage
10005755	Photographic Camera Filters
10001492	Photographic Slide Projectors
10005753	Photographic Studio Flash Gun
10001494	Photography - Replacement Parts/Accessories
10001498	Photography Other

10001496	Photography Variety Packs
10001508	Photograph Enlargers
10001512	Photography Dark Room Safelights
10001511	Photography Drying Equipment
10001515	Photography Printing/Dark Room Equipment - Replacement Parts/Accessories
10001516	Photography Printing/Dark Room Equipment Other
10001514	Photography Printing/Dark Room Equipment Variety Packs
10003686	Photography/Optics Variety Packs
10000807	Bath Massage/Toning
10000758	Body Massage/Toning - Replacement Parts
10000760	Body Massage/Toning Other
10000668	Body Massage/Toning Variety Packs
10000567	Body Toning/Firming Products (Powered)
10000759	Personal Warming/Massaging (Powered)
10000770	Oil Diffusers (Powered)
10000767	Nails - Accessories (Powered)
10000780	Nails - Aids (Powered)
10000828	Hair - Aids (Powered)
10000348	Hair - Perming
10000678	Hair - Styling (Powered)
10000830	Depilation/Epilation (Powered)
10000831	Shaving - Razors (Powered)
10008378	Gum Stimulator/Massager
10005839	Oral Care Centre - Brush/Cleanser/Storage (Powered)
10008374	Oral Cleaner System (Powered)
10008380	Tooth Stain Removers/Whitener (Powered)
10008373	Toothbrush (Powered)
10006246	Penetration Accessories (Powered)
10006248	Suction Devices (Powered)
10000806	Anti-spot Aids (Powered)
10000808	Cleansers/Cosmetics Removers (Powered)
10000809	Sunless Tanning (Powered)
10005560	Bells/Chimes/Buzzers
10006404	Gate/Garage Door Opener Replacement Parts and Accessories
10005673	Gate/Garage Door Opening Systems
10002551	Awnings - Powered
10007039	Window Shutter Motorisation
10002087	Camping Stoves/Grills/Ovens
10002077	Camping Heating/Lighting Equipment Other
10002078	Camping Heating/Lighting Equipment Variety Packs
10004099	Camping Water Heaters
10002075	Tent Heaters
10002097	Camping Showers
10004100	Camping Toilets (Powered)
10000696	Air Fresheners/Deodorisers (Powered)
10008278	Clothes Folder (Powered)
10002023	Clothes Irons (Powered)

10002025	Clothes Presses
10002024	Ironing Boards (Powered)
10002031	Steam Cleaners
10008006	Industrial Floor Cleaner - Powered
10005105	Environmental Respiratory Protection - Powered
10005107	Hearing Protection - Powered
10005109	Helmets - Powered
10001174	Caller ID Displays
10001379	Communication Accessories Other
10001380	Communication Accessories Variety Packs
10005745	Communication Headphones Replacement Parts/Accessories
10001181	Communications Hands Free Kits/Headphones
10005740	Digital Enhanced Cordless Telecommunications (DECT) Repeaters
10001382	Communication Variety Packs
10001184	Answering Machines
10001185	Conferencing Systems
10005677	Fax Machine Consumables
10001186	Fax Machines
10005681	Fixed Communication Devices Accessories
10001383	Fixed Communication Devices Other
10001384	Fixed Communication Devices Variety Packs
10001189	Intercoms
10001190	Telephone Switchboards
10001191	Telephones
10001192	Communication Radio Sets
10001193	GPS Equipment - Mobile Communications
10001194	GPS Software - Mobile Communications
10006237	GPS Software - Mobile Communications - Digital
10003779	Mobile Communication Devices/Services - Replacement Parts
10001385	Mobile Communication Devices/Services Other
10001386	Mobile Communication Devices/Services Variety Packs
10001196	Mobile Phone SIM Cards/SIM Card Adapters
10001197	Mobile Phone Software
10006238	Mobile Phone Software - Digital
10007020	Mobile Phone/Smartphone Accessories
10001198	Mobile Phones/Smartphones
10001199	Pagers
10005711	Personal Digital Broadcasters/Trackers
10001200	Two-way Radios
10006227	Sign - Replacement Part/Accessory
10006225	Signs, Combination
10006223	Signs, Preprinted
10006224	Signs, Unprinted
10001117	Computer Casing/Housing
10001118	Computer Components - Replacement Parts/Accessories
10001119	Computer Components Other
10001120	Computer Components Variety Packs
10001121	Computer Cooling

10001122	Computer Memory
10001123	Computer Motherboards
10001125	Computer Processors
10005683	Computer/Video Games Mass Storage
10001126	Expansion Boards/Cards
10001129	Computer Drives - Replacement Parts/Accessories
10001130	Computer Drives Other
10001131	Computer Drives Variety Packs
10001132	Floppy Disc Drives
10001133	Hard Disc Drives
10001128	Optical Drives - Reading Only
10001127	Optical Drives - Reading/Writing
10001134	Swap Drives
10001135	Tape Drives/Streamers
10001136	Zip/Jaz Disk Drives
10001172	Computer Networking Equipment - Replacement Parts/Accessories
10001170	Computer Networking Equipment Other
10001171	Computer Networking Equipment Variety Packs
10001162	Firewalls
10001163	Gateways
10001164	Modems
10001165	Network Access Points
10001167	Network Interface Cards
10001168	Network Routers
10001169	Network Switches
10001166	Network/USB Hubs
10001173	Repeaters
10005831	USB Internet Stick
10001115	Card Readers
10001116	Computer Casing/Housing Accessories
10001109	Computer Docking Ports/Cradles
10001124	Computer Power Supplies
10005438	Computer Stands/Supports
10001112	Computer Tools/Tool Kits
10001362	Computer/Video Game Accessories Other
10001363	Computer/Video Game Accessories Variety Packs
10001107	Computer/Video Game Cases/Carriers
10001108	Computer/Video Game Cleaning Products
10005741	Computer/Video Game Headsets
10001111	Computer/Video Game Security Products
10001110	Filters/Covers (Electronic Equipment)
10001113	Mats/Rests - Computing
10001114	Personal Data Assistant/Organiser Stylus
10006744	Personal Video Recorder
10005843	Video Editor
10001149	Computer Graphics Tablets
10001150	Computer Keyboards
10001151	Computer Pointing Devices
10001148	Computer/Video Game Control Devices

10001152	Computer/Video Game Control/Input Devices - Replacement Parts/Accessories
10001364	Computer/Video Game Control/Input Devices Other
10001365	Computer/Video Game Control/Input Devices Variety Packs
10005686	Digital Pens
10001154	Computer Speakers/Mini Speakers
10001153	Computer/Video Game Monitors
10001155	Computer/Video Game Peripherals - Replacement Parts/Accessories
10001366	Computer/Video Game Peripherals Other
10001367	Computer/Video Game Peripherals Variety Packs
10006745	Keyboard, Voice, Mouse (KVM) Switch
10001156	Printer Consumables
10001158	Printers
10001159	Projection Systems
10001160	Scanners
10001161	Web-cameras
10001138	Computer Software (Non Games)
10006236	Computer Software (Non Games) - Digital
10001137	Computer/Video Game Gaming Software
10006235	Computer/Video Game Gaming Software - Digital
10001139	Computer/Video Game Software Other
10001140	Computer/Video Game Software Variety Packs
10001141	Computers - Replacement Parts/Accessories
10001142	Computers Other
10001143	Electronic Organisers
10006405	Personal Computers - All-in-One
10001144	Personal Computers - Desktop/Internet Terminal
10001145	Personal Computers - Portable
10006276	Personal Computers - Tablets/E-Book Readers
10001146	Personal Digital Assistants
10001147	Servers
10006743	Smart Watches
10001370	Computers/Video Games Variety Packs
10005763	Console Accessories
10003817	Video Game Consoles - Non Portable
10003818	Video Game Consoles - Portable
10003819	Video Game Consoles - Replacement Parts
10005651	Cable Clips/Grommets/Ties
10005660	Cable Conduit Fittings
10005648	Cable Markers
10005674	Cable Marking Accessories
10005649	Cable Reels/Pullers
10005647	Cable/Wire Conduit/Ducting/Raceways
10005650	Cabling/Wiring Protection/Wrapping
10005757	Audio Visual Cables
10005754	Computer Cables
10005759	Satellite Installation Cables
10005758	Telecommunication Cables

10005541	Electrical Wires
10000546	Batteries
10000704	Batteries/Chargers Variety Packs
10005764	Battery Boxes
10000548	Chargers
10005573	Connectors (Electrical)
10005572	Electrical Connection Variety Packs
10000551	Plugs
10005567	Sockets/Receptacles/Outlets
10005496	Adaptors (Electrical)
10005575	Busbars/Busways
10005622	Capacitors
10005576	Circuit Breakers
10000547	Converters/Transformers
10005583	Distribution Boards/Boxes
10005577	Electrical Distribution Accessories/Fittings
10000549	Fuses
10005682	Multi-use/Universal Electrical Timers/Controllers
10005570	Relays/Contactors
10005568	Splitters
10005585	Surge Suppressors/Protectors
10005586	Switches
10005588	Terminal Blocks/Strips
10008391	Charge/Voltage Regulators
10008395	Electrical Generation Accessories/Fittings
10005211	Generators
10008390	Inverters
10008394	Power Generator Set
10008389	Solar Panels
10005875	Solar Power Stations
10008393	Water Turbines
10008392	Wind Turbines
10008402	Built-in Lighting
10005640	Fibre Optic Lighting
10005641	Freestanding Lighting
10008404	Hanging Lighting
10008292	Led Strips and Replacement Parts/Accessories
10000552	Light Bulbs/Tubes/Light-Emitting Diodes
10008403	Mounted Lighting
10008405	Plug-in Lighting
10005644	Rope/String Lights
10008406	Undercabinet and Mirror Lighting
10005643	Wide-angle and High-beem (work) Lighting
10005637	Lamp Brackets/Fittings Others
10005635	Lampshades
10005636	Lampstands/Bases
10005638	Light Bulb Changers
10007931	Tripod (Lighting)
10005481	Ballasts/Starters
10005634	Dimmers
10005633	Light Sockets
10006896	Electrical Lighting - Other
10005642	Electric Torches/Flashlights

10005661	Circuit Assemblies/Integrated Circuits
10005662	Discreet Components
10005667	Electronic Circuit Accessories
10005546	Bonding/Grounding Braid
10005571	Cable/Wire Pullers
10005742	Electronic Testers
10005559	Extension/Power Supply Cords
10008363	Monitors/Screens
10005599	Voltmeters/Multimeters
10005505	Wall Plates (Electrical)
10000869	Oral Rehydration/Electrolyte Maintenance
10000682	Anti-smoking Aids
10002423	Oral/Mouth Treatments
10000853	Pain Relief (Powered)
10000916	Humidifiers/Vaporisers (Powered)
10000878	Inhalers/Nebulisers/Respirators (Powered)
10000920	Respiratory/Allergy Products Other
10000884	Respiratory/Allergy Products Variety Packs
10000880	Throat Remedies
10000487	Hearing Aids
10000893	Parasite Infestation Equipment (Powered)
10000886	Parasite Infestation Treatments
10000843	Diagnostic Monitors Other
10000455	Home Diagnostic Monitors
10000844	Diagnostic Tests Other
10000648	Diagnostic Tests Variety Packs
10000454	Home Diagnostic Products - Accessories
10000453	Home Diagnostic Tests
10000452	Thermometers
10000647	Home Diagnostics Variety Packs
10005844	Medical Devices
10008118	Support Component of a Medical Device
10008111	Support Component of a Veterinary Medical Device
10006412	Veterinary Medical Devices
10001964	Dishwashers
10001965	Kitchen Washing Appliances Other
10001966	Kitchen Washing Appliances Replacement Parts/Accessories
10005322	Cooker Hoods
10001951	Hobs/Cooktops
10001953	Major Cooking Appliances Other
10001954	Major Cooking Appliances Replacement Parts/Accessories
10001952	Microwave Ovens
10001950	Ovens
10003690	Range Cookers/Stoves (Oven/Hob/Cook Top Combined)
10003691	Steam Ovens
10001959	Clothes Washers
10001961	Combination Clothes Washer/Dryers
10001962	Major Laundry Appliances Other

10001963	Major Laundry Appliances Replacement Parts/Accessories
10003692	Spin/Tumble Dryers
10003712	Water Dispensers - Freestanding
10003710	Beverage Chillers Other
10001940	Coolers/Heaters
10003698	Freezers
10001938	Ice Makers
10001941	Refrigerating/Freezing Appliances Other
10001942	Refrigerating/Freezing Appliances Replacement Parts/Accessories
10003695	Refrigerator/Freezers
10003694	Refrigerators
10001939	Wine Chillers
10001956	Hostess Trolleys (Powered)
10001957	Warming Appliances Other
10001958	Warming Appliances Replacement Parts/Accessories
10001955	Warming Drawers
10001929	Food Waste Disposers
10001928	Trash Compactors
10001930	Waste Disposing/Compacting Appliances Other
10001931	Waste Disposing/Compacting Appliances Replacement Parts/Accessories
10007950	Ash Vacuum Cleaners
10002032	Cleaning Appliances Other
10002033	Cleaning Appliances Replacement Parts/Accessories
10006220	Disinfecting Cabinet
10007952	Ducted Vacuum Cleaner Accessories/Replacement Parts
10007951	Ducted Vacuum Cleaners
10002030	Floor Polishers/Shampoo Cleaner
10008138	Handheld Vacuum Cleaner
10002028	Household Vacuum Cleaners
10007949	Robot Vacuum Cleaners
10003711	Shoe Cleaners/Polishers
10002029	Sweepers (Powered)
10005762	Vacuum Cleaner Bags
10007953	Vacuum Cleaner Filters
10007955	Vacuum Cleaner Heads
10007954	Vacuum Cleaner Hoses/Tubes
10008280	Window Cleaners (Powered)
10000820	Baby Feeding Aids (Powered)
10002015	Butter Makers (Powered)
10002000	Can Openers (Powered)
10002019	Candyfloss Machines
10002016	Carbonated Drinks Makers
10005690	Chocolate Fountains (Powered)
10006852	Coffee Bean Roasters
10002006	Coffee Grinders (Powered)
10005358	Cookie Guns (Powered)
10002018	Dehydrators (Powered)

10002022	Food/Beverage Appliances Variety Packs
10002020	Food/Beverage Preparation Appliances Other
10002021	Food/Beverage Preparation Appliances Replacement Parts/Accessories
10005689	Frozen Drinks Makers/Ice Shavers (Powered)
10002005	Graters (Powered)
10002011	Hot Beverage Makers
10002013	Ice Cream Makers (Powered)
10005357	Ice Crushers/Ice Cube Makers (Powered)
10002007	Juicers (Powered)
10002012	Kettles (Powered)
10006739	Kitchen Blending Appliances
10006737	Kitchen Chopping Appliances
10006735	Kitchen Combination Mixing/Blending/Chopping Appliances
10006738	Kitchen Mixing Appliances
10005695	Kitchen Scales (Powered)
10006736	Kitchen Slicing Appliances
10002002	Knife Sharpeners (Powered)
10001998	Knives (Powered)
10002004	Meat Grinders/Mincers (Powered)
10005868	Party Drink Fountains (Powered)
10006218	Soy/Rice Milk Maker
10002003	Vacuum Sealers (Powered)
10005691	Wine/Bottle Openers (Powered)
10002014	Yogurt Makers
10002026	Laundry Care Appliances Other
10002027	Laundry Care Appliances Replacement Parts/Accessories
10005317	Air Conditioners - Portable
10005335	Air Controlling Appliances - Multifunction - Portable
10005334	Air Coolers - Portable
10006798	Air Dehumidifier - Portable (Non-Powered)
10005332	Air Dehumidifiers - Portable (Powered)
10003992	Air Heaters - Portable
10005331	Air Humidifiers - Portable
10005333	Air Ionisers - Portable
10005336	Air Purifiers - Portable
10005337	Fans - Portable
10005697	Portable Air Control Appliances Replacement Parts/Accessories
10001983	Breadmakers
10006740	Cake / Pie Maker
10001991	Cooking Appliances Variety Packs (Powered)
10005365	Cooking Timers (Powered)
10001981	Deep Fryers
10001980	Egg Cookers
10001969	Electric Grills
10001986	Fondues (Powered)
10005704	Hot Dog Rollers
10001990	Hot Stones (Powered)
10001988	Mexican Diners (Powered)

10001978	Multi-cookers (Powered)
10001989	Paella Makers (Powered)
10001971	Pancake/Doughnut Makers
10001979	Pasta Cookers (Powered)
10001985	Pizza Makers
10001984	Popcorn Makers
10001976	Pressure Cookers (Powered)
10001972	Raclettes (Powered)
10001977	Rice Cookers/Steamers
10001974	Rotisseries/Roasters (Powered)
10001970	Sandwich/Waffle Makers
10001975	Slow Cookers/Hot Pots/Cocottes (Powered)
10002034	Small Cooking Appliances Other
10002035	Small Cooking Appliances Replacement Parts/Accessories (Powered)
10001987	Tajines (Powered)
10001968	Toaster Ovens
10001967	Toasters
10005359	Warming Trays (Powered)
10001982	Woks (Powered)
10006894	Small Domestic Appliances - Other
10003713	Water Dispensers - Tabletop
10007021	Smart Home/Home Automation Equipment - Control Panel
10007024	Smart Home/Home Automation Equipment - Lawn/Garden/Leisure Appliances
10007957	Smart Home/Home Automation Equipment - Power Monitoring Device
10007022	Smart Home/Home Automation Equipment - Security Appliances
10008303	Smart Home/Home Automation Equipment - Smart Plug/Socket
10007023	Smart Home/Home Automation Equipment - Temperature Regulation Appliances
10000801	Baby Bouncing Cradles/Rocker Seats (Powered)
10005197	Blankets/Throws (Powered)
10002208	Household Adjustable Beds (Powered)
10005096	Household Beds - Replacement Parts/Components
10005097	Household/Office Chairs - Replacement Parts/Components
10002192	Household/Office Chairs/Stools (Powered)
10002200	Household/Office Seating Variety Packs
10002194	Household/Office Sofas (Powered)
10007006	Alarm Clocks
10002252	Clocks
10004101	Clocks - Replacement Parts
10003816	Ornamental Furnishings Variety Packs
10008283	Christmas Tree - Artificial (Powered)
10008285	Christmas Wreath and Garland - Artificial (Powered)
10008302	Ornaments (Powered)
10002238	Ornaments Variety Packs

10002237	Seasonal Decorations (Powered)
10008341	Between Bearings Pumps
10008340	Overhung Pumps
10008342	Vertically Suspended Pumps
10008344	Fire Hydrant Systems
10008343	Submersible Pumps
10008355	Industrial Pumps - Electric Engines
10008356	Industrial Pumps -Combustion Engines
10008364	Industrial Pumps – Replacement Parts/Accessories
10008354	Pneumatics Pumps
10008353	Diaphragm Pumps
10008351	Piston Pumps
10008352	Plunger Pumps
10008349	Gear Pumps
10008350	Lobe Pumps
10008346	Peristaltic/Roller Pumps
10008348	Progressive Cavity Pumps
10008345	Screw Pumps
10008347	Vane Pumps
10002152	Cookware/Bakeware Other
10007241	Hob Pots/Pans/Woks/Cocottes Variety Packs
10002151	Kitchen Cookware/Bakeware Variety Packs
10002142	Food Measuring Equipment Other
10002141	Food Measuring Equipment Variety Packs
10002140	Food Thermometers
10002169	Corers/Peelers
10002178	Food Preparation Equipment Other
10002177	Food Preparation Equipment Variety Packs
10002172	Kitchen Slicers/Graters/Cutters
10002176	Multifunction Kitchen Tools
10002175	Openers - Kitchen
10002146	Sieves/Strainers/Colanders
10002183	Kitchen Merchandise Variety Packs
10002124	Kitchen Storage Other
10002121	Kitchen Storage Racks/Stands/Holders/Dispensers
10002123	Kitchen Storage Variety Packs
10002135	Water/Beverage Equipment Other
10002134	Water/Beverage Equipment Variety Packs
10007255	Bar and Wine Variety Pack
10007254	Other Bar and Wine Accessories
10007252	Wine Accessories
10007266	Tableware Accessories Other
10007267	Tableware Accessory Variety Packs
10007265	Tableware Variety Packs
10006853	Animal Scarers/Deterrents (Lawn/Garden) - Powered
10003328	Barbecues
10003330	Cooking Islands (Lawn/Garden)
10005369	Greenhouse Heaters/Ventilators
10003335	Lawn/Garden Cooking/Heating Appliances Other

10003336	Lawn/Garden Cooking/Heating Appliances Replacement Parts/Accessories
10003334	Lawn/Garden Cooking/Heating Appliances Variety Packs
10003323	Outdoor Heaters (Powered)
10006742	Smokers - Cooking
10003332	Warmers/Drawers (Lawn/Garden)
10003869	Applicators/Feeders (Powered)
10003355	Brush Cutters/String Trimmers/Edgers (Powered)
10003359	Chain Saws (Powered)
10003351	Chippers/Shredders/Mulchers (Powered)
10003373	Cultivators/Tillers/Rotary Hoes (Powered)
10003365	Earth Augers (Powered)
10003376	Garden Carts (Powered)
10003408	Garden Power Tools Other
10003407	Garden Power Tools Variety Packs
10004102	Garden Tractors
10003338	Garden Vacuums/Blowers
10003870	Hedge Trimmers (Powered)
10003353	Lawn Mowers/Rakers (Powered)
10003841	Lawn Rollers (Powered)
10003347	Lawn Scarifiers/Aerators (Powered)
10003352	Lawn/Garden Equipment Accessories
10003872	Lawn/Garden Equipment Other
10003873	Lawn/Garden Equipment Variety Packs
10003865	Lawn/Garden Hand Tools Other
10003864	Lawn/Garden Hand Tools Replacement Parts/Accessories
10003866	Lawn/Garden Hand Tools Variety Packs
10003402	Lawn/Garden Power Tools Replacement Parts/Accessories
10003367	Log Splitters (Powered)
10003380	Loppers
10003861	Post Hole Diggers (Powered)
10007939	Pressure Washer Replacement Parts/Accessories
10003375	Pressure Washers (Powered)
10003843	Pruners (Powered)
10003381	Pruners/Secateurs
10003341	Snow Throwers (Powered)
10003368	Stump Grinders/Pullers (Powered)
10003370	Tampers (Powered)
10003401	Weed Burners (Powered)
10003283	Electric Fence/Radio Fences
10003287	Gates (Powered)
10005678	Lawn/Garden Fencing Accessories
10003289	Lawn/Garden Fencing Other
10003288	Lawn/Garden Fencing Variety Packs
10005218	Lawn/Garden Lighting Other
10005217	Lawn/Garden Lighting Replacement Parts/Accessories
10005215	Outdoor Lamps/Torches/Lanterns - Powered
10003215	Garden Water Features

10003225	Lawn/Garden Pools/Ponds/Water Features Other
10003224	Lawn/Garden Pools/Ponds/Water Features Variety Packs
10008367	Pond/Water Feature Accessories and Tools
10003220	Pond/Water Feature Aerators
10003218	Pond/Water Feature Foggers
10003216	Pool/Pond/Water Feature Filters (Powered)
10005253	Pool/Pond/Water feature Supplies/Accessories
10003219	Pool/Pond/Water Feature UV Clarifiers/Sterilizers
10003889	Lawn/Garden Testing Diagnostic Equipment Replacement Parts/Accessories
10003237	Water/Soil Testing Equipment (Powered)
10003264	Irrigation Systems
10003276	Irrigation Timers/Controllers
10003274	Lawn/Garden Watering Equipment Other
10003273	Lawn/Garden Watering Equipment Replacement Parts
10003272	Lawn/Garden Watering Equipment Variety Packs
10003271	Sprinklers/Sprayers/Misters (Powered)
10005318	Anemometers - Powered
10005316	Combination Weather Measuring/Monitoring Equipment - Powered
10003434	Evaporimeters/Atmometers - Powered
10005323	Hygrometers - Powered
10003452	Lawn/Garden Weather Monitoring/Observation Other
10003451	Lawn/Garden Weather Monitoring/Observation Replacement Parts/Accessories
10003453	Lawn/Garden Weather Monitoring/Observation Variety Packs
10003436	Light Meters - Powered
10003432	Psychrometers - Powered
10003433	Pyranometers/Solarimeters - Powered
10005320	Rain Gauges - Powered
10003435	Sunshine Recording Equipment - Powered
10005319	Thermometers - Garden - Powered
10005356	Lubricants Variety Packs
10005283	Lubricants/Protective Compounds Variety Packs
10005268	Lubricating Greases
10005267	Lubricating Oils/Fluids
10005270	Lubricating Products Variety Packs
10005269	Lubricating Waxes
10005273	Anti-corrosives
10005272	Antifreeze/Coolants
10005321	Anti-spatter Products
10005275	Protective Compounds Variety Packs
10005280	Lubricants/Protective Compounds Storage Variety Packs
10004117	Keyboard/Piano Accessories (Powered)
10004123	Metronomes/Tuners (Powered)
10004128	Musical Instrument Accessories Other

10004127	Musical Instrument Accessories Variety Packs
10000938	Brasswind Musical Instruments (Powered)
10000940	Keyboards/Pianos (Powered)
10000939	Musical Instrument Aids (Powered)
10001377	Musical Instruments Other (Powered)
10000941	Percussion Musical Instruments (Powered)
10000942	String Musical Instruments (Powered)
10000943	Woodwind Musical Instruments (Powered)
10004126	Musical Instruments/Accessories Variety Packs
10008105	Personal Fan - Hand (Hand Fan)
10008106	Personal Fan - Impeller
10001104	Watch Accessories/Replacement Parts
10001105	Watches
10001392	Watches Other
10000516	Aquarium Aids/Accessories
10007768	Aquarium/Vivarium
10000736	Pet Accessories Other
10000659	Pet Accessory Variety Packs
10000643	Pet Attire
10000660	Pet Food/Drink Dispenser
10000661	Pet Toys (Powered)
10000652	Pet Training/Control Aids/Accessories (Powered)
10008288	Pet Transportation Means
10006843	Terrarium Aids/Accessories
10000508	Pet Grooming Aids
10003982	Air Conditioners/Coolers - Fixed
10004063	Air Conditioning Equipment - Multifunction - Fixed
10003984	Air Conditioning/Cooling/Ventilation Equipment Replacement Parts/Accessories
10003985	Air Conditioning/Cooling/Ventilation Equipment Variety Packs
10003990	Air Dehumidifiers - Fixed
10003993	Air Humidifiers - Fixed
10006274	Air Monitors
10003988	Air Purifiers/Ionisers - Fixed
10003996	Duct Boosters
10003995	Fans - Ceiling
10003998	Fans - Extractor
10004064	Fans - Window/Exhaust
10005863	Backflow Test Kits
10002624	Bath Lifts
10006232	Hand Dryers
10002623	Shower Thermo Alarms
10004062	Toilet Seats/Lids
10007649	Health and Wellness Fittings - Accessories and Replacement Parts
10007646	Infrared Cabin
10007647	Sauna Cabin
10002660	Central Heating Replacement Parts/Accessories
10006399	Fireplace Tools
10007003	Heating Cable/Heat Tape/Heating Cord
10002662	Heating Equipment Variety Packs

10002653	Heating System Controls
10002658	Household Boilers/Furnaces/Tank Water Heaters
10007005	Household Boilers/Furnaces/Tank Water Heaters Replacement Parts/Accessories
10002657	Immersion Heaters
10002654	Radiators
10005717	Room Heaters
10005479	Tankless Water Heaters
10004002	Thermostats
10004003	Underfloor Heating Systems
10003994	Plumbing/Heating Ventilation/Air Conditioning Variety Packs
10006962	Bathroom Sink Accessories
10002610	Bathroom Suites
10002590	Bathtub/Shower Modules
10004029	Bathtub/Shower Modules - Jetted
10002596	Bathtubs - Jetted (Hot Tubs/Spas)
10007941	Faucet Replacement Parts/Accessories
10002602	Faucets/Taps
10007726	Shower Sets
10004044	Shower Spas
10006961	Toilet Accessories
10007017	Toilet/Bidet/Urinals Replacement Parts/Accessories
10002589	Toilet/Urinal Cisterns
10002586	Toilets
10002587	Urinals
10002611	Macerators
10004049	Septic Tanks
10004006	De-scalers (DIY)
10002649	Scale Inhibitors
10004016	Water Filtration Machines/Systems
10004012	Water Meters
10004008	Water Softeners (DIY)
10007038	Water Softeners Replacement Parts/Accessories
10004055	Pumps
10004024	Valves/Fittings - Water and Gas
10008011	Valves/Fittings Accessories/Replacement Parts - Water and Gas
10000791	Baby Safety Monitoring (Powered)
10006820	Baby Safety/Security/Surveillance - Other
10005385	Public Fire Alarms
10005389	Lifebelts/Life-Jackets/Lifesuits
10003427	Lightning Detectors - Powered
10005391	Lightning Rods/Accessories
10005872	Marine Electronic Chartplotters
10005874	Marine Navigation Radar Systems
10005873	Marine Navigation Software
10005474	Rock Salt/Ice Melting Products
10005394	Transponders
10005473	Alarm Systems Replacement Parts/Accessories
10005396	Burglar Alarms

10005397	Gas/Heat/Smoke Detectors
10007008	Glass Break Detector
10005398	Access Control Security Systems
10007007	Anti-Climb/Deterrent Security Product
10005401	Door Chains/Door Guards
10005399	Door/Gate Entry Intercoms
10005402	Door/Gate Viewers
10005403	Security Doors/Gates
10008069	Smart Doorbells
10005405	Window Burglar Bars/Panels/Shutters
10005407	Fire Blankets
10005408	Fire Extinguishers - Pressurised
10005409	Fire Hoses
10005410	Home/Business Fire Extinguishers Variety Packs
10005417	Home/Business Safety/Security/Surveillance Variety Packs
10005411	Bugging/Debugging Equipment
10005415	Home/Business Surveillance Equipment Variety Packs
10005412	Light/Motion/Sound Sensors
10005413	Security Lights
10005414	Surveillance Cameras/Recorders
10005373	Body Alarms
10005472	Emergency Survival Blankets/Sleeping Bags
10005374	Emergency Whistles
10005375	Key-ring Alarms
10005376	Personal Luggage Alarms
10005382	Personal Safety Devices Variety Packs
10005377	Personal Safety Flares/Signals
10005378	Personal Safety Lights
10006850	Remote Controlled Vehicles
10006851	Remotely Controlled Vehicle Replacement Parts and Accessories
10005380	Stun Guns
10005381	Wearable Wireless Webcams (Inverse Surveillance)
10005418	Safety/Security/Surveillance Variety Packs
10008110	Coin Operated Control Unit
10008109	Vending Machine
10004098	Fencing Sports Equipment (Powered)
10001813	Cycle Sports Equipment Other
10001812	Cycle Sports Equipment Variety Packs
10005815	Cycles (Powered)
10008275	Cycles Accessories - Computers/Navigation Equipment
10008276	Cycles Accessories - Other
10008260	Cycles Parts - Lighting
10001814	Exercise Machines (Powered)
10001822	Sports Exercise Monitors
10001843	Scooter/Skateboard Sports Equipment Other
10001842	Scooter/Skateboard Sports Equipment Variety Packs
10005814	Scooters/Skateboards/Hoverboards (Powered)

10001841	Skateboarding Sports Equipment - Replacement Parts/Accessories
10005703	Pumps (Powered)
10004111	Sports Scoring Equipment (Powered)
10001867	Target Sports Equipment - Replacement Parts/Accessories
10001869	Target Sports Equipment Other
10001868	Target Sports Equipment Variety Packs
10001865	Targets (Powered)
10001242	Calculators/Currency Converters (Powered)
10001243	Cash/Money Registers (Powered)
10001247	Laminating Machines (Powered)
10005229	Multifunctional Devices
10001248	Office Machinery Other
10001250	Office Machinery Variety Packs
10001251	Photocopier Consumables
10001252	Photocopiers
10005676	Typewriter Consumables
10001254	Typewriters (Powered)
10001262	Franking Machines
10001265	Letter Openers (Powered)
10001268	Postal Weighing Scales (Powered)
10005445	Overhead Projectors
10001277	Pointers (Powered)
10006406	Presentation Boards (Powered)
10001281	Presentation Equipment Accessories
10001280	Presentation Equipment Other
10001283	Presentation Equipment Variety Packs
10001288	Binding Machines (Powered)
10001300	Stationery Staplers (Powered)
10001312	Hole Paper Punches (Powered)
10005119	Paper Shredders (Powered)
10001231	Measuring/Geometrical Equipment
10001233	Pencil Sharpeners (Powered)
10006730	Electronic Cigarette Accessories
10006729	Electronic Cigarettes
10003461	Measuring Wheels
10003459	Micrometers
10006776	Moisture Meter (Soil)
10003458	Tape Measures (DIY)
10006777	Thermal Leak Detector
10008057	Military - Engineering Specialty Equipment - Powered
10003679	Hoists/Winches
10003749	Power Tools - Lifting/Handling Equipment Other
10003680	Power Tools - Lifting/Handling Equipment Replacement Parts/Accessories
10006779	Pulley Puller (Powered)
10005221	Wheelbarrows - Powered
10005230	Air Compressors - Stationary
10003597	Band Saws - Stationary
10003668	Belt Sanders - Stationary
10003598	Bench Grinders

10003604	Bench Jointers
10003611	Combination Sanders - Disc/Belt
10003609	Disc Sanders
10003613	Drill Presses/Mortisers
10003730	Jointer Planers - Stationary
10003605	Lathes - Stationary (Powered)
10003608	Power Tools - Stationary - Replacement Parts/Accessories
10003751	Power Tools - Stationary Other
10003603	Radial Arm Saws
10003602	Scroll Saws - Stationary
10003746	Shapers - Stationary
10003610	Spindle Sanders
10003729	Surface Planers - Stationary
10003601	Table Saws - Stationary
10008139	Tool Sharpeners (Powered)
10003596	Wet Saws/Tile/Glass Cutters
10007026	Abrasive Blasters/Sandblasters
10003555	Air Compressors - Portable
10003644	Angle Grinders
10003619	Angle Measurers (Powered)
10003651	Arc Welders
10005231	Band Saws - Portable
10003742	Belt Sanders - Portable
10005718	Biscuit Joiners
10003664	Caulking Guns (Powered)
10005214	Cement/Mortar Mixing Machines
10003643	Chisels (Powered)
10005223	Circular Saws
10003645	Cut-off Tools
10007028	Demolition Hammer
10003672	Detail Sanders
10005248	Disc Sanders/Drywall Sanders - Portable
10003618	Distance/Linear Measurers (Powered)
10003741	Drain Augers (Powered)
10003653	Drill/Drivers (Powered)
10003658	Drills - Combination (Powered)
10007029	Endoscope Camera (DIY)
10003669	Finishing Sanders
10003638	Foam Cutters - Powered
10005213	Glue Guns - Powered
10003663	Grease Guns (Powered)
10007027	Hammer Drill and Impact Driver Kit
10003659	Hammer Drills
10003662	Heat Guns
10007030	Hole Saw
10003655	Impact Drivers
10003656	Impact Wrenches
10007976	Industrial Wet/Dry Construction Vacuum Cleaner Filters
10007978	Industrial Wet/Dry Construction Vacuum Cleaner Heads

10007977	Industrial Wet/Dry Construction Vacuum Cleaner Hoses/Tubes
10007975	Industrial Wet/Dry Construction Vacuum Cleaners
10003631	Jigsaws - Powered
10003616	Jointer Planers - Portable
10003626	Laminate Trimmers
10003620	Laser Levels
10006277	Metal Detectors
10003738	Mitre Saws - Portable
10007031	Mixer/Vibrator
10003666	Nail Guns (Powered)
10003632	Nibblers/Shears - Metal (Powered)
10007032	Oscillating Multitools
10005653	Paint Applicators - Powered
10003640	Pipe Cutters (Powered)
10003750	Power Tools - Hand-held Portable Other
10003747	Power Tools - Hand-held Portable Replacement Parts/Accessories
10003629	Reciprocating Saws
10003660	Rotary Hammers
10007033	Rotary Multitools
10003641	Rotary Saws
10003737	Routers
10007034	Sanding Rollers (Powered)
10003657	Screw Guns
10003654	Screwdrivers (Powered)
10003649	Soldering/Brazing Irons
10003665	Staplers (Powered)
10003647	Straight/Die Grinders
10005869	Stud Finders/Detectors/Sensors
10003648	Surface Grinders
10003615	Surface/Thickness Planers - Portable
10003627	Table Saws - Portable
10007035	Wall Slotter (Powered)
10003884	Wall/Ceiling Covering Tools - Powered
10003744	Welding/Blow Torches
10007936	Welding/Blow Torches Replacement Parts/Accessories
10007937	Welding/Blow Torches Rods/Wire/Solder
10003682	Tools/Equipment - Power Variety Packs
10005134	Board Games (Powered)
10005136	Board Games/Cards/Puzzles Other
10005137	Board Games/Cards/Puzzles Variety Packs
10005139	Card Games (Powered)
10005141	Puzzles (Powered)
10005154	Baby/Infant Stimulation Toys (Powered)
10005155	Bath/Pool Water Toys
10005157	Communication Toys (Powered)
10005159	Developmental/Educational Toys Other
10005160	Developmental/Educational Toys Variety Packs
10005162	Push/Pull-along Toys (Powered)
10005164	Scientific Toys (Powered)

10005165	Spinning Tops/Yo-Yos
10005167	Toy Building Blocks (Powered)
10005712	Toy Computer Accessories
10005158	Toy Computers
10005442	Toy Drawing Boards/Accessories
10005169	Toy Model Construction (Powered)
10005171	Viewing Toys (Powered)
10006396	Action Figures (Powered)
10005144	Dolls/Puppets/Soft Toys Other
10005143	Dolls/Soft Toys (Powered)
10005145	Puppets
10006397	Action Figure Accessories
10005147	Dolls Buildings/Settings
10005149	Dolls Furniture
10005150	Dolls/Puppets/Soft Toys Accessories Other
10005151	Dolls/Puppets/Soft Toys Accessories Variety Packs
10005152	Puppet Theatres
10005440	Styling Dolls Heads (Powered)
10005176	Fancy Dress Accessories (Powered)
10005172	Fancy Dress Costumes
10005173	Fancy Dress Costumes/Accessories Other
10005174	Fancy Dress Costumes/Accessories Variety Packs
10005181	Indoor/Outdoor Games
10005182	Outdoor Play Structures
10005178	Musical Toys (Powered)
10005179	Musical Toys Other
10005684	Role Play - Housekeeping/Gardening/DIY Toys
10005250	Role Play - Kitchen Toys
10005685	Role Play - Shopping/Office/Business Toys
10005184	Table Games (Powered)
10005185	Table Games Other
10005192	Car/Train Set - Replacement Parts/Accessories
10005191	Car/Train Sets (Powered)
10005194	Toy Vehicles - Non-ride (Powered)
10005195	Toy Vehicles - Non-ride Other
10005196	Toy Vehicles - Non-ride Variety Packs
10005188	Toys - Ride-on (Powered)
10005441	Toys - Ride-on Accessories
10005189	Toys - Ride-on Other
10005443	Practical Jokes
10006899	Toys/Games - Other
10005186	Toys/Games Variety Packs