This document contains the comments the MPCA received during the Request for Comments public comment period September 25, 2023, through November 28, 2023, for the planned new rules governing PFAS in Products Reporting, Revisor ID # R-4828.

39507 Minnesota Pollution Control Agency Request for Comments on PFAS in Products Reporting Rule

Closed Nov 28, 2023 · Discussion · 35 Participants · 1 Topics · 37 Answers · 0 Replies · 0 Votes

35	1	37	0	0
PARTICIPANTS	TOPICS	ANSWERS	REPLIES	VOTES

SUMMARY OF TOPICS

SUBMIT A COMMENT

37 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.

Steven Kooy · Citizen · (Postal Code: unknown) · Nov 17, 2023 8:21 am

0 Votes

Please see comments attached.

Dawn Friest · Citizen · (Postal Code: unknown) · Nov 21, 2023 1:49 pm

0 Votes

Please see attached comments of the Truck and Engine Manufacturers Association.

Charles Fox · Citizen · (Postal Code: unknown) · Nov 23, 2023 9:41 am

0 Votes

OE Electrics Inc as a small importer of Electrical products for office use has the same concerns as expressed by BIFMA and EMA regarding the difficulty of reporting PFAS at the electrical/electronic/mechanical component level, for example PFAS is universally used in thermoplastics to ensure material compliance with UL electrical standards. If there is no reporting waivers for this category in particular where PFAS is not intentionally added to te final product in an external coating or fabric treatment the state could end up having thousands of reporting submissions of little value and spend considerable time and thus cost dealing with individual submissions for waivers.

Robert Denney · Citizen · (Postal Code: unknown) · Nov 27, 2023 1:03 pm

0 Votes

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

Javaneh Tarter · Citizen · (Postal Code: unknown) · Nov 27, 2023 1:22 pm
0 Votes

Please see attached comments submitted on behalf of Lac-Mac Limited

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Jared Rothstein · Citizen · (Postal Code: unknown) · Nov 27, 2023 1:48 pm
0 Votes

Please see attached comments submitted on behalf of the Consumer Brands Association.

Shivani Swami · Citizen · (Postal Code: unknown) · Nov 27, 2023 2:15 pm
0 Votes

Dear members of the Minnesota Office of Administrative Hearings,

Attached please find the comments of Gujarat Fluorochemicals Limited (“GFL”) supporting science-based development of the PFAS in Products Reporting Rule. The comments focus on the distinction between certain fluoropolymers and other chemicals included in the parent Act's definition of PFAS. GFL welcomes the opportunity to discuss its comments in greater detail. Please do not hesitate to contact GFL or Akin should that be of interest.

Thank you!

Robert Denney · Citizen · (Postal Code: unknown) · Nov 27, 2023 4:11 pm
0 Votes

Please see attached comments submitted on behalf of a client who is a worldwide leader in the manufacture of information and communications technology products.

Christopher Finarelli · Citizen · (Postal Code: unknown) · Nov 27, 2023 4:47 pm
0 Votes

Please see attached comments submitted on behalf of the Household & Commercial Products Association (HCPA).

Erica Corser · Citizen · (Postal Code: unknown) · Nov 27, 2023 5:24 pm
0 Votes

Please see attached comments for the PFAS in Products Reporting Rule submitted on behalf Honeywell.

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Emi Yamamoto · Citizen · (Postal Code: unknown) · Nov 27, 2023 5:35 pm
0 Votes

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

Peter Glessing · Citizen · (Postal Code: unknown) · Nov 27, 2023 7:46 pm
0 Votes

Attached is the public comment submission from Medical Alley pertaining to the MPCA's Request for Comment on PFAS in Products Reporting Rule

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Rosanna Imholte · Citizen · (Postal Code: unknown) · Nov 28, 2023 7:59 am
0 Votes

Please see attached comments submitted on behalf of Polar Semiconductor.

Andrew Bemus · Citizen · (Postal Code: unknown) · Nov 28, 2023 9:26 am
0 Votes

Please see attached comments submitted on behalf of the Sustainable PFAS Action Network (SPAN).

Avonna Starck · Citizen · (Postal Code: unknown) · Nov 28, 2023 9:33 am
0 Votes

Clean Water Action Minnesota comments are attached. Thank you.

Judah Prero · Citizen · (Postal Code: unknown) · Nov 28, 2023 9:54 am
0 Votes

Attached, please find the comments of the Chemical Users Coalition (CUC).

Riaz Zaman · Citizen · (Postal Code: unknown) · Nov 28, 2023 10:09 am
0 Votes

Please see attached comments from the American Coatings Association (ACA).

Mary Schilling · Citizen · (Postal Code: unknown) · Nov 28, 2023 11:48 am
0 Votes

Comments from the Personal Care Products Council are attached. Thank you for this opportunity.

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John Keane · Citizen · (Postal Code: unknown) · Nov 28, 2023 12:06 pm
0 Votes

Please see attached comments from the Association of Home Appliance Manufacturers (AHAM).

Lori Austino · Citizen · (Postal Code: unknown) · Nov 28, 2023 12:43 pm
0 Votes

Please see attached comments from DuPont de Nemours, Inc.

Kami Thoen · Citizen · (Postal Code: unknown) · Nov 28, 2023 1:02 pm
0 Votes

Please see attached comments submitted on behalf of Kindeva Drug Delivery L.P.

Tony Kwilas · Citizen · (Postal Code: unknown) · Nov 28, 2023 1:08 pm
0 Votes

Minnesota Chamber of Commerce comments

Catherine Palin · Citizen · (Postal Code: unknown) · Nov 28, 2023 1:24 pm
0 Votes

Please see the attached comments filed by the Alliance for Automotive Innovation.

Jay West · Citizen · (Postal Code: unknown) · Nov 28, 2023 1:51 pm
0 Votes

Please see the attached comments from the American Chemistry Council's Performance Fluoropolymer Partnership.

Ben Kallen · Citizen · (Postal Code: unknown) · Nov 28, 2023 2:02 pm
0 Votes

Please see the attached comments submitted on behalf of SEMI.

Peggy J Horst · Citizen · (Postal Code: unknown) · Nov 28, 2023 2:32 pm
0 Votes

Please see attached comments for the Reporting Rule on behalf of W. L. Gore & Associates, Inc. We are also including 2 additional attachments with this submission, as well as a second submission (2 additional attachments) which supports these comments.

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Peggy J Horst · Citizen · (Postal Code: unknown) · Nov 28, 2023 2:33 pm
0 Votes

Please see the attached, additional attachments, that are submitted in support of the previously comments for the Reporting Rule, as submitted by W. L. Gore & Associates, Inc.

Michael Blume · Citizen · (Postal Code: unknown) · Nov 28, 2023 2:46 pm
0 Votes

Please see the attached comments.

Steve Barthel · Citizen · (Postal Code: unknown) · Nov 28, 2023 2:59 pm
0 Votes

Please see attached comments from the Minnesota Grocers Association.

Roxolana Kozyckyj · Citizen · (Postal Code: unknown) · Nov 28, 2023 3:00 pm
0 Votes

Please see attached comments from AdvaMed, the largest national trade association representing manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems.

Jason Malcore · Citizen · (Postal Code: unknown) · Nov 28, 2023 3:03 pm
0 Votes

Please see attached comments from the Association of Equipment Manufacturers.

Edith Nagy · Citizen · (Postal Code: unknown) · Nov 28, 2023 3:12 pm
0 Votes

Please see attached comments submitted on behalf of the Coalition of Manufacturers of Complex Products.

Amanda Hagan · Citizen · (Postal Code: unknown) · Nov 28, 2023 3:15 pm
0 Votes

Comments from the Animal Health Institute are attached.

Jesse McArdell · Citizen · (Postal Code: unknown) · Nov 28, 2023 3:25 pm
0 Votes

Please see the attached comments from the National Marine Manufacturers Association (NMMA), the Water Sports Industry Association (WSIA), and the Marine Retailers Association of the Americas (MRAA).

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Daniel Moyer · Citizen · (Postal Code: unknown) · Nov 28, 2023 3:28 pm

0 Votes

Please see the attached comments from the Consumer Technology Association

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Marcus Branstad · Citizen · (Postal Code: unknown) · Nov 28, 2023 3:49 pm

0 Votes

Please see attached Comments on PFAS in Products Reporting; OAH Docket No. 65-9003-39507 on behalf of the American Chemistry Council, the Performance Fluoropolymer Partnership, the Alliance for Telomer Chemistry Stewardship, and the Center for the Polyurethanes Industry.

Best Technology · Citizen · (Postal Code: unknown) · Nov 28, 2023 3:56 pm

0 Votes

Please see the attached comments from Best Technology

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 (MPCA)

From: Steve Kooy

Date: November 17th, 2023

Subject: **PFAS in Products Reporting Rule**

The Business Institutional Furniture Manufacturers Association (BIFMA) appreciates the opportunity to comment on the Products Reporting Rule. BIFMA represents over 150 North American manufacturers and suppliers who provide the majority of contact 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.

Please consider the following comments pertaining to Session Law – 2023, chapter 60, article 3, section 21, subdivision 2, specifically answers to the questions raised in the request for comments document.

1) Are there definitions in subdivision 1 for which clarification would be useful to understanding reporting responsibilities?

[BIFMA]: Definitions as written are suitable.

2) Are there terms or processes in subdivision 2 for which clarifications will help reporting entities determine reporting status or data-gathering process?

[BIFMA]: We recommend aligning with California's AB-1817 legislation. The legislation focused on PFAS contained in textiles. Electrical and mechanical (e.g. cylinders) componentry and paint should be exempt from reporting. These components are not specific to our industry rather manufactured at large scales for automotive, housing (e.g. electrical sockets), and other consumer based industries. Collecting data and/or phasing out PFAS from these sources is beyond the reach of BIFMA members given their small buying power.

3) How should the MPCA balance public availability of data and trade secrecy as part of the reporting requirements?

[BIFMA] Our members and their clients continue to push full product transparency. As a result ecolabels such as Declare® and Health Product Declarations are common. These programs allow proprietary information regarding ingredients to remain confidential; however, risk (e.g., toxicity) is communicated. This is extremely important as Non-Disclosure Agreements (NDAs) are common practice to obtain chemical ingredient information. BIFMA recommends respecting NDAs in place to promote better quality data collection.

4) Are there any terms used in subdivision 3 that should be further defined or where examples would be helpful?

[BIFMA] No comment

5) Are there specific portions of the reporting process that should not be defined through guidance or the development of an application form?

[BIFMA] We encourage the adoption of the state of Washington and/or other states to drive consistency in guidance, reporting information, etc.

6) Other questions or comments relating to reporting or the process of reporting.

[BIFMA] We request electrical, mechanical, and paint related information be exempt from the reporting requirements. We believe this will drive better quality data while meeting the intent of the requirements related to upholstered furniture.

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 further information.

Thank you,

Steve Kooy
Director of Health and Sustainability
BIFMA

Truck & Engine Manufacturers Association®
Bringing Clean Power to the World™

333 West Wacker Drive, Suite 810
Chicago, Illinois, 60606
Phone/Fax: (312) 929-1970
www.truckandenginemanufacturers.org

November 21, 2023

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

Minnesota Pollution Control Agency
Resource Management and Assistance Division

Re: Request for Comments – PFAS in Products Reporting Rule

The Truck and Engine Manufacturers Association (EMA) hereby submits comments on the planned new rules for submission of required information about products containing Per-and polyfluoroalkyl substances (PFAS). The rulemaking is referred to as the PFAS in Products Reporting Rule (the Rule).

The Minnesota Pollution Control Agency (MPCA) has issued a Request for Comments, giving notice of its intent to begin rulemaking. The Rule establishes a program for the MPCA to collect information about products containing PFAS, as required by Minnesota Session Law – 2023, chapter 60, article 3, section 21, (Minnesota Statutes 116.943)(the Minnesota Law).

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. Consequently, EMA's members are significantly and directly impacted by the Rule.

Duplicative Reporting Requirements and Associated Fees

The Environmental Protection Agency (EPA) has finalized a PFAS reporting rule under TSCA § 8(a)(7). 88 FR 70516, October 11, 2023. EPA is directing resources to implement the comprehensive approach outlined in the PFAS Strategic Roadmap and manufacturers are working to respond to federal activity. In addition, state activity is developing that overlaps with EPA efforts to identify and address PFAS use. State activity will only complicate an already extraordinarily complex issue. Duplicative reporting efforts will consume time and effort that would be better directed at the core issue of identification of PFAS and associated supply chain management.

Duplicative or overlapping state and federal requirements will overwhelm manufacturers and will be particularly burdensome for manufacturers of complex products that rely on global supply chains. Many of the rules also include a fee component. The cumulative impact of fee collection by multiple authorities and the human resource burden of reporting to multiple state authorities, in addition to the substantial reporting burden associated with the EPA PFAS reporting rule will be significant, even with an approach that recognizes disclosures to other regulatory authorities. Inconsistencies in the definitions and the reporting format will add complexity and increase the time needed to manage reporting obligations.

If states insist on proceeding with state specific requirements, they should include a mechanism that waives reporting requirements where information has been disclosed to other jurisdictions at the state or federal level. We note the reference to a waiver provision where the commissioner determines that substantially equivalent information is already publicly available. (Minnesota Statutes 116.943, s. 21, subd. 3). Identification and notification of substantially equivalent information should be made public so that MPCA can avoid individually assessing repeated waiver requests that reference submissions to the same agency (EPA or another state). An updated list of substantially equivalent sources of information should be maintained by Maine DEP and made accessible to regulated parties. Maintaining an updated list will improve consistency and certainty in the implementation of the regulation. Data entry can be time-consuming and reentry of data submitted to other jurisdictions should not be required.

Ideally Minnesota and other states should allow EPA to lead in PFAS regulatory requirements to avoid duplicative, and potentially conflicting requirements. However, recognizing that legislative requirements may require regulatory agencies to develop PFAS rules, we urge state regulatory agencies to seek an aligned approach, specifically with respect to definitions and the reporting format. Moreover, we urge states to provide a clear mechanism to recognize PFAS disclosures to EPA under TSCA requirements, and disclosures to other states that may adopt reporting obligations, although we strongly discourage such state action. Failure to consider the cumulative impact of multiple reporting requirements may result in unintended consequences as manufacturers seek ways to manage the expanding burden.

Methodology for Reporting

Complex products, like heavy-duty 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. This high level of customization should not necessitate reporting for each component or product group that could be installed on vehicles or equipment.

Manufacturers should be permitted to report on the basis of the highest level of assembly that a manufacturer produces for sale. For example, a complete engine, vehicle or piece of equipment should be considered under a single notification without any additional sub-identification of PFAS in individual components. Moreover, the reporting methodology must allow for the reality that even within a single model designation, not all vehicles and equipment will have identical PFAS content.

PFAS Definition

The proposed PFAS definition is extremely broad and could encompass over 12,000 PFAS chemistries. We request that MPCA establish de minimus reporting thresholds and provide a defined list of CAS identified PFAS chemistries that are subject to the requirements. Without reasonable limits on the scope of the reporting requirements, manufacturers face an unworkable task of investigating thousands of parts in a global supply chain consisting of hundreds of suppliers.

Responsibility for Reporting

We have noted that under the definition of "Manufacturer" on page 2 of the Request for comments, MPCA references imported product. However it is unclear how the reporting obligations may apply to such manufacturers. The language that references a "presence in the United States" is vague and does not provide sufficient certainty to determine which entities would have reporting obligations. Global manufacturers should not be responsible for reporting obligations when products enter the Minnesota market without the prior knowledge of the global manufacturer.

Timeline for 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 may need to investigate thousands of components. We anticipate that the process could take at least 2 years to complete for complex products. Moreover, development of a database and reporting format cannot be fully completed until the details of a final rule are available, which cannot occur prior to 2024 and reporting obligations must be met by January 1, 2026. Consequently, we expect that additional time will be required to meet the reporting obligations and we request that the proposed rule provide an extension of the reporting deadline to January 1, 2027, at the earliest.

Impacts of Restrictions and Bans

We encourage MPCA to fully consider the potential impacts of restrictions and bans of the use of PFAS. Substitutes for PFAS chemicals will not be easily identified and may not be available in any event. We understand that the Law allows for identification of "Currently unavoidable use" of PFAS. In many instances, their use is necessary in order to achieve compliance with other regulatory requirements related to flame resistance (i.e., the Federal Motor Vehicle Safety Standard No. 302, Flammability of Interior Materials) and durability requirements to ensure the long-term durability of components, including emissions components. PFAS, as broadly defined in the proposed rule, may also include some refrigerants, like HFC-134a, and HFO-1234yf, which are widely used because of their extremely low global warming potential. In fact, the transition to HFO-1234yf has been spurred by Federal rulemaking activity related to reducing HFCs. MPCA should also consider that PFAS is used in alternative power technologies, including batteries and

hydrogen fuel cells to imbue vital functional properties. Many PFAS compounds are very expensive and these compounds are used because they are effective and no suitable alternatives have been identified.

Where PFAS is used in components subject to other federal requirements (like engines and vehicles), any substitution or change in the components may require significant and time-consuming, testing, verification and certification of any redesign or substitute. Where durability requirements are applicable, testing burdens can be significant. Resources for such testing are finite and are already overburdened with demands related to design and certification of new products. Introducing the additional project of identifying chemical substitutes and proving them out for durability, safety and emissions verification purposes will certainly create timing and resource management challenges that may lead to supply shortages for critical components and products.

MPCA must consider the nature of the products impacted. Heavy duty engines, vehicles and equipment are not the same as a mattresses, frying pans, carpets, and other disposable consumer products, and they should not be treated the same under the proposed rule. Commercial vehicles, engines and equipment are long-lasting, durable by design and regulatory mandate, and utilize end-of-life design provisions to ensure that potentially problematic substances are captured and recycled. Remanufacturing processes are an integral part of the heavy-duty industry and support the development of a circular economy while promoting robust waste management to prevent releases of pollutants to the environment. Aftermarket parts and components must also be considered to ensure that in-service equipment is not impacted by restrictions on legacy parts. Transition to substitutes for PFAS will be extremely challenging for new products moving forward. Expectations that legacy parts and components will also transition to substitutes is simply unrealistic. Failure to recognize this fundamental obstacle will lead to critical shortages of parts and will lead to in-service equipment being rendered obsolete, short of their expected full useful life.

Additionally, the overly broad definition of PFAS and lack of alignment with known reporting formats will undoubtably lead to overreporting. The scope of the proposed reporting obligations and the volume of information that will be captured under the proposed requirements will be overwhelming for manufacturers and regulators alike. This fact cannot be overstated. The reporting approach in the proposed rule has the potential to bury MPCA in information of questionable value, much of which will not be helpful in addressing legitimate concerns with PFAS and potential releases into the environment. Regulatory efforts should focus on high risk PFAS chemicals and high-risk end-use applications.

Conclusion

It is critically important that the MPCA consider the potential impacts of reporting requirements, restrictions and bans on the use of PFAS. PFAS plays an important role in the functionality, durability, and safety of many products. Alternatives have not been identified for many critical PFAS uses in engines, vehicles and equipment and as such, the use of PFAS in these applications should be considered a “Currently unavoidable use”.

The definition of PFAS must be narrowed. A de minimus reporting threshold must be identified. The reporting requirements and format should align with EPA and recognize reports submitted to other jurisdictions and should not duplicate or conflict with federal efforts. EPA should lead efforts on PFAS reporting and restrictions.

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

133966.3

Ryan J Carra
1900 N Street, NW, Suite 100
Washington, DC 20036
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RCarra@bdlaw.com

November 27, 2023

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 to MPCA's Planned New Rule on Reporting for PFAS-Containing Products

Dear Commissioner Kessler:

The PFAS Pharmaceutical Working Group ("PPWG")[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") planned new rule concerning submission of information on products containing PFAS (the "Reporting Rule"), implementing Minn. Stat. § 116.943 ("Section 116.943"), subdivision 2. The MCPA rule should state expressly that U.S. Food and Drug Administration ("FDA") regulated products and their packaging are out of scope of the Reporting Rule. This would be consistent with principles of federal preemption. Such language would avoid disputes about the scope of federal preemption and provide certainty to regulated entities, medical professionals, and patients that products will remain on the market in Minnesota. Manufacturers of such products would also not be subject to associated reporting fees, which we understand is the subject of a concurrent MPCA request for comments.

I. INTRODUCTION

Section 116.943, subdivision 2 requires that, on or before January 1, 2026, a manufacturer of a product sold, offered for sale, or distributed in Minnesota that contains intentionally added PFAS must submit to the MPCA information including a description of the product, the purpose of the PFAS in the product, the amount of each PFAS in the product, the manufacturer's contact information, and any additional information requested by the agency as necessary to implement the law. Subsection (d) of subdivision 2 makes it unlawful for any person to sell, offer for sale, or distribute in Minnesota a product subject to reporting if the manufacturer has failed to submit the required notification and that person has received notification under subdivision 4. Subdivision 4 in turn authorizes the MPCA to order testing if

[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.

the agency has reason to believe a product contains intentionally added PFAS; if testing demonstrates that the product contains intentionally added PFAS but the product has not been reported pursuant to subsection 2, the manufacturer must notify (and the MPCA may notify) persons who sell or offer for sale the product that the sale is prohibited in Minnesota. Subdivision 5 of the law includes material restrictions, including a prohibition on the sale, offer for sale, and distribution in commerce of any product containing intentionally added PFAS beginning January 1, 2032.

Subdivision 8 of the law includes exemptions, including an exemption from subdivisions 4 and 5 for "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 [FDA]." This statutory exemption for FDA-regulated products does not by its text extend to the law's reporting requirements in subdivision 2. However, Section 116.943, subdivision 9 authorizes the MPCA to "adopt rules necessary to implement this section." Under principles of federal preemption, and as described in these comments, an express exemption in the Reporting Rule for drugs and devices (which should extend to these products' packaging) is "necessary" as authorized by the Minnesota Legislature.

States are largely preempted from regulating medical and pharmaceutical products, including these products' packaging, because these items are heavily regulated by the FDA. This preemption extends to both material restrictions and notification requirements imposed by states on these items, and therefore we request that the Reporting Rule include an express exemption for FDA-regulated products and their packaging. The promulgation of the Reporting Rule without this exemption would impose a significant and unreasonable burden on PPWG's members' abilities to serve patients, healthcare providers, and other customers. Without this exemption, and because Section 116.943 prohibits the sale and distribution of regulated products if the manufacturer has failed to report the required information and the ordered testing demonstrates the products contain intentionally added PFAS, the Reporting Rule could result in the withdrawal of certain drugs and devices entirely from the market to the detriment of public health.

II. FDA GOVERNS AND CONTROLS THE PRESENCE OF PFAS IN REGULATED PRODUCTS AND THEIR PACKAGING, THEREBY EXEMPTING THEM FROM THE REPORTING RULE

a. Requested Exemption Language

The provisions of this chapter do not apply to any of the following:

> *(a) A product regulated as a drug, medical device, or dietary supplement by the United States Food and Drug Administration.*
>
> *(b) A medical equipment or product used in medical settings that is regulated by the United States Food and Drug Administration.*
>
> *(c) A product intended for animals that is regulated as animal drugs, biologics, parasiticides, medical devices, and diagnostics used to treat or are administered to animals under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), the federal Virus-Serum-Toxin Act (21*

U.S.C. Sec. 151 et seq.), or the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 136 et seq.).

(d) Packaging used for the products described in subsections (a) – (c) of this section.

The above exemption language was modeled after the exemption in California AB2247, which was passed by the California Legislature.[2] The scope of the California exemption is also consistent with the U.S. Environmental Protection Agency's ("EPA's") newly finalized PFAS reporting rule under the Toxic Substances Control Act ("TSCA"). *See* 88 Fed. Reg. 70516 (Oct. 11, 2023) (drugs and devices are exempt from TSCA pursuant to 15 U.S.C. § 2602(2)). As these examples show, regulators commonly provide exemptions for medical and pharmaceutical products in their chemical laws and regulations, and for good reason. These exemptions avoid disputes about the scope of federal preemption, and they are also critical for medical professionals and patients who rely on these products staying on the market. This is especially the case for application of the Reporting Rule since the sale and distribution of in-scope products under Section 116.943 is prohibited if the manufacturer fails to report and the ordered testing demonstrates the products contain intentionally added PFAS.

b. Medical and Pharmaceutical Products Already Undergo Intense Safety Review and Reporting Processes at the Federal Level and FDA has Determined that they Have a Favorable Benefit-Risk Profile

The medical and pharmaceutical manufacturing industry is one of the most highly regulated industries in the United States. The industry's products do not enter the market without first undergoing intense federal agency review to evaluate product safety and efficacy. Regulated products include, but are not necessarily limited to, drugs, biologics, medical devices, combination products, animal drugs, and animal devices. The federal statutes that these products are subject to include the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 et seq.; the Public Health Services Act ("PHSA"), 42 U.S.C. § 201 et seq.; and the Virus-Serum-Toxin Act ("VSTA"), 21 U.S.C. § 151 et seq.

Medical and pharmaceutical products are also subject to stringent federal regulations that implement the above statutes, such as from FDA's pre-market approval ("PMA") requirements for certain medical devices, 21 C.F.R. § 814, and the agency's Current Good Manufacturing Practice ("CGMP") regulations, *id*. § 210 et seq. Through the New Drug Application ("NDA," for new traditional drugs), Abbreviated New Drug Application ("ANDA," for generic drugs), Biological License Application ("BLA," for biologic drugs and biosimilars), and over-the-counter ("OTC") monograph (for OTC drugs) approval pathways, FDA considers and makes its safety determinations in light of detailed information from the manufacturer regarding all drug product components. For instance, an NDA is a lengthy compilation of materials that must

[2] Governor Newsom vetoed the legislation for reasons unrelated to the exemption language. The veto statement observed that implementing the legislation would be overly expensive for the state as well as duplicative of federal efforts. California AB 2247 Veto Statement (Sept. 29, 2022), https://www.gov.ca.gov/wp-content/uploads/2022/09/AB-2247-VETO.pdf?emrc=cc359d. California AB2247 did not include a subsection explicitly exempting the packaging used for drugs and devices (which we added above as subsection (d)), but such an exemption is warranted as explained below.

include, among other information, "any . . . data or information relevant to an evaluation of the safety and effectiveness of the drug product." *Id.* §§ 314.50(d)(5)(iv).

Approval pathways are likewise available for animal drugs in the form of New Animal Drug Applications ("NADAs") and Abbreviated New Animal Drug Applications ("ANADAs"). Like with human drug applications, animal drug applications must include extensive information on the components of the proposed product, including "a full list of the articles used as components of such drug," "a full statement of the composition of such drug," and "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug." 21 U.S.C. §§ 360b(b)(1), (n)(1)(G).

Medical devices are also regulated strictly under federal law. The FDA began regulating medical devices in 1976, when Congress enacted the Medical Device Amendments to the FFDCA, Pub. L. No. 94-295, 90 Stat. 539 (1976). The FDA classifies medical devices into three classes based on their risk profiles, and the agency regulates those classes separately. Class I devices, such as bandages and toothbrushes, are subject to "general controls," which include prohibitions on adulteration and misbranding, a requirement that the device producers register with the FDA, and various recordkeeping and reporting requirements. 21 U.S.C. §§ 351, 352, 360, 360i. Class II devices, such as powered wheelchairs and some pregnancy test kits, are subject to both general and special controls. Special controls are usually device-specific and may include "the promulgation of performance standards . . . and other appropriate actions as the Secretary deems necessary to provide such assurance." *Id.* § 360c(a)(1)(B).

Class III devices usually sustain or support life, are implanted, or present potentially unreasonable risk of illness or injury, and include stents, pacemakers, and breast implants. Such devices are subject to general controls and to the FDA's PMA process. Approval may be achieved by submission of a PMA application or by a "510(k) notification," including a demonstration that the device is "substantially equivalent" to an already-approved Class III device. *Id.* § 360c(f)(1)(A)(ii). A PMA must include an intensive collection of materials and descriptions, including a "a complete description of . . . [e]ach of the functional components or ingredients of the device if the device consists of more than one physical component or ingredient." 21 C.F.R. § 814.20(b)(4).

This federal oversight and control over the exact composition of drug products and medical devices necessarily includes any PFAS that may be present in those products. Medical and pharmaceutical products that have been authorized for marketing, and continue to be monitored under, these rigorous approval or clearance processes have been deemed to have a favorable safety and effectiveness profile by the federal government for their intended uses. A state PFAS reporting regulation that does not exempt these products, especially one that ties the reporting obligation to a company's ability to sell and distribute product such as in Minnesota, would risk compromising the federal process and depriving patients of life-enhancing or life-saving medical treatments.

c. The Exemption Would Ensure Continued Access to Critical Medical and Pharmaceutical Products

Several PFAS laws contain unrealistic reporting and restriction timelines for manufacturers of in-scope products. Product manufacturers have observed, and regulators have acknowledged, that significant lead time is required to meet these obligations. For instance, the Maine Department of Environmental Protection ("DEP") was unable to even *propose* regulations to implement the notification requirement in the state's PFAS law until months after the statutory deadline for notification had passed.[3] Given this difficulty, Maine enacted an amendment to the law that extends the statutory deadline for notification by two years. The amendment also provides more flexibility in the substance of the notification and makes clarifications such as codifying express exemptions for packaging. *Id*. We also understand that members of Maine DEP's PFAS team presented testimony at a recent legislative meeting concerning the state's PFAS law held by the Maine Legislature Joint Standing Committee on Environment and Natural Resources on October 2, 2023.[4] In its presentation, Maine DEP acknowledged challenges it has encountered and anticipates in promulgating its regulations. Implicit in the agency's presentation were reservations about how Maine DEP would manage a large database of potentially confidential business information, prevent double-counting of PFAS in products with multiple components, and evaluate continued extension requests from companies that may need more time to comply with the disclosure requirement.

In addition, EPA was required by Congress in TSCA section 8(a)(7), 15 U.S.C. § 2607(a)(7), to promulgate a PFAS reporting rule by January 1, 2023. That rule was not published until October 11, 2023, in part because an Initial Regulatory Flexibility Analysis released by the agency in late 2022 demonstrated that the proposed rule would carry compliance costs of over $875 million, which were 80 times more than the $10.8 million originally projected. *See* 87 Fed. Reg. 72440 (Nov. 25, 2022). EPA reported in the final rule that compliance costs will be $843 million, which is still a significant increase from what was originally proposed. *See* 88 Fed. Reg. 70517 (Oct. 11, 2023).

If a manufacturer's notification obligations under Section 116.943 cannot be timely met, consistent with a manufacturer's other legal obligations and its obligations to customers to provide safe and effective products, the product must be removed from the market if the ordered testing demonstrates the product contains intentionally added PFAS. For manufacturers in the highly regulated medical and pharmaceutical products industries, this consequence could very well become reality. These manufacturers may rely on starting materials, intermediates, and other components that contain PFAS for stability and durability properties, and there is a real risk that the January 1, 2026 deadline to determine whether their products contain intentionally added PFAS will not be met given these manufacturers' vast supply chains and potentially varying uses of PFAS. If the deadline is not met, the MPCA may order testing and then the product may have

[3] The original statute contained a deadline of January 1, 2023 for entities to report the products they sell in Maine which contain intentionally added PFAS. Maine DEP granted extensions to this deadline for thousands of companies, thereby implicitly conceding that the timeline set out in the statute was far too ambitious. *See* Maine DEP, 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.

[4] *See* Maine Legislature Joint Standing Committee on Environment and Natural Resources, Materials for October 2, 2023 Meeting, https://legislature.maine.gov/doc/10288.

to be pulled from the market. Under this scenario, the manufacturer would have to develop a product alternative that does not contain intentionally added PFAS, though this would take years given that drug and device manufacturers often must seek and receive approval from the appropriate regulatory authority for changes to their products and packaging. Moreover, the identification and use of alternative materials may entail substantial research and testing, and alternatives may not be readily available without impacting the safety, quality, or efficacy of those products. Given this possible years-long delay in developing and producing product alternatives, removal of medical and pharmaceutical products from the market would harm the millions of patients that depend on them. An express exemption in the Reporting Rule for medical and pharmaceutical products would confirm this would not happen.

d. The Exemption Should Explicitly Cover Packaging

Like the products themselves, the packaging for medical and pharmaceutical products is already highly regulated under federal law. This is because product packaging can be critical to appropriate product administration and preservation of product quality for drugs and devices. FDA approves the product and packaging to ensure that the product remains safe and effective and can be used consistent with its labeled uses until product expiration. Changes to packaging must be carefully assessed and approved by FDA because some changes, such those prompted by a PFAS reporting obligation where failure to report may cause the product to be pulled from the market, could have unintended consequences for product integrity or use.

For instance, once a small molecule drug—whether brand-name or generic—is approved by FDA, its manufacturer is prohibited from making any "major changes" to the product without FDA approval. 21 C.F.R. §§ 314.70(b)(1), (3). "Major changes" include "any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product." *Id.* § 314.70(b)(1). Examples of such changes that require FDA approval include "[c]hanges in a drug product container closure system that controls the drug product delivered to a patient or changes in the type (e.g., glass to high density polyethylene (HDPE), HDPE to polyvinyl chloride, vial to syringe) or composition (e.g., one HDPE resin to another HDPE resin) of a packaging component that may affect the impurity profile of the drug product." *Id.* § 314.70(b)(2)(vi). Therefore, a drug manufacturer often may not alter the formulation of a drug product's packaging without FDA's further approval.

III. UNDER THE PRINCIPLES OF FEDERAL PREEMPTION, THE REPORTING RULE DOES NOT APPLY TO MEDICAL AND PHARMACEUTICAL PRODUCTS

a. Principles of Federal Preemption

The Supremacy Clause of the U.S. Constitution provides that federal law "shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. This clause gives Congress the power to preempt state law, such that "state law that conflicts with federal law is without effect." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992). "[T]he purpose of Congress is the ultimate touchstone of preemption analysis." *Id.* at 516; *see also Consumer Data Indus. Ass'n v.*

Frey, 26 F.4th 1, 5–6 (1st Cir. 2022) ("To illuminate this intent, we start with the text and context of the provision itself.") (quotations omitted).

"In general, there are three different types of preemption – express, conflict, and field." *Consumer Data Indus.*, 26 F.4th at 5 (quotations omitted). "Express preemption occurs when congressional intent to preempt state law is made explicit in the language of a federal statute." *Id*. By contrast, "[c]onflict preemption takes place when state law imposes a duty that is 'inconsistent—i.e., in conflict—with federal law.'" *Id*. (quoting *Murphy v. Nat'l Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1480 (2018)). Conflict preemption is itself divided into two types: obstacle preemption and impossibility preemption. "Obstacle preemption is implicated when 'the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' . . . 'What is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects.'" *Maine Forest Prod. Council v. Cormier*, 51 F.4th 1, 6 (1st Cir. 2022) (quoting *Arizona v. United States*, 567 U.S. 387, 399 (2012), and *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000), respectively).

Impossibility preemption arises from a more direct conflict of federal and state laws, "where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce." *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963); *see also In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 779 F.3d 34, 40 (1st Cir. 2015) ("Federal law impliedly preempts state law where it is impossible for a private party to comply with both state and federal requirements.") (quotations omitted). Finally, "[f]ield preemption comes about when federal law occupies a field of regulation 'so comprehensively that it has left no room for supplementary state legislation.'" *Consumer Data Indus.*, 26 F.4th at 5 (quoting *Murphy*, 138 S. Ct. at 1480).

Federal courts generally begin their preemption analysis "with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Maine Forest*, 51 F.4th at 6 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). This presumption "does not apply, though, 'when the State regulates in an area where there has been a history of significant federal presence.'" *Id*. (quoting *United States v. Locke*, 529 U.S. 89, 108 (2000)).

Most case law related to the federal preemption of state regulation of FDA-regulated drugs, biologics, animal drugs, or medical devices concerns state labeling or warning requirements for such products, often as imposed through state product liability causes of action. *See, e.g.*, *Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that FFDCA does not preempt a state cause of action for failure to warn that would require label statements beyond those required or approved by FDA); *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) (holding that federal law preempts state law imposing a duty to change a generic drug's label when FFDCA prohibits such changes absent FDA approval); *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472 (2013) (holding that federal law preempts state causes of action for design defect when FFDCA prohibits unilateral generic drug label changes to strengthen warnings). As discussed below, the FFDCA, PHSA, and other federal laws would implicitly and explicitly preempt application of the Reporting Rule to FDA-regulated products and packaging.

b. Federal Preemption as Applied to Human and Animal Drugs

Federal law preempts any state law that purports to control or ban the ingredients, components, or packaging of FDA-approved drug products (including biological products and animal drugs) because such laws stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. This is independent of whether the state law contains a preemption clause. The FDA's codified mission statement makes clear that Congress intended the agency to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner" and "protect the public health by ensuring that . . . human and veterinary drugs are safe and effective." 21 U.S.C. § 393(b). The FFDCA delegates the task of balancing patient safety and drug availability to the FDA through various approval and licensing pathways available for human drugs, human biologics, and animal drugs. FDA's approval of a new or generic human or animal drug, its licensing of an originator biologic or biosimilar, and its promulgation of an OTC monograph or indexing of certain minor animal drugs all require the agency to determine that such product is "safe" for its approved conditions of use.

Federal courts have held that state determinations contrary to FDA approval of a drug interfere with Congress' intent in enacting the FFDCA. The District Court for the District of Massachusetts recently held that Massachusetts could not ban an approved drug or require that it only be sold in a dosage form not yet approved by FDA. *See Zogenix, Inc. v. Patrick*, No. 14-11689-RWZ, 2014 WL 1454696 (D. Mass. Apr. 15, 2014). "If [a state] were able to countermand the FDA's determinations and substitute its own requirements, it would undermine the FDA's ability to make drugs available to promote and protect the public health. [Such a state law] thus stands in the way of the accomplishment and execution of an important federal objective. The Constitution does not allow it to do so." *Id*. at *2. Similarly, the District Court for the District of Maryland has held (and the Fourth Circuit affirmed) that no state law "could . . . exist" that would "compel generic manufacturers to stop production of a drug that under federal law they have the authority to produce" because "it would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be marketed in interstate commerce." *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 659 (D. Md. 2011), *aff'd sub nom. Drager v. PLIVA USA, Inc.*, 741 F.3d 470 (4th Cir. 2014); *see also* Peter H. Schuck, *Multi-Culturalism Redux: Science, Law, and Politics*, 11 Yale L. & Pol'y Rev. 1, 39 (1993) ("For better or for worse, the FDA is the agency that the public has empowered to make authoritative judgments of this kind on its behalf.").

Additionally, the FDA's approval of an NDA amounts not merely to federal permission to market a drug product but a license to do so. Lars Noah, *State Affronts to Federal Primacy in the Licensure of Pharmaceutical Products*, 2016 Mich. St. L. Rev. 1, 32 (2016). The same logic applies to the agency's approval of an ANDA, BLA, NADA, or ANADA. A state may not unilaterally decline to recognize such a federal license. *See Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 210, 240 (1824) (holding that "the laws of New-York . . . have, in their application to this case, come into collision with an act of Congress, and deprived a citizen of a right to which that act entitles him"); *see also Jacobs Wind Elec. Co. v. Fla. Dep't of Transp.*, 919 F.2d 726, 728 (Fed. Cir. 1990) (noting that "a state court is without power to invalidate an issued patent").

The legislative intent for Section 116.943, and the regulatory intent for the Reporting Rule, is presumably similar to why Maine enacted its PFAS law; namely, because of concerns that such products may "pose[] a significant threat to the environment of the State and to the health of its citizens." 2021 Me. Legis. Serv. ch. 477 (H.P. 1113) (L.D. 1503). This is likely a similar intent as that of the Minnesota lawmakers who passed Section 116.943; for example, Representative Jeff Brand (a drafter of the new law) was quoted as saying "[Section 116.943] is the first step of the major changes needed to protect families and our environmental legacy."[5]

As applied to FDA-approved drug products and these products' packaging, state regulation of PFAS in medical products and packaging runs directly counter to the FDA's own risk analysis and safety determination. This conclusion extends to state reporting obligations, such as from the Reporting Rule, which are executed to analyze health and safety information about these products. "The Constitution does not allow" a state to "countermand the FDA's determinations" and so "undermine the FDA's ability to make drugs available to promote the public health." *Zogenix*, 2014 WL 1454696 at *2. "Whether a drug may be marketed" is solely the FDA's decision to make. *Gross*, 825 F. Supp. 2d at 659. And states are additionally prohibited from unilaterally declining a drug manufacturer's license to sell afforded by FDA's approval of its NDA, ANDA, BLA, NADA, or ANADA. The Reporting Rule, if promulgated, would therefore be preempted by federal law as applied to drug products and their packaging. This is because the purpose of reporting would be for the MPCA to gather and assess the health and safety attributes of these items, in contradiction to FDA's determination that drugs and their packaging have a favorable benefit-risk profile. The sales prohibition tied to the failure to report is likewise preempted because it would impose a direct barrier to the market for drugs that the FDA has approved for sale because they are safe and effective.

The fact that the Reporting Rule will impose information-gathering obligations, rather than a direct material restriction, does not save it from being preempted. "Pre-emption is not a matter of semantics. A State may not evade the pre-emptive force of federal law by resorting to creative statutory interpretation or description at odds with the statute's intended operation and effect." *Wos v. E.M.A. ex rel. Johnson*, 568 U.S. 627, 636 (2013). Section 116.943's reporting requirements are clearly "at odds with" the sweeping purpose of the FDA, as authorized under the FFDCA, to "protect the public health" by making sure that "drugs are safe and effective." 21 U.S.C. § 393(b)(2)(B). This conclusion is underscored by, but is not dependent on, the fact that subdivision 2 contains a sales prohibition tied to the failure to report.

c. Federal Preemption as Applied to Medical Devices

The FFDCA expressly preempts state regulations with regard to medical devices. Specifically, "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a). At minimum, this provision

[5] Olivia Rosane, *'This is the First Step': Minnesota Passes Most Comprehensive PFAS Ban in the Nation*, Common Dreams (May 26, 2023), https://www.commondreams.org/news/minnesota-passes-nation-s-most-comprehensive-pfas-ban.

expressly preempts the Reporting Rule as applied to Class III devices subject to the FDA's pre-market approval.

In passing Section 116.943 and by promulgating the Reporting Rule, the Minnesota Legislature and the MPCA, respectively, presumably did so and will do so for the purported protection of public health and safety, as Maine did for its recent PFAS law. *See* 2021 Me. Legis. Serv. ch. 477 (H.P. 1113) (L.D. 1503) (finding that the legislation was "immediately necessary for the preservation of the public peace, health and safety"). As applied to medical devices, the Reporting Rule would therefore "relate[] to the safety or effectiveness of the device." 21 U.S.C. § 360k(a)(2).

The requirements of the Reporting Rule will also certainly be "different from" and "in addition to" any imposed on medical devices under federal law. A statutory provision that preempts "different" or "additional" requirements "sweeps widely" and "prevents a State from imposing any additional or different—even if non-conflicting—requirements that fall within the scope of the Act and concern" the regulated topic. *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 459–60 (2012) (interpreting a preemption provision under the Federal Meat Inspection Act nearly identical to the FFDCA's medical device regulation preemption provision). The Reporting Rule will plainly be "different from" and "in addition to" federal controls on device safety and will therefore be expressly preempted.

The FFDCA's express preemption provision preempts state requirements that differ from federal "requirements" related to device safety. The Supreme Court has thus held that state regulation related to the safety of Class III medical devices that have gone through the FDA's pre-market approval process is preempted, as the pre-market approval process imposes numerous "requirements" with regard to such devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322–23 (2008). The Reporting Rule, if promulgated, is therefore expressly preempted by federal law as applied to FDA-approved Class III devices.

Moreover, at the very least, the material restriction tied to in-scope products that are not reported under the Reporting Rule would be implicitly preempted by federal law for <u>all</u> medical devices. The Medical Device Amendments to the FFDCA were intended to provide, through FDA regulation and oversight, a "reasonable assurance of the safety and effectiveness" of medical devices. 21 U.S.C. § 360c(a)(1)(A)(i). The Supreme Court has held that a state regulation that "requires a manufacturer's [medical device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme." *Riegel*, 552 U.S. at 325. The Reporting Rule would presumably be intended to increase safety without regard for product efficacy. As applied to medical devices, it therefore "disrupts the federal scheme" and so "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" in delegating regulation of medical devices to the FDA. *Maine Forest Prod. Council*, 51 F.4th at 6. The logic applied to state bans on FDA-approved drugs in *Zogenix* and thus also applies to medical devices for which the FDA has established general and special controls and issued pre-market approvals or substantial equivalence determinations: a state ban on devices for which the FDA has found "a reasonable assurance of . . . safety" would "undermine the FDA's ability to make [devices] available to promote and protect the public health." *Zogenix*, 2014 WL 1454696 at *2 (altering "drugs" to "devices"). The material restriction tied to in-scope products that are not reported under Reporting Rule, if promulgated, is therefore implicitly preempted by

federal law as applied to all medical device products. The Reporting Rule as a whole is also expressly preempted as applied to FDA-approved Class III devices, as mentioned above.

IV. THE MPCA HAS THE AUTHORITY AND OBLIGATION TO INCLUDE AN EXEMPTION IN THE REPORTING RULE FOR MEDICAL AND PHARMACEUTICAL PRODUCTS

Notwithstanding the fact that Section 116.943's exemption for FDA-regulated products does not by its text extend to the law's reporting provision, the Minnesota Legislature authorized the MPCA in subdivision 9 to "adopt rules necessary to implement this section." This broad delegation of power gives the MPCA the discretion to make choices about what is "necessary" to implement the law in the Reporting Rule. Likewise, Minnesota's Administrative Procedure Act at Minn. St. § 14.002 states that "whenever feasible, state agencies must develop rules and regulatory programs that emphasize superior achievement in meeting the agency's regulatory objectives and maximum flexibility for the regulated party and the agency in meeting those goals." Recognizing this legislative directive, "Minnesota courts have sanctioned regulatory schemes that incorporate agency discretion in enforcement, particularly in complex, evolving areas and particularly when procedural safeguards are in place." *Minnesota Ctr. for Env't Advoc. v. Minnesota Dep't of Nat. Res.*, No. A18-1956, 2019 WL 3545839, at *8 (Minn. Ct. App. Aug. 5, 2019) (citing *Can Mfrs. Inst., Inc. v. State*, 289 N.W.2d 416 422-24 (Minn. 1979); *Coal. of Greater Minnesota Cities v. MPCA*, 765 N.W.2d 159, 167-68 (Minn. Ct. App. 2009)).

As explained above in these comments, an express exemption for medical and pharmaceutical products, as well as for these products' packaging, is necessary to include in the rule under principles of federal preemption. This exemption will avoid disputes about the scope of federal preemption, and it is also critical for medical professionals and patients who rely on these products staying on the market, given that compliance with Section 116.943's reporting requirements is tied to the ability of in-scope products to be distributed and sold. In addition, medical and pharmaceutical products already undergo intense safety review and reporting processes at the federal level and the FDA has determined that approved products have a favorable benefit-risk profile. This represents a prime example of the MPCA's authority to prescribe regulatory exemptions in "complex and evolving areas," (e.g., PFAS regulation) "particularly when procedural safeguards are in place" (represented by FDA's existing regulatory scheme). Our requested exemption is consistent with the principles of federal preemption and is in line with the public health and safety objectives of Section 116.943, meaning that the MPCA has the authority and obligation to include it in the Reporting Rule.

V. CONCLUSION

PPWG thanks the MPCA for considering its comments to inform future drafting of the Reporting Rule. If you have any questions, please feel free to contact me.

Sincerely,

Ryan J. Carra
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November 28, 2023

Katrina Kessler, Commissioner
Minnesota Pollution Control Agency (MPCA)
520 Lafayette Road North
St. Paul, Minnesota 55155-4194

Re: Comments on MPCA Proposal "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

Dear Ms. Kessler,

Lac-Mac Limited (Lac-Mac) appreciates the opportunity to provide these comments[1] in response to MPCA's proposal "Planned New Rules Governing Reporting by Manufacturers Upon Submission of Required Information about Products Containing Per-and Polyfluoroalkyl Substances (PFAS)."

Located in Canada, Lac-Mac is North America's leading manufacturer of reusable protective clothing for blood borne pathogen protection (surgical protection), liquid chemical splash protection, flame resistant/ARC protection for utilities, and high-visibility liquid-proof protection. We specialize in quality, high-performance, liquid-proof, breathable personal protective equipment (PPE) products. We sell our products in the United States, including in the state of Minnesota.

MPCA is proposing to establish a program to collect information, starting in 2026, about products containing PFAS intentionally added to products sold, offered for sale, or distributed in Minnesota as required by Minnesota Statutes 116.943[2] ("PFAS in Products Law"). MPCA is seeking comment on any relevant issues related to this rulemaking that should be considered.

The PFAS in Products Law also prohibits the sale and distribution of certain products containing intentionally added PFAS starting in 2025 (e.g., carpets and rugs, cleaning products, cookware, textile furnishings, etc.), and then *all* products containing intentionally added PFAS starting in 2032. MPCA has the authority to exempt "currently unavoidable uses" of PFAS, which are uses that MPCA has determined to be "essential for health, safety, or the functioning of society and for which alternatives are not reasonably available."

As MPCA develops its rules to implement its PFAS in Products Law, the agency should consider what products it believes are "currently unavoidable uses" of PFAS which should not be banned for health and safety reasons. **We urge MPCA to determine, by rule, that PPE products like the products we sell are "currently unavoidable uses" of PFAS** and, therefore, would be exempt from any future prohibitions on the sale or distribution of PFAS-containing products in the State of Minnesota.

PPE is essential for the health, safety and functioning of society and for which alternatives are not reasonably available. PPE products provide critical protection for workers who are exposed to various physical and chemical hazards in the workplace. Particularly in chemical facilities and in healthcare settings, it is vital for safety and public

[1] Comments have been submitted electronically to: https://minnesotaoah.granicusideas.com/discussions/39507-minnesota-pollution-control-agency-request-for-comments-on-pfas-in-products-reporting-rule.
[2] https://www.revisor.mn.gov/laws/2023/0/Session+Law/Chapter/60/#laws.3.21.2.

health to ensure the workforce in Minnesota has continued access to necessary PPE. Our concern is that without an exemption for "currently unavoidable uses," PPE manufacturers like Lac-Mac or other companies will be forced

to no longer sell its products in Minnesota and leave thousands of workplaces with far more limited options for available protective clothing, creating a public health emergency or exposing workers to more risks in the workplace. This is contrary to the intent of Minnesota's PFAS law, which is to protect individuals from exposures to chemicals.

Further, there is legal precedent for Minnesota to adopt this approach. The two other states that have enacted similar prohibitions on the sale of PFAS in apparel or textiles, California and New York, have provided exclusions for PPE:

> California Health & Safety Code 108970[3]: The law prohibits the manufacture, sale or distribution of textile articles containing regulated PFAS starting January 1, 2025. The law excludes from the definition of apparel "personal protective equipment."
>
> New York Env. Chapter 43-B, 37-0121[4]: The law prohibits the sale of apparel containing intentionally-added PFAS starting January 1, 2025. The law excludes from the definition of apparel "professional uniforms that are worn to protect the wearer from health or environmental hazards, including personal protective equipment."

The state of Maine's PFAS and Products Law, 38 MRSA 1614[5], which prohibits all products containing intentionally added PFAS starting January 1, 2030, also allows for exemptions for "currently unavoidable uses" of PFAS and defines this term the same as Minnesota's law. Maine is still developing its regulations to implement the law.[6]

Therefore, Minnesota would be aligning with other states in exempting the use of PFAS in PPE from any ban so that essential medical supplies and worker safety garments will continue to be available for employers and workers.

Thank you for the opportunity to comment and please contact Shelley Petrovskis if you would like more information from us.

Sincerely,

S. Petrovskis

Shelley Petrovskis
Director of Marketing and Regulatory Affairs
Lac-Mac Limited

[3] https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=HSC&division=104.&title=&part=3.&chapter=13.5.&article=.
[4] https://www.nysenate.gov/legislation/laws/ENV/37-0121.
[5] https://legislature.maine.gov/statutes/38/title38sec1614.html.
[6] Lac-Mac is submitting similar comments to the Maine Department of Environmental Protection for consideration as it develops rules to implement its PFAS in Products Law.

November 27, 2023

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

Via OAH Rulemaking eComment Website

RE: Minnesota Pollution Control Agency Request for Comments on PFAS in Products Reporting & Fees Rules; OAH Docket No. 65-9003-39507 & 71-9003-39506

Dear Ms. Lynn:

As the association for the consumer-packaged goods (CPG) industry, including makers of food, beverage, personal care, and household products, the Consumer Brands Association[1] advocates for uniform, workable, and durable regulatory frameworks that are informed by risk-based science, promote consumer choice, and build consumer trust across the sectors we represent. Consumer Brands is committed to partnering with state and federal policymakers on practical and effective solutions for addressing the use and presence of PFAS in CPG products. We appreciate the opportunity to provide comment to the Minnesota Pollution Control Agency ("MPCA" or "Agency") on its proposed rules governing the program to assess fees and collect information on products that contain intentionally added per- and polyfluoroalkyl substances (PFAS). Our recommendations, provided below, would bring clarity to the scope of the proposed requirements for reporters and mitigate negative impacts the rule could have on interstate commerce in Minnesota.

As the MPCA initiates the development of its PFAS product reporting regulation, Consumer Brands recommends that:

- The Agency should work to harmonize its reporting systems and forms with the Maine Department of Environmental Protection (DEP) to minimize regulatory burdens on respondents. The statute allows the MPCA to enter into agreement with other states or political entities to facilitate the information collection requirements that are specified under the law.[2] Both Minnesota and Maine have functionally equivalent statutes that require the same types of information to be reported on products that contain intentionally added

[1] The Consumer Brands Association (Consumer Brands) champions the industry whose products Americans depend on every day, representing more than 2,000 iconic brands. From household and personal care products to food and beverage products, the consumer-packaged goods (CPG) industry plays a vital role in powering the U.S. economy, contributing $2 trillion to the U.S. GDP and supporting more than 20 million American jobs.

[2] Minnesota Session Law – 2023, Chapter, 60, Section 21, Subdivision 3(c): "The commissioner may enter into an agreement with one or more other states or political subdivisions of a state to collect information and may accept information to a shared system as meeting the information requirement under subdivision 2."

PFAS, and it would very practical and achievable for both states to synchronize their respective approaches for reporting product information.[3]

- The Agency should develop a regulatory mechanism that allows manufacturers to request reporting extensions in cases where they can demonstrate that they have taken actions to ascertain the information sought in the regulation, yet still remain unable to comply. The statute allows for reporting extensions in such circumstances and does not specify a limit to the frequency or length in which the Agency may extend the deadline for any individual company.[4] Manufacturers still face significant difficulties in complying with the PFAS notification requirements, including an inability to obtain information from upstream suppliers, the complexity of their brand portfolios and production chains, as well as limited commercial laboratory capacity and a lack of validated PFAS test methods. We anticipate these myriad issues will persist beyond the January 1, 2026 compliance date, making a system to request extensions critical for regulated entities.

- The Agency should clarify the definition of "Manufacturer", as the current definition is unclear as to who has the burden to report. In certain cases (namely trademark licenses to third parties), the definition may be interpreted to place the burden on two parties – the manufacturer/distributor and the brand owner. These entities are not always the same, can shift according to sourcing and supply chain variability, and including the brand owner in the definition actually introduces additional confusion and ambiguity. Because the definition of "manufacturer" is already established in Minnesota law[5], we recommend providing clarification of the definition in Subdivision 1. We believe that the intent of the definition is to assign the obligation of reporting to the entity that is responsible for putting the product on the market, and this should be made clear to stakeholders. For relevant perspective, the definition used in California's AB1200 has defined "manufacturer" in a way that is clear and could be used as a model framework for clarification in the Minnesota product reporting regulation.[6] As such, Consumer Brands recommends that the MPCA clarify that "Manufacturer" means either of the following:
    - (1) A person or entity who manufactures the [product] and whose name appears on the product label.
    - (2) A person or entity who the [product] is manufactured for or distributed by, identified by the product label pursuant to the federal Fair Packaging and Labeling Act (15 U.S.C. Sec. 1451 et seq.).

- The Agency should address when a product is considered 'offered for sale' in state commerce. Given that products can remain in circulation for months (and in some instances over a year depending on localized market conditions and sell-through rates), it would be extremely difficult, if not impossible, for manufacturers to accurately identify product for notification that has entered retail circulation prior to the compliance date. The Agency should specify that the compliance date for reporting will apply to the production date of the finished good that enters state commerce, rather than the date at which the

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[3] Maine Public Law 2021, c. 477, An Act To Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution, https://www.mainelegislature.org/legis/bills/getPDF.asp?paper=HP1113&item=5&snum=130.

[4] Minnesota Session Law – 2023, Chapter, 60, Section 21, Subdivision 3(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."

[5] Minnesota Session Law – 2023, Chapter, 60, Section 21, Subdivision 1(n).

[6] See California Assembly Bill No. 1200, Chapter 503, Plant-based food packaging: cookware: hazardous chemicals. https://legiscan.com/CA/text/AB1200/id/2435956

product became available for purchase on store shelves in the state. Doing so is a reasonable means to ensure that industry can effectively comply with notification at the initial point in the supply chain where they have greater control and visibility over distribution.

- In response to the Agency's request for input on how program fees for the PFAS reporting regulation should be calculated, Consumer Brands recommends that the fees be based on the volume/weight of PFAS used in the manufacturer's products or placed into the state marketplace. This approach is based on how the California Air Resources Board (CARB) assesses fees on manufacturers of consumer products in order to recover the costs of CARB's volatile organic compound (VOC) emissions programs.[7] When calculating program fees, it may be appropriate for the MPCA to consider a minimum limit in view of small volume PFAS users and small businesses that represent minimal contributions to PFAS uses in products offered for sale in Minnesota.

- The Agency should provide clarity in the regulation for products that are offered for sale via online retail platforms. In many instances, products may be distributed directly from the online seller to the consumer without the knowledge of the manufacturer or importer, who in frequent circumstances offer products on a wholesale basis to the retailer without being informed of how the products will be further distributed across every state and locality. The MPCA should clarify product reporting responsibilities in e-commerce scenarios such as this.

- The Agency should develop practicable concentration ranges for reporting the amount of PFAS in a product, based on the current capabilities (and sensitivities) of commercially available analytical methods to detect intentionally added PFAS. The more precise the quantity of each PFAS that has to be reported, the more difficult it will be for companies to obtain that information. Chemical concentration can also be considered proprietary information that suppliers do not generally disclose. Furthermore, there is a lack of validated test methods for evaluating the presence or concentration of PFAS in products, which creates uncertainty regarding precision of measurement. Providing concentration ranges that are practicable will help protect confidentiality for suppliers, improve the feasibility of testing for PFAS, decrease the amount of time needed to provide notification, and ensure that the regulated community is able to reduce potential PFAS exposure.

- The Agency should address scenarios when, through discovery or testing, PFAS is detected in a product that is being offered for sale in the state. The MPCA will likely encounter situations where an underlying supplier did not disclose the presence of intentionally added PFAS to the manufacturer, situations where *de minimis* levels of PFAS are present in a product non-intentionally due to uptake from external or environmental sources, or situations where a false positive detection occurred in the test sample. Such scenarios merit the development of an enforcement discretion policy and a reasonable process to allow manufacturers to confirm the source of the PFAS that was detected, determine if its presence was intentional, and conduct mitigation if the presence was in fact intentional.

- The Agency should ensure that Confidential Business Information (CBI) claims can be made at the time of reporting. Claims that have been approved by the federal

[7] See California Health and Safety Code, Section 39613, https://law.justia.com/codes/california/2022/code-hsc/division-26/part-2/chapter-3/section-39613/.

Environmental Protection Agency for inclusion on the Toxic Substances Control Act (TSCA) Confidential Inventory, or for which the manufacturer or its supplier claim protection under the Uniform Trade Secrets Act, should be granted protection under the reporting regulations. The MPCA should also clarify in the regulation how CBI claims will be managed including how manufacturers would provide information to the agency before it is granted protection from disclosure; which data elements can be granted CBI protection; in what circumstances the CBI data elements may be withheld from disclosure or provided in a generic/sanitized manner; and how the reporting information will be ultimately secured and protected.

Consumer Brands appreciates the opportunity to provide feedback and recommendations on the draft product reporting regulation, and we look forward to working with the MPCA to ensure that Minnesota consumers can continue to access CPG products essential to their health and wellbeing. Thank you for your attention to our comments, please do not hesitate to contact me with any questions.

Respectfully submitted,

Jared Rothstein
Director, Regulatory Affairs

GUJARAT FLUOROCHEMICALS
VALUE THROUGH GREEN CHEMISTRY
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November 27, 2023

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

To,

Minnesota Office of Administrative Hearings, and

Minnesota Pollution Control Agency, Resource Management and Assistance Division

OAH Docket No. 65-9003-39507

Re: Comments Supporting Science-Based New Rules Governing development of the *PFAS in Products Reporting Rule*

Gujarat Fluorochemicals Limited ("GFL" or the "Company") is grateful for the opportunity to submit important information in response to the Minnesota Pollution Control Agency's ("MPCA's") request for comments related to its "Planned New Rules Governing Reporting by Manufacturers … about Products Containing Per-and polyfluoroalkyl substances (PFAS)" – hereinafter the "PFAS in Products Reporting Rule" ("Rule") – pursuant to Minnesota Session Law – 2023, chapter 60, article 3, section 21, (the "Act"). According to MPCA, the purpose of the rulemaking "is to establish a program for the MPCA to collect information about products containing intentionally added PFAS."

GFL supports reporting obligations that provide regulators and the public with additional information about the presence of persistent, bio-accumulative and toxic PFAS in products. The Company writes today because it is concerned that the Act imposes an overly broad definition of PFAS and urges MPCA to further refine the definition through its rulemaking so as not to impose unnecessary reporting requirements on manufacturers of safe products containing fluoropolymers sold in Minnesota. GFL and GFL Americas, LLC (a U.S.-based wholly-owned subsidiary), manufacture certain fluoropolymers, a distinct class of PFAS used primarily in industrial applications, and provide comments herein on: (1) the inherent safety of those fluoropolymers; and (2) considerations to facilitate the refinement of the definition of PFAS included in the Act to distinguish between these inherently safe fluoropolymers and PFAS of concern ("PFOC"). Without adequately clarifying that fluoropolymers are distinct from PFOC, the Rule will impose unnecessary burdens on manufacturers of industrial products which contain fluoropolymers, and which do not create a risk to human health or the environment, including renewable energy,

transportation, electric vehicles, semiconductors, food and water treatment technologies, safe chemical processing, and pharmaceutical and medical devices.[1]

Fluoropolymers Exhibit Different Toxicological and Environmental Profiles from PFOC and Should Not Be Regulated as If They Were the Same

The Act defines PFAS broadly to encompass the entire "class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom." While this definition includes per- and polyfluoroalkyl carboxylic acids ("PFCAs") and sulfonic acids ("PFSAs"), which are toxic, bio-accumulative, persistent and mobile, it also includes fluoropolymers, a distinct class of PFAS – 38 in number – such as polytetrafluoroethylene ("PTFE"), polyvinylidene difluoride ("PVDF"), fluoroelastomer ("FKM") and perfluoroalkoxy alkanes ("PFA").[2] Fluoropolymers are high molecular weight, safe substances. Because of their negligible solubility in water and high molecular weight, fluoropolymers cannot bio-accumulate in the human bloodstream.[3] They are non-mobile, non-bio-accumulative, non-toxic chemicals that do not pose any risk to water quality, human health or the environment and fulfill the thirteen

[1] Fluoropolymers are crucial to, and irreplaceable in, the manufacturing of solar panels and windmill blades for clean energy systems. In electric vehicles, fluoropolymers are critical for optimal performance of lithium-ion batteries and hydrogen fuel cells. Without fluoropolymers, sustainability goals would be seriously compromised. Due to their resistance to harsh chemicals, fluoropolymers are essential for manufacturing semiconductors, providing an impurity-free environment. Without fluoropolymers, the semiconductor industry will be unable to produce microchips that allow for the development of modern electronic devices such as mobile phones, laptops and many other high-tech equipment. Fluoropolymers are utilized in water filtration systems (which avoids the need to use chemicals for water treatment), and in food processing systems to guarantee adequate sanitary conditions and protect consumers from harmful contamination. Catheters and medical implants contain fluoropolymers due to their biological compatibility, inertness and durability. Furthermore, the production of medicines and vaccines requires ultra-pure conditions which can only be achieved with equipment based on fluoropolymer materials. Because fluoropolymers are unmatched in resistance to chemical attack and performance under wide temperature variations, they are the safest, most secure material for processing and containing chemicals. Fluoropolymers are found in all kinds of industrial equipment, as well as joints and gaskets to secure operation and containment of chemicals. Further, fluoropolymers contribute to both fuel efficiency and safety, playing a key role in systems such as brakes in cars or wing flaps in aircrafts. They are also the best option available (due to their high resistance and high flexibility) to protect electrical cables in aircrafts, where high reliability of such cables, which can be exposed to thermal as well as chemical pressure, is fundamental. Lastly, fluoropolymers are used in highly efficient air conditioning and refrigeration systems, as well as in heat pumps. Fluoropolymers also play a key role in modern construction systems, used in many buildings to boost durability and sustainability.

[2] Fluoropolymers account for a small portion of the 9,000 PFAS. *See* Appendix A to this letter. These comments focus on an even smaller subset of fluoropolymers made without the use of fluorinated polymerization aids that includes PTFE, PVDF, FKM and PFA.

[3] Chemservice Technical Report: Analysis of Alternatives to Fluoropolymers and Potential Impacts Related to Substitution in Different Sectors of Use; Version 1, July 19, 2022.

criteria established by the Organization for Economic Cooperation and Development ("OECD") to be regarded as "Polymers of Low Concern."[4]

Not only are fluoropolymers themselves safe substances, their entire lifecycle, including their manufacturing and management at end-of-life, can be completed without the use or generation of low molecular weight PFOC. To the extent there may be a valid concern related to fluoropolymers, it is the use and potential emission of fluorinated surfactants (also called PFAS polymerization aids) in the polymerization of certain fluoropolymers. However, many fluoropolymers can be produced without the use of fluorinated surfactants, thereby eliminating this concern. GFL already produces the four fluoropolymers delineated above (PTFE, PVDF, FKM and PFA) largely without fluorinated polymerization aids, and by 2024, GFL will produce its entire fluoropolymer portfolio without the use of these aids.

Similarly, fluoropolymers do not degrade to PFOC under intended use conditions or under the environmental conditions at the end-of-life phase of their application.[5] GFL has recently conducted an independent incineration study at the Karlsruhe Institute of Technology in Germany proving that fluoropolymers can be completely thermally destroyed at standard incineration conditions. This is yet another important distinction among fluoropolymers and PFOC, which are currently perceived as "forever chemicals" because of their resistance to standard incineration and for which select, innovative companies are only beginning to develop methods of destruction at end-of-life.

Through its rulemaking, MPCA either should: (a) refine the definition of PFAS in subdivision 1 of the Act to exclude all fluoropolymers, which it could accomplish using language similar to that used in the June 22, 2023, bipartisan U.S. Senate Environment and Public Works ("EPW") Committee draft PFAS legislation;[6] or (b) exclude from any reporting obligations under the Rule any product which contains only non-mobile, non-bio-accumulative and non-toxic PFAS that are produced without the use of PFAS polymerization aids, including by explicitly identifying these four fluoropolymers.

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[4] Henry, Barbara J., et al. "A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers." *Integrated Environmental Assessment and Management* 14.3 (2018): 316-334; and Korzeniowski, S. H., et al. "A Critical Review of the Application of Polymer of Low Concern Regulatory Criteria to Fluoropolymers II: Fluoroplastics and Fluoroelastomers." Integrated Environmental Assessment and Management (2022). The thirteen criteria considered by OECD when making a Polymer of Low Concern determination are: polymer composition, molecular weight, percentage of oligomer, electrical charge, Reactive Functional Groups ("RFG"), Functional Group Equivalent Weight ("FDEW"), low molecular weight leachables, water/lipid solubility, particle size, polymer stability, thermal stability, abiotic stability, and biotic stability. The vast majority of fluoropolymers used today meet all of the OECD Polymer of Low Concern criteria and are non-toxic; non-bio accumulative; non-mobile; insoluble in water; thermally, chemically and biologically stable; durable; and not Substances of Very High Concern ("SVHC").

[5] *Id.*

[6] EPW's draft legislation defines PFAS as: (i) a non-polymeric perfluoroalkyl or 2 polyfluoroalkyl substance; and (ii) a side chain fluorinated polymer that is a member of a group of human made chemicals that contain at least 2 fully fluorinated carbon atoms.

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VALUE THROUGH GREEN CHEMISTRY
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The Definition of PFAS Should Be Clarified to Exclude those Fluoropolymers Manufactured Without the Use of Fluorinated Polymerization Aids

There is no single, globally-harmonized definition for PFAS. The Act relies on the structure and atomic composition of PFAS and specifically the carbon-fluorine ("C-F") bond found in PFAS. As stated above, these C-F bond-based definitions cover a broad group of about 9,000 substances. While fluoropolymers do share structural similarities with other PFAS, these structural similarities or the existence of a single C-F bond across chemical substances in itself is not representative of a risk to human health and environment.[7] Whether a PFAS is a cause of concern to human health and environment is determined by other traits such as its potential to bio-accumulate and to be persistent and/or mobile in the environment. Using this rationale, it makes sense to identify and include certain PFAS, such as perfluorooctanoic acid ("PFOA") and perfluorooctane sulfonic acid ("PFOS") as PFOC due to their solubility in water, bio-accumulative properties, and toxicity. It does not make sense, however, to sweep up all fluoropolymers into the same definition for the reasons described above.

The United States Environmental Protection Agency ("U.S. EPA") acknowledges the importance of categorizing PFAS and regulating them commensurate to their toxicity and impact in its PFAS Strategic Roadmap for the years 2021 to 2024 ("Roadmap"). One of four guiding principles of the Roadmap is to "ensure science based decision making." The Roadmap notes that the current body of science ties only specific PFAS to significant hazards and that there are significant gaps in the understanding of impacts of other PFAS. It states, "[r]egulatory development, either at the state or federal level, would greatly benefit from a deeper scientific understanding of the exposure pathways, toxicities, and potential health impacts of less-studied PFAS." Further, in October 2023, the Department of Defense ("DoD") submitted its "Report on Critical Per- and Polyfluoroalkyl Substance Uses" ("Report") with a focus on fluoropolymers to the Committees on Armed Services of the House and the Senate outlining the uses of PFAS that are critical to the national security of the United States. The Report highlights that several subgroups of PFAS may be more or less stable, persistent, and/or bio-accumulative compared to well-studied PFAS such as PFOS and PFOA and warns that the chemical-structure-based (rather than hazard- or risk-based) definitions would make emerging PFAS environmental regulations unpredictable and uninformed by the specificity of individual PFAS risk relative to their use. It especially emphasizes the impact of such regulation on fluoropolymers, which have great utility in critical industrial sectors that bolster the national security of the United States.[8] Similarly, a regulatory management option analysis ("RMOA") published by the UK's

[7] A OECD report, which defined PFAS as fluorinated substances that contain in their structure at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), that is, with a few noted exceptions, any chemical with at least a perfluorinated methyl group (–CF3) or a perfluorinated methylene group (–CF2–; OECD, 2021), acknowledges that the term "PFAS" is broad, general, and nonspecific, and does not inform whether a compound presents risk or not, but only communicates that the compounds under this term share the same structural trait of having a fully fluorinated methyl or methylene carbon moiety. While some of these substances have been shown to be of concern to human health and the environment, not all the substances in this vast group exhibit the same toxicological properties. https://one.oecd.org/document/ENV/CBC/MONO(2021)25/En/pdf

[8] The Report notes that fluoropolymers are essential to maintaining kinetic capabilities since they are used as ingredients in polymer bonded explosives, pyrotechnics, and propellant components used in munitions, decoy flares, and chaff. The Report also notes that manufacturers use fluoropolymers like PTFE in subcomponents of Li-ion

Health and Safety Executive ("HSE") in April 2023, suggests that the current regulatory framework for PFAS in the UK could be streamlined by providing exemptions for fluoropolymers since comprehensive, reliable evidence of their low hazard or safe use is available, and because they are particularly important to the industrial, automotive, aerospace and defense sectors.

The state of the science should inform the Rule. MPCA should focus the Rule on those products that contain intentionally-added PFAS that are toxic, bio-available, mobile and bio-accumulative. MPCA should endeavor to clarify the definition of PFAS to exclude those that are safe, including the above mentioned four fluoropolymers so long as they are manufactured without the use of fluorinated surfactants.

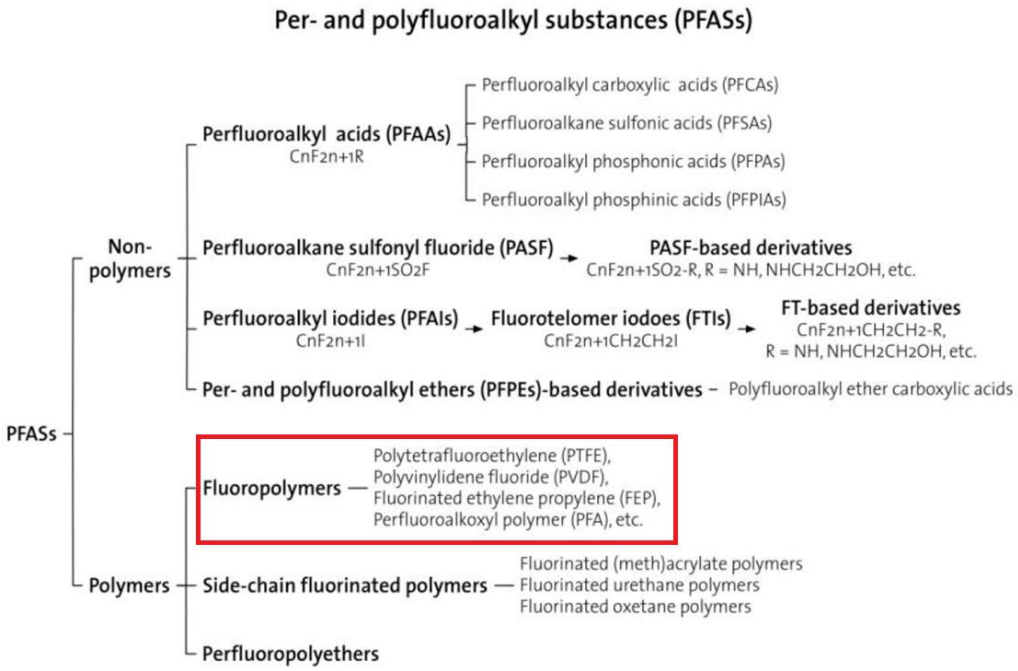
CONCLUSION

In sum, MPCA's rule development can be scientifically driven, consumer-minded, and ensure the protection of human health and the environment for the citizens of Minnesota. With the above discussed recommendations, the *PFAS in Products Reporting Rule* would avoid unnecessary and adverse burdens upon to the large number of manufacturers of products in industrial applications in which the addition of fluoropolymers does not create a risk to human health or the environment. Such drafting will support continued innovation, including in renewable energy, transportation, electric vehicles, semiconductors, food and water treatment technologies, safe chemical processing, and pharmaceutical and medical devices and beyond.

GFL would be pleased to answer any questions and to provide additional technical assistance as MPCA engages in this critical piece of rulemaking.

batteries (where they serve as heat transfer materials or insulation and provide weather resistance and ultraviolet light resistant functionalities to final components) and that fluoropolymers like PVDF, FKM, and PFAs are essential for microelectronic and semiconductor manufacturing due to their "exceptional combination of heat and chemical resistance and chemical inertness."

Appendix A


Per- and polyfluoroalkyl substances (PFASs)
PFASs
Non-polymers
Perfluoroalkyl acids (PFAAs)
CnF2n+1R
Perfluoroalkyl carboxylic acids (PFCAs)
Perfluoroalkane sulfonic acids (PFSAs)
Perfluoroalkyl phosphonic acids (PFPAs)
Perfluoroalkyl phosphinic acids (PFPIAs)
Perfluoroalkane sulfonyl fluoride (PASF)
CnF2n+1SO2F
PASF-based derivatives
CnF2n+1SO2-R, R = NH, NHCH2CH2OH, etc.
Perfluoroalkyl iodides (PFAIs)
CnF2n+1I
Fluorotelomer iodoes (FTIs)
CnF2n+1CH2CH2I
FT-based derivatives
CnF2n+1CH2CH2-R,
R = NH, NHCH2CH2OH, etc.
Per- and polyfluoroalkyl ethers (PFPEs)-based derivatives
Polyfluoroalkyl ether carboxylic acids
Polymers
Fluoropolymers
Polytetrafluoroethylene (PTFE),
Polyvinylidene fluoride (PVDF),
Fluorinated ethylene propylene (FEP),
Perfluoroalkoxyl polymer (PFA), etc.
Side-chain fluorinated polymers
Fluorinated (meth)acrylate polymers
Fluorinated urethane polymers
Fluorinated oxetane polymers
Perfluoropolyethers

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November 27, 2023

Katrina Kessler
Commissioner, Minnesota Pollution Control Agency
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Submitted via the Minnesota Office of Administrative Hearings eComments Website

Re: ICT Client Comments on MPCA's Planned Rule on Reporting for PFAS-Containing Products

Dear Commissioner Kessler:

On behalf of a client who is a worldwide leader in the manufacture of information and communications technology products ("Client"), thank you for the opportunity to provide comments on the Minnesota Pollution Control Agency ("MPCA") rulemaking concerning submission of information on products containing PFAS (the "Reporting Rule"), implementing Minn. Stat. § 116.943 ("Section 116.943"), subdivision 2. Our Client is committed to environmental stewardship and to phasing out the uses of chemicals, as appropriate, commensurate with public health and safety.

Tracking individual substances – let alone a structurally defined class of chemicals that has not been identified by distinct Chemical Abstract Service (CAS) Numbers – through information and communications technology ("ICT") supply chains is an extremely burdensome and time-consuming challenge. No organization has full insight into the use of PFAS in the ICT industry. Regulators and legislators have consistently underestimated the challenges of identifying and restricting PFAS in complex equipment and we urge the MPCA not to do so.

These comments continue in six sections:

- In Section I, we request an extension from the notification deadline for electronic products. This extension should last at least two years, and it is necessary given that electronic products contain many components and involve complex supply chains that require more time to assess and gather reportable data.

- In Section II, we advocate for reporting mechanisms that promote flexibility and reflect reality for complex products such as electronics. Specifically, we recommend that the MPCA list reportable concentration ranges directly in the Reporting Rule and permit PFAS to be reported as total organic fluorine if the amount of each PFAS compound is unknown. We also recommend that the Reporting Rule apply the Toxic Substance Control Act's ("TSCA's") "known to or reasonably ascertainable or known by" standard used by the U.S. Environmental Protection Agency ("EPA") in its PFAS reporting rule. We request that the MPCA allow at least a one-month period for when reporting is required for new products first sold, offered for sale, or distributed

in Minnesota after the initial reporting deadline, and limit the need to revise reports to the addition of an intentionally added PFAS in the product and to changes in contact information.

- In Section III, we recommend that the Reporting Rule define PFAS through a list of CAS Numbers and with an exclusion for fluoropolymers. Without a specified list of chemical names with CAS Numbers, tracking a class of thousands of chemicals is functionally impossible. In addition, an exclusion for fluoropolymers is justified given their low environmental and human health concerns and due to their high cost of regulation.

- In Section IV, we request scope exclusions from reporting on PFAS below a de minimis threshold of 0.1% by weight in the product, for spare parts, and for packaging. This de minimis threshold is in line with that in other jurisdictions, and it also eases the reporting burden on manufacturers and the MPCA to a manageable level. An exclusion for spare parts supports a circular economy, and an exclusion for packaging is harmonious with an exclusion recently added by amendment into Maine's similar PFAS law.

- In Section V, we call for clarity in the reporting platform the MPCA will use, including the need for manufacturers to have access to the platform several months in advance of the reporting deadline to understand how the platform works. Likewise, we recommend that the MPCA coordinate with other states implementing similar PFAS reporting programs, such as Maine, to provide consistency in the reporting platform.

- In Section VI, we ask that the Reporting Rule include provisions that adequately protect confidential business information ("CBI") and trade secrets. These provisions should explain how manufacturers will provide information to the MPCA, how the agency will determine what CBI data may be withheld or provided in a generic/sanitized manner, and how that information will be stored and ultimately protected from unlawful disclosure to third parties.

I. Grant an Extension from the Notification Deadline for ICT Products

Subdivision 3(d) of Section 116.943 provides that the MPCA "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 request that the MPCA exercise its authority provided in subdivision 3 by issuing a blanket extension for ICT products for at least two years, thereby requiring reporting by January 1, 2028 at the earliest for these products. This extension should be proscribed directly in the Reporting Rule as follows:

> *Pursuant to Minnesota Statutes, section 116.943, subdivision 3(d), the deadline for submission by a manufacturer of an electronic product is January 1, 2028. An electronic product includes, but is not limited to, a personal computer, audio and video equipment, calculator, wireless phone, game console, handheld device incorporating a video screen, or any associated peripheral such as a mouse, keyboard, power supply unit, or power cord.*

The representative list of electronic products in the above provision is taken from the exclusion for children's electronic products found in Section 116.943's definition of "juvenile product." Since electronic products are manufactured through complex global supply chains, companies will require sufficient lead time to implement the Reporting Rule. A single electronic product can have thousands of components which are sourced from multiple suppliers from which manufacturers will have to obtain

the necessary reporting information. 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, offered for sale, or distributed in Minnesota. In addition, all of these information requests will have to go through this process through multiple levels of the value chain.

Until the MPCA finalizes the Reporting Rule, manufacturers cannot know exactly what information will be needed. Electronics manufacturers cannot say with certainty exactly how long it will take to supply the reportable information at present without knowing threshold limits and reporting ranges – issues which we address further below. Given the complexity of the issue and the extensive reporting Section 116.943 requires, we respectfully ask that the MPCA grant a two-year extension to the ICT sector.

This extension will also avoid the implementation difficulties in executing Maine's similar PFAS reporting scheme. The Maine Department of Environmental Protection ("DEP") did not even propose regulations to implement the notification requirement in the state's PFAS law until months after the statutory deadline for notification had passed.[1] Given this shortfall, Maine enacted an amendment to the law that, among other things, extends the statutory deadline for notification by two years. 38 M.R.S. § 1614 (amended June 8, 2023).

In addition, EPA was required by Congress to finalize its PFAS reporting rule under TSCA by January 1, 2023. 15 U.S.C. § 2607(a)(7). After adverse industry comments on the proposed rule, EPA calculated a compliance cost estimate of $875 million, an 80-fold increase from the original estimate. *See* 87 Fed. Reg. 72440 (Nov. 25, 2022). In part because of this, EPA did not finalize its rule until over nine months after the statutory deadline. That final rule is estimated to cost the private sector $843 million. *See* 88 Fed. Reg. 70516 (Oct. 11, 2023). Extending the reporting deadline for ICT products at the very least will give both the MPCA and affected manufacturers an opportunity to harmonize reporting obligations with those in other states such as Maine and as recently finalized at the federal level.

II. Adopt Reporting Mechanisms that Promote Flexibility and Reflect Reality for Complex Products

a. Allow Flexibility in How the Amount of PFAS in Products is Determined

We request that the following language be included in the Reporting Rule when describing how manufacturers may determine and report the amount of PFAS in products:

> *The amount of each PFAS, identified by its chemical abstracts service registry number, in the product shall be reported as falling within [the range listed by the MPCA below], or as the amount of total organic fluorine if the amount of each PFAS compound is not known, determined using commercially available analytical methods or based on information provided by a supplier as falling within [the range listed by the MPCA below].*

[1] The original statute contained a deadline of January 1, 2023 for entities to report products they sell in Maine which contain intentionally added PFAS. Maine DEP granted extensions to this deadline for thousands of companies, thereby implicitly conceding that the timeline set out in the statute was far too ambitious. *See* Maine DEP, List of Manufacturers with an Approved Extension Request of the January 1, 2023 PFAS in Products Reporting Deadline, https://www.maine.gov/dep/spills/topics/pfas/PFAS-products/Approved-manufacturers.pdf.

To ease industry's burdens, MPCA's ranges should be harmonized with those enacted by EPA under the TSCA PFAS reporting rule for articles (but with an exclusion for products containing less than 0.1% PFAS):

- 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.

See 88 Fed. Reg. at 70556 (Table 3).

This provision would accomplish the following:

i. **It Lists Reporting Concentration Ranges**

Subdivision 2(a), ¶3 of Section 116.943 gives the MPCA the explicit authority to designate reporting concentration ranges in lieu of reporting exact quantities of PFAS determined using commercially available analytical methods. Compliance with the Reporting Rule for many PFAS substances will be impossible without ranges promulgated by the MPCA because there is no commercially available methodology for identifying an exact quantity of PFAS. However, without knowing these ranges in advance, manufacturers have no way to plan for using them. Like with Section 116.943, Maine's PFAS law delegated range approvals to Maine DEP, though over two years have passed since the statute was enacted and the agency has yet to approve any ranges. The MPCA should avoid this situation.

Moreover, disclosing chemical concentration in ranges has been a long-established practice in other regulatory regimes such as the Globally Harmonized System of Classification and Labeling of Chemicals for Composition and Information on Ingredients; EU reporting for Substances of Concern in Products; and EU Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH").

As part of this rulemaking, the MPCA should therefore specify concentration ranges for all in-scope PFAS or groups of PFAS. These ranges should give manufacturers the flexibility to report the amount of PFAS as a weight or concentration within the defined ranges, since requiring the calculation of a concentration would add an unnecessary layer of complexity that could negatively affect the accuracy of the information reported.

ii. **It Permits PFAS to be Reported as the Amount of Total Organic Fluorine if the Amount of Each PFAS Compound is Unknown**

Allowing reporting of total organic fluorine is consistent with the amendment to Maine's law, which added this option. *See* 38 M.R.S. § 1614, subdivision 2, ¶ A (amended June 8, 2023).

iii. **It Allows the Amount of PFAS to be Based on Information Provided by a Supplier**

Like with reporting total organic fluorine, the amendment to Maine's law added the option to base the PFAS amount on supplier information. *See id*. This would allow for a more timely and efficient reporting process, as suppliers may be in a better position than manufacturers to know the amount of PFAS in product components.

b. **Reporting Should Apply TSCA's "Known to or Reasonably Ascertainable By" Standard**

We request that the following provision be included in the Reporting Rule:

> *A manufacturer is only required to report information under this part to the extent such information is known to or reasonably ascertainable by that manufacturer. Whether information is known to or reasonably ascertainable by a manufacturer shall have the same meaning as those terms are given under the U.S. Environmental Protection Agency's Toxic Substances Control Act Reporting and Recordkeeping Requirements for PFAS.*

Application of TSCA's "known to or reasonably ascertainable by" standard would allow notifying entities to rely on supplier declarations and to limit to manageable levels the scope of due diligence that manufacturers would be expected to undertake with upstream suppliers. 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. *See, e.g.*, 40 C.F.R. § 711.15; 88 Fed. Reg. 70516. The MPCA should therefore mirror this standard. Failure to do so would make the Reporting Rule broader than EPA's PFAS reporting rule and thus far more expensive to implement than EPA's $843 million estimate.

c. **Include At Least a One-Month Period for Reporting on New Products, and Limit Revisions for a "Significant Change" to the Addition of an Intentionally Added PFAS and Changes in Contact Information**

Subdivision 2(c) of Section 116.943 provides that a manufacturer must submit the required information "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 a significant change in the information or when requested to do so by the commissioner." We recommend that the following provisions be included in the Reporting Rule to implement this statutory language:

> *A manufacturer of a new product containing intentionally added PFAS which is first sold, offered for sale, or distributed in the state after the initial reporting deadline must submit to the commissioner the required information on or before one month from that first sale, offer for sale, or distribution in the state.*
>
> *"Significant change" means a change in the composition of a product which results in the addition of an intentionally added PFAS or a change in manufacturer contact information.*

Allowing at least one month for reporting on new products will provide manufacturers with time between product launch and the reporting deadline. Likewise, cabining the definition of "significant change" to the addition of an intentionally added PFAS and changes to contact information will help limit reporting burdens. Maine DEP's proposed rule to implement the state's PFAS law also defined significant change using a 10% increase in the amount of PFAS in the product. *See* Maine DEP, Chapter 90 Draft Rule, Section 2(V), https://www.maine.gov/tools/whatsnew/attach.php?id=10415809&an=2. However, for certain complex products such as many electronics, the manufacturing processes are not so exact as to detect a small percentage change in the concentration of PFAS. "Significant change" in the Reporting Rule should therefore be limited to the addition of an intentionally added PFAS or, at a minimum, be set to a much higher percentage than 10%.

III. Define PFAS Through a List of CAS Numbers and with a Fluoropolymer Exclusion

We request that the Reporting Rule define "PFAS" as follows:

"PFAS" means any chemical or group of chemicals listed in [MPCA rule citation]. "PFAS" does not include (1) chemicals without CAS numbers; or (2) fluoropolymers.

We strongly encourage the MPCA to issue a finite list of PFAS that are subject to the Reporting Rule. Without a specified list of chemical names with CAS Numbers, tracking a class of thousands of chemicals through complex supply chains is virtually impossible. Limiting reporting to PFAS with CAS Numbers is supported directly by the text of subdivision 2(a), ¶ 3 in Section 116.943 which requires reporting of "the amount of each PFAS, identified by its chemical abstracts service registry number, in the product" (emphasis added). This exclusion is also consistent with Maine DEP's proposed PFAS rule. *See* Maine DEP, Chapter 90 Draft Rule, Section 2(P), n.2 ("chemicals which do not have CAS numbers assigned are not subject to this Chapter"). We likewise recommend that reporting be allowed by PFAS group instead of only by discrete PFAS substance.

In addition, the Reporting Rule's PFAS definition should explicitly exclude fluoropolymers. An exclusion for fluoropolymers is necessary because these substances are critical components of products in almost every major sector of the economy and there are currently no viable alternatives. Moreover, fluoropolymers cannot dissolve in water or enter a person's bloodstream, and they meet the Organisation for Economic Co-operation and Development's criteria for "polymers of low concern" because they do not present a significant toxicity concern. Rather than burden the MPCA with processing notifications for these substances, the PFAS definition should simply exclude fluoropolymers due to their low concerns and extremely high cost of regulation.

IV. Requested Scope Exclusions

We request the following scope exclusions be included in the Reporting Rule:

This part does not apply to the sale, offer for sale, or distribution in the state of:

(a) Products containing less than 0.1% by weight of PFAS;

(b) Spare parts to repair finished electronic products placed on the market before January 1, 2026; or

(c) Product packaging, except when that packaging is sold individually and not used in the marketing handling, or protection of a product.

a. Products Containing PFAS Below a De Minimis Concentration Threshold Should Be Excluded

Our recommended 0.1% by weight threshold is in line with other jurisdictions' chemical reporting and restriction requirements, including EU REACH which provides a 0.1% by weight threshold for substances of very high concern. *See* EU REACH, Art. 7(2).[2] This threshold has been in place in the EU for nearly fifteen years. The EU Restriction of Hazardous Substances Directive ("RoHS") also restricts the presence of nine chemicals or categories to a 0.1% threshold. *See* EU RoHS, Annex II.[3]

A 0.1% by weight threshold provides a rational, reasonable level that promotes the safe use of substances of high concern without overly burdening supply chains by requiring excessive and destructive testing to determine whether trace amounts of these substances are present in products.

[2] This EU REACH 0.1% threshold is calculated with reference to the weight of an article.

[3] This EU RoHS 0.1% threshold is calculated with reference to the weight of a homogenous material.

This threshold would also help ease the burden on the MPCA by preventing hundreds of thousands of notifications related to parts and components that contain only trace PFAS amounts.

b. **Spare Parts Should Be Excluded**

An exclusion for spare parts would implement the "repair as produced" principle that is commonly incorporated into material restriction laws, including EU RoHS and REACH.[4] This well-established principle allows finished electronic products already on the market before a compliance date to be repaired using spare parts that were compliant before that date. The principle recognizes that, particularly for equipment in the ICT sector that involves significant capital expenditures, certain products can continue to productively operate for many years, even after the applicable compliance date passes. This principle is particularly relevant to the Reporting Rule, as subdivision 2(d) in Section 116.943 prohibits the sale, offer for sale, and distribution in the state of a product containing intentionally added PFAS if the manufacturer has failed to report that product and the manufacturer has received a notice to test the product under subdivision 4.

Like the exclusion for used products that is included in Section 116.943, an exclusion for spare parts in the Reporting Rule supports a circular economy by keeping used products functional and on the market as long as practicable. As manufacturers move to eliminate PFAS in their new production cycles, the current inventory of spare parts that contain PFAS will decline over time, therefore limiting the value of reporting data tied to these parts. Moreover, it would be wasteful to discard existing spare parts that contain PFAS should the restriction in subdivision 2(d) in Section 116.943 be triggered.

c. **Packaging Should Be Excluded**

The recently enacted amendment to Maine's law incorporates an explicit exclusion for packaging. *See* 38 M.R.S. § 1614(4)(B). An exclusion in the Reporting Rule for packaging would therefore prevent a jurisdictional patchwork of state PFAS reporting requirements from forming on this topic.

V. **Provide Clarity on the Reporting Platform and Coordinate Reporting with Other States**

There is a high degree of uncertainty among manufacturers on a large number of procedural details on exactly how and what data will be required for reporting. Many of these details will not be clear until companies can actually see the reporting platform that the MPCA plans to use. Given this uncertainty, we encourage the MPCA to allow manufacturers access to the reporting platform for several months before the reporting deadline so that they can test and accurately prepare their data. At a minimum, the MPCA should provide all the mandatory data fields and data requirements that will be in the reporting platform before finalizing the Reporting Rule and well before reporting is due. It will take considerable time for manufacturers to develop and master the logistics of reporting.

Likewise, EPA should coordinate with other states, including Maine, to use the same PFAS reporting platform across applicable jurisdictions. This will not only streamline reporting for manufacturers (particularly for electronics manufacturers who sell their product across the country), but it will also reduce the burden on the MPCA to create its own reporting platform from scratch.

[4] RoHS Directive, Article 4(4) incorporates the "repair as produced" exemption for all in-scope electronic products. REACH Annex XVII Entry 68, Paragraph 9 includes a "repaired as produced" derogation for semiconductors used in spare or replacement parts for finished electronic equipment placed on the market before December 31, 2023.

VI. **Include Provisions to Adequately Protect CBI and Trade Secrets**

A well-defined CBI framework for the Reporting Rule and all future rulemakings to implement Section 116.943 will be essential for the protection of valuable intellectual property that might otherwise be jeopardized. We therefore urge the MPCA to adopt highly protective and enforceable CBI protections in its Reporting Rule.

The technology sector treats the chemical composition of materials as proprietary information that is carefully protected and of significant commercial value. The MPCA's regulations should contain explicit language explaining how manufacturers would provide the reporting information to the agency, how the MPCA will determine what CBI data may be withheld or provided in a generic/sanitized manner, and how that information will be stored and ultimately protected from unlawful disclosure to third parties.

Section 116.943 does not require disclosure to the public of any information reported to the MPCA. We request that the MPCA explicitly protect from disclosure under Minnesota's Government Data Practices Act information such as a manufacturer's production and sales volume data, the volume and concentration of PFAS in a product, and any information relating to sales volumes or production volumes. Additionally, we request that the MPCA confirm these protections as part of this rulemaking.

We also request that the Reporting Rule include robust provisions that will allow protection of CBI and trade secrets through the use of generic chemical names and broad chemical ranges in any information that is released to the public. EPA's recently finalized rule to centralize CBI claims under TSCA may serve as a model. *See* 88 Fed. Reg. 37155 (Aug. 7, 2023). In order to provide certainty to the regulated community, the EPA rule identifies specific information that submissions must include and the type of information that could qualify as confidential and, thereby, be shielded from disclosure under the federal Freedom of Information Act or other means. Minnesota should consider doing similarly.

Sales information, particularly future sales projections, if required by the MPCA, should also be protected from disclosure. We have significant reservations with the obligation for companies to report sales data. If sales data reporting is to be required, it should be limited to aggregated data within a past year and not include future forecasts. Recent historic sales data should be explicitly protected as CBI by the MPCA. We encourage the agency to develop strategies that would aggregate any sales data by product categories or across industry members through third party reporting.

We appreciate your attention to our comments and welcome the opportunity to respond to questions or engage with you further.

Sincerely,

K. Russell LaMotte
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RECEIVED
By: OAH on 11/27/2023
Christopher Finarelli Attachment

November 27, 2023

Minnesota Pollution Control Agency
Attn: Mary H. Lynn
520 Lafayette Road North
St. Paul, Minnesota 55155-4194

Submitted Via OAH Portal

Dear Ms. Lynn:

The Household & Commercial Products Association (HCPA) would like to express its gratitude for the opportunity to provide comments to the Minnesota Pollution Control Agency (MPCA) regarding the forthcoming implementation of Minnesota Session Law H.F. No. 2310 (2023, Chapter 60).

HCPA is committed to promoting responsible production, use, and management of fluorinated substances, with a strong focus on regulatory requirements that safeguard both human health and the environment, particularly in cases involving substances that are persistent, bioaccumulative, and toxic (PBT). While HCPA acknowledges that MPCA is bound by the broad definition of PFAS as outlined in the law, we believe it is crucial to consider the diversity of chemicals falling under this broad definition and their unique applications. Adopting a singular policy approach towards PFAS in products does not align with the current marketplace. In addition, we strongly advise the agency to closely monitor related activities undertaken by the U.S. Environmental Protection Agency (EPA) and other state regulators.

PFAS "Alternatives"
HCPA values the inclusion of the term and definition for "Currently unavoidable use" in the legislation. However, we encourage MPCA to provide further clarification on the term "alternative" as used in the same definition. Specifically, HCPA believes that any alternative to an existing use of a PFAS substance can only be considered a true replacement if it is both technologically and commercially feasible. In other words, it should be both functionally equivalent and economically viable. If a potential replacement is functionally similar and reduces potential harm to human health or the environment but is not economically viable or scalable to meet market demands, it cannot be considered a practical alternative.

"Essential for Health, Safety, or the Functioning of Society"
HCPA appreciates the term "Essential for Health, Safety, or the Functioning of Society." However, we request additional clarification on this definition, particularly regarding how the Agency would determine what is considered essential in various contexts such as climate mitigation, critical infrastructure, delivery of medicine, lifesaving equipment, public transport, and construction. For example, HCPA members often manufacture pesticidal products that play a vital role in public health pest control. It is essential to determine whether these products fall within this definition, especially in the context of Regulation under Minnesota Session Law S.F. No. 1955 (2023, Chapter 43).

“Responsible Party”
HCPA is concerned about potential confusion surrounding the identification of the responsible party required to report PFAS applications as defined by the law. The law states that the responsible party is the company that produces the product *or* whose brand name is associated with it. In scenarios where these are two different entities, determining the responsible party may prove challenging. Furthermore, there are uncertainties regarding reporting obligations throughout the supply chain. The term "Product" is broadly defined, and in cases where a company sells components to an entity in Minnesota that assembles the end-use product, there is ambiguity about whether the component supplier is subject to reporting requirements. HCPA recommends that MPCA define the term "responsible party" and establish a reporting hierarchy, providing clear terminology to ensure clarity among stakeholders obligated to report.

"Significant Change"
The interpretation of the term "Significant Change" is likely to vary across different applications. HCPA emphasizes that a uniform approach in defining this term is not ideal. Instead, HCPA suggests that MPCA should establish a process through which responsible parties can provide information outlining what they consider a significant change within their specific application. While the information presented to MPCA will naturally differ based on the application, any guidance or general topics that MPCA seeks from stakeholders would be welcomed. Additionally, harmonizing this process with reporting requirements in other states would reduce compliance burdens.

Chemical Abstracts Service Number
Subd. 2 and 4 of the law require the disclosure of the amount and Chemical Abstracts Service (CAS) registry number for PFAS. Many PFAS substances required to be reported do not have unique CAS numbers. Additionally, the manufacturer of the final product and the responsible party may not possess this information. HCPA encourages MPCA to develop an alternative process when this information is not feasible.

Testing Methods
HCPA suggests that the definition of "Commercially Available Analytical Method" should be clarified in the regulations. Allowable testing methods should be flexible to ensure companies and third-party laboratories can use the most accurate and up-to-date methods. Given the complexity of PFAS substances, very few analytical test methods are currently robust enough to accurately test them. HCPA recommends that companies and third-party laboratories have the flexibility to modify existing methods or develop new validated ones. For instance, Total Organic Fluorine (TOF) analysis measures all fluorine materials associated with organic fluorine but does not identify individual PFAS substances (it is more like a screening process). Furthermore, various products have the potential to create interferences within the testing of TOF, creating additional challenges across different matrices. There are more specified methods under development that can predict the degradation and release of polymeric PFAS but may have limitations. HCPA encourages MPCA to collaborate with industry and intergovernmental agencies to ensure robust and accurate testing requirements.

Certification
HCPA acknowledges the reference to a "certificate" in Subd. 4 in the event that MPCA believes a product contains intentionally added PFAS and is being sold or offered for sale in violation. However, clarity is

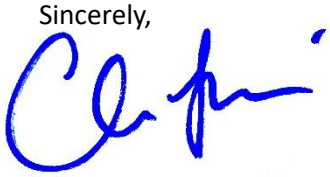
needed on the threshold for MPCA's belief a violation has occurred and the requirements for the certificate in cases where no violation has occurred. Furthermore, HCPA requests guidance on what MPCA expects to be submitted if a company claims the PFAS found in a product originates from a contaminant. Clear guidelines for certifying compliance are greatly appreciated.

Confidential Business Information
HCPA anticipates a need for claims of confidential business information (CBI) by many companies across various reporting elements. Specific byproducts and impurities within formulations can be considered CBI if their disclosure might reveal proprietary processes or formulation-related information. The final rule should simplify electronic reporting to enable "joint submissions" and acknowledge that companies can assert claims of CBI for any PFAS already approved by EPA for inclusion on the TSCA Confidential Inventory or protected under the Uniform Trade Secrets Act. The final rule should also clarify what information elements can be claimed as confidential and offer simplified substantiation procedures for CBI claims to reduce the burden on submitters.

Shared Reporting Services with Other States and the EPA
Subd. 3 of the law grants MPCA the authority to waive all or part of the notification if equivalent information is already publicly available. HCPA encourages MPCA to leverage this authority and existing agreements with other states to reduce duplicative actions stemming from multiple state regulations on PFAS. EPA is currently working on a comprehensive process that requires manufacturers and importers of identified PFAS to report information. HCPA believes that this work by EPA presents an opportunity for Minnesota and other states to streamline reporting requirements and make use of data gathered by the federal environmental regulator.

In closing, HCPA appreciates the opportunity to provide these comments and looks forward to collaborating with MPCA and other stakeholders to ensure that the residents of Minnesota continue to have access to products that enhance their daily lives. If the Agency staff would like to discuss our comments further, please do not hesitate to contact us.

Sincerely,



Christopher Finarelli
Sr. Director, State Government Relations & Public Policy - Western Region

Honeywell

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Washington, DC 20001
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November 27, 2023

Office of Administrative Hearings
600 North Robert Street
P.O. Box 64620
Saint Paul, Minnesota 55164-0620

Re: In the Matter of the Proposed Rules of the Minnesota Pollution Control Agency regarding PFAS in Products Reporting Rule/PFAS in Products Fee Rule; OAH Docket No. 65-9003-39507 and OAH Docket No. 71-9003-39506; Governor's Revisor's ID Numbers: R-4828 and R-4827

To Whom It May Concern:

Minnesota Pollution Control Agency requests that the Office of Administrative Hearings review comments on its proposed rules governing PFAS in Products under statutory authority of Minnesota Session Law – 2023, chapter 60, article 3, section 21, (***Minnesota Statutes 116.943***) for the following two items:

i. **Fee**; Minnesota Session Law – 2023, chapter 60, article 3, section 21, (*Minnesota Statutes 116.943*) subdivision 6 (**R-4827)**

ii. **Reporting**; Minnesota Session Law – 2023, chapter 60, article 3, section 21, (*Minnesota Statutes 116.943*) subdivision 2 (**R-4828)**

Enclosed for your review are the request for comments required by Office of Administrative Hearings Rules

A. Enclosed: The request for comments as published in the State Register OAH Docket No. 65-9003-39507 and OAH Docket No. 71-9003-39506; on September 25, 2023.

Should you have any questions or concerns with our submission please don't hesitate to get in touch with us.

Sincerely,

Atashi Bell, PhD
Senior Director, Global Government Relations
Atashi.Bell@honeywell.com

Honeywell

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Mr. William Moore
Minnesota Office of Administrative Hearings
600 North Robert Street
St. Paul, MN 55164

RE: Comments to the Minnesota Pollution Control Agency on Planned New Rules Governing Reporting by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS) ("Planned Rules"), Revisor's ID Number R-4828, OAH Docket No. 65-9003-39507

Dear Mr. Moore:

Honeywell appreciates the opportunity to comment on the above-referenced Planned Rules on reporting requirements for Per- and Polyfluoroalkyl Substances ("PFAS") pursuant to Minn. Stat. § 116.943 issued by the Minnesota Pollution Control Agency ("MPCA" or the "Agency").

Honeywell is an integrated operating company serving a broad range of industries and geographies around the world. Our business is aligned with three powerful megatrends - automation, the future of aviation, and energy transition - underpinned by our Honeywell Accelerator operating system and Honeywell Connected Enterprise integrated software platform. As a trusted partner, we help organizations solve the world's toughest, most complex challenges, providing actionable solutions and innovations that help make the world smarter, safer, and more sustainable. The company traces its roots in Minnesota back to 1927 when the Honeywell Heating Specialty Company merged with the Minneapolis Heat Regulator Company to form the Minneapolis-Honeywell Regulator Company.

Today, Honeywell's workforce in Minnesota includes approximately 1,870 employees at five facilities across the State. Three of these sites develop and manufacture various equipment and materials for the aviation, space, and defense sectors ("Aerospace & Defense" or "A&D").[1] Within the A&D sector, fluorinated substances comprise critical components of aircrafts, vessels, satellites, rockets, and missile actuation systems, and enable critical functions including thermal management, life support, avionics, fuel supply, engine operation, auxiliary power, navigation, communication, microelectronics, sensors, radars, insulation, and hydraulics. In addition to A&D, Honeywell operates two additional sites in Minnesota that produce a variety of switches, safety shut-off valves, flow meters, flame detectors, pressure regulators, residential heat, water, gas meters, and other materials in the smart energy and thermal solutions sectors.

Honeywell is also a manufacturer of various fluorinated gases, including hydrofluorocarbons ("HFC"), hydrochlorofluoro-olefins ("HCFO"), hydrofluoroolefins ("HFO") refrigerants and their mixtures ("Blends"), used in refrigeration, heating, ventilation and air conditioning ("RHVAC"), mobile air conditioning ("MAC"), thermal management systems ("TMS") in electric vehicles ("EV"), propellants in medical dose inhalers ("MDI") and insulation foam blowing agent applications, as well as a particular fluoropolymer - polychlorotrifluoroethylene ("PCTFE") - used in the primary and secondary packaging of medicinal products, medical devices, and over-the-counter ("OTC") medications.

[1] Across the United States, the Aerospace and Defense industry supported 2.1 million jobs in 2022. *See* https://www.aia-aerospace.org/industry-impact/.

Honeywell

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Introduction

On May 24, 2023, Minnesota Governor Tim Walz signed into law Minnesota Session Law – 2023, chapter 60, article 3, section 21, (Minn. Stat. § 116.943) ("Minnesota Statute"). The Minnesota Statute requires "a manufacturer of a product sold, offered for sale, or distributed in the state that contains intentionally added PFAS" to submit certain information to the MPCA "[o]n or before January 1, 2026[.]" Subdivision 9 of the Minnesota Statute allows the MPCA to adopt "rules necessary to implement this section." Accordingly, the MPCA issued a request for comments regarding the Planned Rules on September 11, 2023. These comments address the specific questions posed by MPCA as well as other possible aspects of the Planned Rules that may assist MPCA in its rulemaking.

Honeywell fully supports MPCA's authority to collect information that has a bearing on human health and the environment and to mitigate unreasonable risks with sensible regulations when such risks are presented by specific chemical substances. However, Honeywell is concerned the Planned Rules will impose considerable burdens on the regulated community without achieving commensurate benefit to human health or the environment and would be duplicative of new federal product reporting requirements. Accordingly, Honeywell offers comments on opportunities to improve effectiveness in gathering information which will be critical to MPCA's mission of assessing and mitigating potential risks to human health and the environment.

I. The Planned Rules should more clearly define the following terms in Subdivision 1 of the Minnesota Statute.

"Perfluoroalkyl and polyfluoroalkyl substances" or "PFAS" "PFAS" as it is written under the statute is currently defined as "a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom." The proposed PFAS class is unified only by a single chemical feature, which results in an overly broad group of substances with vastly different physico-chemical, toxicological and degradation properties, such that treating the whole class as a "toxic substance" departs from the aim of targeting well-defined groups of substances that have been demonstrated to have actual or potential hazardous effects on the environment or on human health.

Honeywell believes that the scope of any PFAS reporting requirement should be tailored to exclude substances with no established persistent and bioaccumulation characteristics. For instance, molecules with smaller and larger carbon chain lengths (< C4 or > C20) have been systematically shown not to exhibit bioaccumulative properties. Certain PFAS compounds with short carbon chain lengths (shorter than 3-carbons) or alternative chemical structures are known to be non-persistent such as the new generation of F-gases, i.e. HFOs, which were specifically designed to have short lifetimes in the environment (10-26 days) and have been deemed by multiple regulatory authorities across the globe not to have bioaccumulation or toxicity potential.

Honeywell emphasizes and notes that an overly broad definition of PFAS will include chemicals that are non-toxic and non-bioaccumulative. Many are approved for their respective end-use applications by the United States Environmental Protection Agency ("EPA") under Section 612 of the Clean Air Act ("CAA"), as well as

specific Toxic Substances Control Act ("TSCA") significant new use rules and various Section 5(e) Consent Orders, and these substances also are already subject to CAA and TSCA reporting requirements.

According to the most recent United Nations Environment Programme, Environmental Effects Assessment Panel (EEAP) 2022 Assessment Report, "all PFAS should not be grouped together, persistence alone is not sufficient for grouping PFAS for the purposes of assessing human health risk, and that the definition of appropriate subgroups can only be defined on a case-by-case manner" and "it is inappropriate to assume equal toxicity/potency across the diverse class of PFAS."

i. The EPA's approach to "PFAS"

The EPA has taken several key federal actions to regulate PFAS, and Honeywell believes that there is value in Minnesota looking at these approaches in more detail as it decides its policy options. Per the EPA's approach, there are multiple definitions of PFAS, and the choice of definition determines which fluorinated chemicals are subject to regulation based on the agency's goals of addressing and prioritizing those PFAS compounds that have demonstrated persistence, bioaccumulation potential, and toxicity risk.

The EPA introduced its own definition of PFAS in 2021 through the National PFAS Testing Strategy: "chemicals with at least two adjacent carbon atoms, where one carbon is fully fluorinated and the other is at least partially fluorinated." The EPA's narrower definition is based on the agency's goal of identifying and regulating PFAS compounds that have been demonstrated to pose the highest potential risk to the environment and human health. By targeting compounds that EPA considers to be highest risk, the EPA can prioritize its resources and efforts on those PFAS compounds that have a demonstrated persistence, bioaccumulation potential and toxicity risk**.**

The EPA has also continued to propose new structural approaches to defining the scope of PFAS that are better addressed under other regulatory schemes such as the TSCA PFAS reporting rule, the Safe Drinking Water Act Contaminant Candidate List and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).

Most recently, the EPA announced its planned framework for reviewing new PFAS and new uses of PFAS.[2] This latest framework proposes extensive review of PFAS before they enter the market. Further, the definition of PFAS that has been proposed under this approach is based on chemical structure and is narrower and more appropriate. The framework includes differing levels of PFAS classification based on the potential for exposure and environmental release.

If a new PFAS chemical or one proposed for a new use is determined to be persistent, bioaccumulative, and toxic, the EPA has stated it will qualitatively consider the potential extent of exposure to the general population, consumers, and the environment, throughout the lifecycle of the PFAS. For PFAS designated as persistent, bio-accumulative, and toxic, the EPA said there will be three categories for regulation:

[2] EPA Framework for TSCA New Chemicals Review of PFAS Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs), dated June 28, 2023.

- **Negligible potential for exposure and environmental release**: if the PFAS will not result in worker, general population or consumer exposure and is not expected to result in releases to the environment, it is likely to be allowed to enter commerce after the agency receives some basic information;
- **Low but greater than negligible potential for exposure and environmental release**: the EPA expects it will require test data on PFAS physical/chemical properties before allowing manufacturing. And if initial test results cause the EPA any concern, the agency said it will require additional testing and risk mitigation; and
- **Higher potential for exposure and environmental release**: for persistent, bio-accumulative, and toxic PFAS that are expected to lead to exposure and environmental releases, and absent a critical or military need for the substance that necessitates limited and restricted manufacture while testing is ongoing, EPA will restrict entrance to commerce while extensive testing is conducted on physical/chemical properties, toxicity, and its behavior in the environment.

If a PFAS chemical is not found to be persistent, bio-accumulative, and toxic, the EPA has stated it will go through a typical new chemical assessment process. The EPA's approach to PFAS regulation specifically targets PFAS compounds that meet its defined criteria, focusing on drinking water contamination and potential health risks associated with those specific substances.

ii. Fluorinated Gases

A number of subclasses of PFAS caught by the overly broad definition in the Minnesota Statute have not been found to be hazardous. There is a robust body of scientific evidence that demonstrates a low or negligible risk profile for fluorinated gases, such that many regulatory agencies, including the EPA in its final rules for PFAS reporting pursuant to TSCA,[3] have deemed these substances out of scope.[4] For example, fluorinated gases such as HFO-1234ze(E), HFO-1336mzz(E), HFO-1336mzz(Z), and HCFO-1233zd(E), have degradation pathways that do not result in "extreme persistence" in the environment.

As part of its most recent Significant New Alternatives Policy (SNAP) Rule 25, published in April 2023, the EPA also states that "in evaluating alternatives using its comparative risk framework, Significant New Alternatives Policy (SNAP) already considers potential risks to human health and the environment. Regardless of what definition of PFAS is used, not all PFAS are the same in terms of toxicity or any other risk. Some PFAS included in the Minnesota Statute's definition have been shown to have extremely low toxicity, for example. If a chemical has been found to present lower overall risk to human health or the environment, it might be found acceptable under SNAP regardless of whether or not it falls under a particular definition of

[3]EPA's reporting rules at 40 CFR § 705.3 define *Per- and polyfluoroalkyl substances* or *PFAS as* any chemical substance or mixture containing a chemical substance that structurally contains at least one of the following three sub-structures: (1) R-(CF2)-CF(R')R", where both the CF2 and CF moieties are saturated carbons; (2) R-CF2OCF2-R', where R and R '□can either be F, O, or saturated carbons; (3) CF3C(CF3)R'R", where R ' and R" can either be F or saturated carbons.

[4] EPA has acknowledged that its definition of PFAS (i.e., "structurally contain the unit R-(CF2)-C(F)(R')R") excludes "fluorinated compounds that contain only one CF3 group, such as some fluorinated gases[.]" *See* EPA, Response to Comments Document on the Draft Fifth Contaminant Candidate List (CCL 5).

PFAS."[5]

iii. Fluoropolymers

Fluoropolymers have unique properties distinct from non-polymeric substances within the PFAS group.[6] They exhibit low reactivity, low water solubility, and a high average molecular weight with low levels of oligomers and residual monomers, and do not degrade under typical conditions of use. They are not subject to long-range transport, and with an average molecular weight well over 100,000 Da, fluoropolymers cannot cross the cell membrane, and thus are not bioavailable or bioaccumulative. Due to these characteristics, fluoropolymers exhibit low human and environmental toxicity concerns.

As previously mentioned, Honeywell operates three A&D sites within the State of Minnesota. Numerous key components of this equipment such as adhesives, seals, batteries, bearings, gaskets, hoses, O-rings, insulation, tubing, cables and wiring, filters, barrier films, refrigerants, fire suppression gases, etc. contain certain PFAS. Due to their unique physicochemical properties, these fluorinated substances exhibit exceptional characteristics for materials and equipment required by the A&D industry and mandated under applicable SAE Aerospace Standards (AMS) as well as European Union Aviation Safety Agency ("EASA") regulations/certificates and competent aviation authorities worldwide (e.g., the U.S. Department of Defense, Federal Aviation Administration, etc.). All technical specifications (*see*, e.g., AMS3255 or AMS3678 standards) need to be complied with simultaneously in all jurisdictions where aircrafts are produced, used, flown, and serviced. Most materials called into question for these uses by the Minnesota Statute are fluoropolymers with unique physicochemical characteristics and exposure, satisfy the OECD criteria for a Polymer of Low Concern (PLC)[7], and are deemed to be environmentally and humanly benign.

b. *"Currently unavoidable use"*

i. "Essential for health, safety, or the functioning of society"

Honeywell recommends clarification of the concept of "essential for health, safety, or the functioning of society" within the definition of "currently unavoidable use." MPCA should identify critical PFAS and certain uses that have undergone federal authorizations for specific uses pursuant to programs such as, but not limited to, the SNAP program under the Clean Air Act, the EPA's new chemical review program under Section 5 of the Toxic Substances Control Act, the Food and Drug Act, and other federal programs whereby either the PFAS, or products containing them, have been deemed acceptable for their intended use by federal government agencies. PFAS-containing products that are subject to, or necessary for, meeting federal

[5] Page 26414, Federal Register, Vol. 88, No. 82, Friday, April 28, 2023, Rules and Regulations, 2023-08663.pdf (govinfo.gov).

[6] A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers, Integrated Environmental Assessment and Management, Volume 14, Number 3, pp. 316–334 (2018).

[7] See detailed analysis in *A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers*, Stephen H. Korzeniowski *at al.*, Integrated Environmental Assessment and Management — Volume 19, Number 2—pp. 326–354, 2022.

specifications (e.g., military specifications, United States Federal Aviation Administration (FAA)-issued standards, National Aeronautics and Space Administration (NASA) requirements) also should be considered currently unavoidable use. Such an approach will help MPCA concentrate its efforts on non-essential consumer products. Fairness and market stability should be assured to businesses that have successfully completed federal reviews for their PFAS-containing products under these statutes or provide products that must meet military or similar government specifications.

Furthermore, Honeywell recommends the rulemaking also establish both a clear-cut process and criteria whereby any PFAS-containing product producer may seek a "currently unavoidable use" determination. MPCA may want to exercise its authority to issue such determinations carefully and with conditions. For example, exemptions from a prohibition might be granted subject to an appropriate time limitation (with the ability to seek extensions) Periodic reporting by the exemption recipient also could be a condition of the currently unavoidable use designation.

When making a "currently unavoidable use" determination, MPCA should consider the following factors:

- benefits to public health, the environment, community safety, national security, critical infrastructure, or other critical function of society;
- the known effects of the PFAS or PFAS-containing product on human health and the environment including the specific substance's physical-chemical characteristics, its environmental fate, as well as its toxicity, including how such characteristics compare to other substances which provide the same performance characteristics;
- the availability of technically and economically feasible chemical alternatives that can be used for the same purpose and which can be demonstrated to be environmentally preferable to the PFAS under consideration;
- whether the use of the PFAS or PFAS-containing product contributes to achieving environmental objectives, including the mitigation of climate change;
- whether the use of the PFAS or PFAS-containing product is of value to society because it contributes to the safety, efficacy, or accuracy of useful activities and products including those used in scientific research, medical equipment, or treatments, in pharmaceuticals and their packaging and in medical devices, and in the manufacture of components in critical goods; and
- whether the use is beneficial in other applications or commercial uses in important sectors of the economy (such as aerospace, defense, industrial and commercial equipment, and automotive sectors).

Honeywell's Solstice® Hydrofluoroolefin ("HFO") technology is an example of a fluorotechnology that meets important societal needs while providing significant environmental benefit. To date, use of Honeywell HFO technology has helped avoid the potential release of the equivalent of more than 326 million metric tons of carbon dioxide into the atmosphere, equal to the carbon emissions from nearly 70 million gasoline-powered

passenger vehicles per year.[8]

Further, as confirmed in recent analyses from Oak Ridge National Laboratory, HFOs represent greater energy efficiencies across important commercial applications, including in appliances, residential air conditioning, supermarket refrigeration systems, and spray foam insulation. In commercial refrigeration applications, HFO solutions will consume **5% to 21% lower energy as compared to propane systems** over the lifetime of the system (15 years), and **8% to 50% lower energy as compared to CO2 systems** over the lifetime of the system (15 years).[9] When evaluating the performance attributes of HFO blowing agents to evaluate energy efficiency, as well as safety attributes to identify HFOs' flammability characteristics, Oak Ridge National Laboratory researchers concluded that "**HFOs can effectively replace higher GWP solutions, such as HFCs, to reduce emissions and mitigate the use of flammable and explosive materials in high-density, urban areas."**[10]

ii. "alternatives"

Honeywell requests that MPCA provide a detailed definition of "alternatives" as that term is used within the definition of "currently unavoidable use." The definition should include concepts of functional equivalency and reducing potential risk to human health or the environment. The basis for those concepts must be consistent, fair, transparent, and well-defined.

For example, in the Montreal Protocol on Substances that Deplete the Ozone Layer, an international treaty designed to protect the ozone layer by phasing out the production and consumption of ozone-depleting substances (ODS), defines "alternatives" as substances or technologies that:

- Do not deplete the ozone layer: Alternatives must not have ozone-depleting potential or, at the very least, have significantly lower potential compared to the substances they are intended to replace.
- Are more environmentally friendly: Alternatives should have a reduced impact on the environment, including lower global warming potential and lower potential for other environmental impacts.
- Are technically and economically feasible: Alternatives should be practical and viable from both a technical and economic standpoint to ensure that industries can transition smoothly away from ozone-depleting substances.

The definition of alternatives is crucial to the success of the Montreal Protocol, as it guides the efforts to find and adopt substitutes for ODS in various industrial processes and applications. The protocol encourages the development and use of alternatives to accelerate the phase-out of substances like chlorofluorocarbons (CFCs), halons, and other ozone-depleting chemicals.

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[8] Calculations are based on actual sales of Solstice products (in lbs) from Jan 2010 through Jan 2022, and utilize the EPA GHG equivalency calculator for conversion.

[9] Oak Ridge National Laboratory Study "*Technology Options for Low Environmental Impact Air-Conditioning and Refrigeration Systems*"

[10] Oak Ridge National Laboratory Study "*Assessment of the Performance of Hydrofluoroolefins, Hydrochlorofluoroolefins, and Halogen-Free Foam Blowing Agents in Cellular Plastic Foams*"

Another example is the definition of "substitute or alternative" under EPA's SNAP program, which defines the term as "any chemical, product substitute, or alternative manufacturing process, existing or new, that could replace a class I or II substance."[11] EPA also takes into account an alternative that "(1) reduces overall risk to human health and the environment, and (2) is currently or potentially available.

Defining alternatives with respect to A&D companies will be challenging. These alternatives must be qualified (i.e., evaluated and tested) in the context of the aircraft system or sub-systems. These processes must be repeated where the alternatives are found to be unsuitable. Once qualified, the system must be revalidated to maintain certification of the product (e.g., aircraft, vessel, vehicle, etc.). Certification is strictly controlled by regulatory bodies in both the United States and other jurisdictions, in both the civil aerospace and military domains. Examples include the EASA, the FAA, and their military counterparts.

A&D products are subjected to some of the most austere environments around the world. They must operate successfully in extremes, including but not limited to altitude, temperature, pressure, and precipitation, while having to fulfil the highest possible technical reliability and safety requirements. To ensure aircraft safety, comprehensive airworthiness regulations have been in place around the world for decades. These regulations require qualification of all materials and processes according to a systematic and rigorous process to meet stringent safety requirements that are ultimately subject to independent certification and approval. Such rigorous testing and qualification processes are required to assure that any changes do not compromise the integrity of the affected components or the safety of the product as a whole.

iii. "Reasonably Available"

Honeywell requests that the MPCA provide a detailed definition of "reasonably available" as that term is used within the definition of "currently unavoidable use." How the MPCA will determine when alternatives are not reasonably available should also be explained in the regulation and should include the concepts of performance, safety, cost, and supply chain considerations.

For example, due to the specifics of A&D uses, known alternative materials are not available to simultaneously satisfy all required properties, such as low flammability, high service temperature (above ~200 °C), low dielectric constant, electric arc tracking resistance, mechanical strength and elasticity, and chemical resistance/inertness to even the most aggressive chemicals. In many essential A&D applications **only,** fluorinated substances can fulfil all required technical (AMS3255, AMS3678, ASM3659, ASTM D1710, AMS7276, AMS7287, AMS3651, AMS3667) and miliary specifications (MIL-S-46163, MIL-PRF-276717).[12] A&D production also needs to adhere to strict quality standards like ISO AS9100 and Nadcap.

Moreover, the combination of properties required in most A&D applications will be difficult to achieve in a new material. Even after a material with the suitable combination of properties would be discovered or invented, it will take decades to approve its uses by the overall A&D industry (e.g., all major aircraft producers should test and approve) and to certify it under all applicable standards worldwide. It is estimated

[11] 40 CFR § 82.172 "Substitute or alternative"

[12] For example, technical specifications for PTFE/ETFE insulated wire under M22759 (SAE AS22759) standards or requirements for heat transfer fluids, solvent resistance O-rings, etc.

that, in practice, this process would require approximately 30 years (on average) for many critical aircraft components.

The Agency should consider establishing a transparent and well-defined framework in making its determination of the reasonable availability of alternatives. Subsection (i) of the American Innovation and Manufacturing Act of 2020 (AIM Act), entitled "Technology Transitions," may serve as a useful example of criteria that a substitute, or alternative, must meet prior to EPA establishing restrictions on the use of a substance being substituted. Specifically, when determining whether to restrict the use of a substance, EPA, under this provision, is required to consider "the availability of substitutes for use taking into account technological achievability, commercial demands, affordability for residential and small business consumers, safety, consumer costs, building codes, appliance efficiency standards, contractor training costs, and other relevant factors…". Honeywell urges the MPCA to consider adopting a similar approach in assessing substitutes to PFAS, and to identify the criteria that the MPCA intends to use in ascertaining the reasonable availability of alternatives. Honeywell further requests that the MPCA make the information used in conducting an assessment or evaluation of alternatives publicly available for review and comment.

c. "Manufacturer"

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 reporting requirement.

The Planned Rule also does not adequately account for the possibility, and likelihood, that manufacturers whose products are sold by distributors may be unaware that their products are being offered for sale in MN and therefore may, as a practical matter, be unable to report under the rule. The final rule must appropriately account for this type of scenario – for example by requiring the distributor to report instead of the manufacturer.

For products sold directly to distributors outside of MN and not directly to retailers or individuals in MN, it will be virtually impossible for the original product manufacturer to report on sales into MN. For example, if a manufacturer in State #1 sells a product containing intentionally added PFAS to a distributor in State #2, who then sells to retail outlets in MN, the original manufacturer of the product will not have access to the distributor's data for products sold into MN, the manufacturer will only know what it sells to the distributor. This is not an uncommon scenario, particularly for common consumer and household products.

The same is true for sales made through on-line platforms where the original manufacturer is not the entity fulfilling the sale of the product into MN products sold to members of the public through on-line platforms, as those can come from anywhere, and the original manufacturer has little to no control over that sale or the ability to get sales information through such channels. The Department needs to address these realities in the definition of "manufacturer" and in the description of data and information that a "manufacturer" as currently defined will be reasonably expected to provide.

Honeywell recommends that MPCA clarify how the reporting requirements apply to multiple businesses in the supply chain for finished products that will be distributed with multiple PFAS containing components; when sales can be made through online platforms; as well as situations where the manufacturer may sell the good to a distributor outside the state and further transactions bring the product into scope when it crosses state lines.

The proposed regulation must make clear whether the responsibility falls upon the maker of the PFAS-containing components, the brand owner, a brand licensee, an importer, toller, filler or the company that is distributing the finished product for sale within the state when multiple parties fit into the definition of manufacturer. If left undefined, Honeywell predicts significant confusion and a high likelihood of duplicative reporting emerging from the current definition of manufacturer, which will likely result in an overestimation of the amount of PFAS in products in Minnesota and any conclusions about human or environmental exposure will be erroneously based on such estimates.

d. "Product" and "Product Component"

Honeywell requests that the MPCA clarify that the definitions of "product" and "product component" are limited to those products made available to consumers for their personal use. This will permit MPCA to focus its attention and resources first on PFAS-containing consumer products.

The inclusion in the definition of "product" of items made available to consumers for "commercial, or industrial use" or "for use in making other products" unintentionally expands the scope of the products on which focus should remain. MPCA should include language in the proposal to make clear that PFAS-containing products that are used in commercial settings (e.g., office equipment) and in industrial, manufacturing applications (e.g., industrial and commercial devices, such as mechanized systems and robotics) are excluded from the reporting and the prohibitions requirements under the law.

Honeywell also requests that MPCA confirm that its definition of "product" and "product component" exclude manufacturers of chemistries used in these items. Honeywell interprets the Minnesota Statute as requiring the manufacturer who takes its chemistries and uses it in the manufacture or production of a product or product component as the entity ultimately responsible for reporting to the Commissioner.

Inclusion of chemical manufacturers and producers in the definition of products or product components would expand the number of submissions to the Commissioner and potentially lead to double or triple counting of chemistries entering Minnesota. For example, a household refrigerator is a product that contains a refrigeration system—comprised of a compressor, evaporator coils, and other refrigeration components—such as gaskets and foams. Some of these individual elements, which Honeywell interprets as "product components" under the Minnesota Statute would use Honeywell chemistry, defined as PFAS by the Minnesota Statute, to function. In this example, the refrigeration system and its components would contain a refrigerant that circulates through these product components for its heat transfer properties. The foam would be made using a foam blowing agent (also a Honeywell product) for insulation purposes. If Honeywell's regulated chemistries are considered products or product components, then the company would be required to report on chemistries sold to manufacturers of the refrigerator (the OEM). The

refrigerator manufacturer would potentially need to report on the quantity of refrigerant in its system, the quantity of foam blowing agent in its foam, and any other PFAS quantities used in other components such as gaskets and seals. Therefore, MPCA would potentially receive the same information from at least two sources in the aforementioned scenario. The chemical itself does not perform any function until it is deployed in the product or equipment where it will be used. Thus, Honeywell believes that to avoid any double counting and avoid confusion, the chemical manufacture should not be required to report.

This interpretation is consistent with how EPA views containers of chemicals under the American Innovation and Manufacturing Act of 2020 (AIM Act). EPA uses the term "bulk" to make a distinction between a product that would use our chemistry and the chemistry being transported in a container. Consider the description of bulk from the Allocation Framework Rule[13]:

> *EPA defines [bulk] as "a regulated substance of any amount that is in a container for the transportation or storage of that substance such as cylinders, drums, ISO tanks, and small cans. A regulated substance that must first be transferred from a container to another container, vessel, or piece of equipment in order to realize its intended use is a bulk substance. A regulated substance contained in a manufactured product such as an appliance, an aerosol can, or a foam is not a bulk substance." The examples provided in the definition are not exclusive. This definition serves to distinguish between a regulated substance that is in a container from a regulated substance that is in a product or other type of use system.*

Furthermore, Honeywell sells its chemistries to nationwide distributors, wholesalers, and OEMs, and oftentimes does not have any visibility into which states these products are sold. As explained above, it would be virtually impossible to keep track of this information (i.e., products sold directly to distributors outside of MN and not directly to retailers or individuals in MN).

II. <u>There are key terms and processes in Subdivision 2 where MPCA clarification will help reporting entities determine reporting status and obligations.</u>

a. "amount of each PFAS"

Subdivision 2 of the Minnesota Statute calls for manufacturers to report "the amount of each PFAS, identified by its chemical abstracts service registry number." The MPCA should also allow for alternatives to CAS numbers, such as EPA-assigned Accession numbers, for proprietary chemicals with CAS numbers that are federally protected as confidential and for which the manufacture can substantiate both the need for ongoing protection to sustain a commercial advantage and steps the manufacturer takes to maintain confidentiality.

b. "commercially available analytical methods"

Analytical methods must be appropriate for the PFAS that are the target of the analysis and for the physical

[13] 86 FR 55116

form of the product, e.g., gas, liquid, or solid. Analytical methods differ in which PFAS they are capable of detecting. For example, the analytical method EPA uses to identify PFAS in food contact materials targets 17 different PFAS. In contrast, EPA's Draft Method 1633 is designed to identify 40 different PFAS in aqueous media (i.e., water, wastewater, landfill leachate), soil, biosolids, sediment, and biological tissues.

To ensure clarity, the MPCA should elaborate in proposed regulations its intention regarding baseline criteria or performance standards for "any test methodology." It would be inappropriate in our view for the MPCA to allow the use of any method that any commercial lab says it can perform on any product matrix with no consideration of whether the method is fit for that purpose or has undergone any multi-laboratory validation or otherwise has been assessed for the purpose for which they are being used (i.e., accuracy, precision, specificity, detection limit, and quantification limit). Doing so would be well outside the realm of good regulatory science. Honeywell also recommends that the MPCA incorporate the concept of validation into its regulatory explanation of what "commercially available analytical methods" will be acceptable.

Finally, it is critically important for the MPCA to recognize that a large number of commercial PFAS compounds are proprietary chemicals for which there are no commercially available analytical methods. Moreover, without analytical standards for these proprietary chemicals, commercial laboratories will not be able to develop analytical methods. In addition, determining exact PFAS concentrations for complex articles in robust supply chains like automotive or aerospace; which are wholly dependent on full material supplier disclosure and product knowledge, can be a case where suppliers do not disclose certain information where unintentional omissions could occur. As a result, it will be impossible for manufacturers of products containing these PFAS chemistries to comply with the requirements of subdivision 2 of the statute unless the department establishes clear methods, standards, and approved reporting ranges for known PFAS compounds where identification and quantification is possible.

c. "range approved for reporting purposes"

The ranges approved for reporting purposes should be codified in regulation well in advance of the first reporting deadline so that manufacturers with reporting obligations can prepare accordingly. Honeywell recommends that the MPCA not develop ranges for different types of products. Doing so would create unnecessary confusion about the definition of products falling within each range and further complicate the ability of manufacturers with reporting obligations to report accurately and in a timely manner.

d. "significant Change"

The phrase "significant change" needs to be defined so that a manufacturer does not unknowingly violate the MPCA's expectation when, in the manufacturer's legitimate view, only minor changes have been made to a product.

III. The Planned Rule should treat Confidential Business Information (CBI) consistent with other Minnesota privacy practices.

Like the TSCA PFAS reporting rule, MPCA should similarly clarify what information can be claimed as "Confidential Business Information" and, therefore, not available to the public. *See* 40 CFR § 705.30. MPCA

should also establish an efficient procedure for manufacturers to identify information as CBI or trade secret in its rulemaking.

As a model, the TSCA PFAS reporting rule allows, with certain exceptions, reported information such as specific chemical identities that are not on the public inventory, company identifier information, and production volumes to be treated as CBI confidential business information. *See* 40 CFR § 705.30(b)(2). Certain information likely to be CBI does not require additional substantiation such as production or import volumes or specific chemical identities and molecular structures when the substance has not been introduced into commerce. MPCA should follow a similar approach for categories of requested information likely to be CBI or trade secret.

Under existing Minnesota law, much of the information requested by MPCA is similarly considered trade secret and should not be made publicly available. Minn. Stat. § 13.37, Subd. 2 identifies "trade secret information" as not available to the public pursuant to the Minnesota Data Practices Act. "Trade secret information" is defined under Minnesota law as "government data, including a formula, pattern, compilation, program, device, method, technique or process (1) that was supplied by the affected individual or organization, (2) that is the subject of efforts by the individual or organization that are reasonable under the circumstances to maintain its secrecy, and (3) that derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use." Minn. Stat. § 13.37, Subd. 1(b).

MPCA should apply this standard and pre-identify categories of information provided under the Minnesota Statute as trade secret and not publicly available pursuant to the Minnesota Data Practices Act. Such required information would include non-public numeric codes assigned to products and volumetric PFAS data with respect to each reported product.

IV. The term "substantially equivalent information" in Subdivision 3 should be further defined and federal PFAS and other reporting requirements that meet this definition should be specifically identified by MPCA.

Subdivision 3 of the Minnesota Statute clearly gives the MPCA authority to "waive all or part of the notification requirement under subdivision 2 if the commissioner determines that substantially equivalent information is already publicly available." The MPCA should define in the Planned Rule what it will consider "substantially equivalent information" and identify federal reporting programs for which existing product reporting or agency review processes would meet this definition.

a. Products Subject to TSCA Reporting Requirements Should be Exempt from Reporting Obligations Under the Planned Rule.

Honeywell believes the MPCA Rules should avoid unnecessary or duplicative reporting. Reporting obligations should only be imposed on those entities most likely to have relevant information not otherwise available to the MPCA.

On September 28, 2023, the EPA issued a final rule requiring PFAS manufacturers, including importers of

articles containing certain PFAS, to report certain information to RPA pursuant to Section 8(a)(7) of TSCA. Generally, the TSCA PFAS reporting requirement applies to entities that have manufactured or imported PFAS for a commercial purpose in any year since January 1, 2011, alone or in any type of industrial or consumer product subject to EPA's authority.

There is significant overlap between the TSCA PFAS reporting requirement and the Minnesota Statute PFAS reporting requirement:

	Federal (TSCA, Section 8(a)(7); 40 CFR § 705)	**State (MN Stat. § 116.943)**
Regulatory Agency	Environment Protection Agency	MN Pollution Control Agency
Applicable period of reporting	January 1, 2011 to Present, by May 8, 2025 for most regulated businesses (small businesses that import articles have until November 10, 2025).	No later than January 1, 2026 for regulated products sold, offered for sale, or distributed in Minnesota as of that date.
Who must report?	PFAS manufacturers and processors, including article importers, used in consumer and commercial product (*See* § 8(a)(1)(A))	Manufacturers of products that contain intentionally added PFAS (*See* § 116.943, Subd. 2(a))
What must be reported?	1. The common name and molecular structure of the chemical. 2. Categories of use of the product. 3. Total amount manufactured or processed. 4. Description of byproducts from the manufacturing and/or processing of PFAS 5. All existing information concerning the environmental and health effects. 6. The number of people exposed, potentially exposed, and the length of exposure in their workplace. 7. Manner and method of disposal (*See* § 8(a)(2)(A-G)	1. Product description 2. PFAS purpose in product 3. Volume of PFAS in product 4. Manufacturer contact information and specific person for the manufacturer 5. Any additional information as requested by the commissioner (*See* § 116.943, Subd. 2(a)(1-5)). OR Upon approval by the commissioner report all information (Subd. 2(a)(1-5)) per category or type of product (*See* § 116.943, Subd. 2(b)).
What chemicals are covered?	The PFAS definition relies on a structural definition and includes compounds with at least one of the following three structures: • R-(CF2)-CF(R')R'', where both the CF2 and CF moieties are saturated carbons • R-CF2OCF2-R', where R and	PFAS is defined as "a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom." (Minn. Stat. § 116.943, Subd. 1).

	R' can either be F, O or saturated carbons • CF3C(CF3)R'R'', where R' and R'' can either be F or saturated carbons EPA estimates that at least 1,462 PFAS that are known to have been made or used in the United States since 2011 based on this definition.	

Regulated manufacturers of products containing PFAS will already be under a significant regulatory burden to comply with the TSCA PFAS reporting rule and such information, much of which will be publicly available, should meet the Minnesota statutory desire for this information.

Subdivision 3(a) of the Minnesota Statute authorizes the MPCA to "waive all or part of the information requirement under subdivision 2 if the commissioner determines that substantially equivalent information is already publicly available." Based on this language, MPCA should exempt any manufacturer from reporting to the MPCA any product that is already reported to EPA under the new TSCA reporting rule as detailed above. Given the significant but not identical overlap between the TSCA PFAS reporting requirements and the Minnesota Statute, MPCA should explicitly identify that any products identified in submissions to EPA pursuant to 40 CFR § 705 do not need to be duplicatively reported to MPCA pursuant to the Planned Rule.

Under the TSCA PFAS reporting rule, EPA also eliminated the need to report "duplicative" information if a PFAS manufacturer has previously submitted the requested information to EPA for that same PFAS in that same year through Chemical Data Reporting (CDR), Toxics Release Inventory (TRI), Greenhouse Gas Reporting Program (GHGRP), TSCA Sections 8(d) and 8(e), or is also reporting a PFAS byproduct on its own reporting form. *See* 40 CFR § 705.22. MPCA should similarly limit its reporting requirement if such reporting to Minnesota would be duplicative of reporting through these other federal programs.

b. Federal review programs for products and packaging should also meet this definition and constitute a waiver of Minnesota PFAS reporting obligations.

Products and packaging subject to review by a federal agency prior to commercialization should be exempt from reporting to MPCA. For example, pharmaceutical packaging is a component of a Drug Master File submitted to FDA for review and approval. Thus, state-level reporting related to pharmaceutical packaging is duplicative and does not advance the interest of the state. Likewise, products approved for food contact as codified in 21 CFR § 177, *et seq.* should not be subject to state-level reporting because such reporting would be duplicative, unduly burdensome, and would not advance the interests of the State of Minnesota.

Products reviewed by EPA, such as those approved through the SNAP process should not be subject to state-level reporting after already receiving federal approval as alternative products with enhanced environmental attributes. Duplicative reporting does not improve transparency for consumers, nor does it advance the purpose of this law. Accordingly, the MPCA should allow a reporting waiver for products already subject to federal agency review.

c. MPCA should not develop a multi-state shared system at this time.

Subdivision 3(c) of the Statute allows MPCA to "enter into an agreement with one or more other states or political subdivisions of a state to collect information and may accept information to a shared system as meeting the information requirement under subdivision 2." While the State of Maine is undergoing a similar rule making process to implement Maine Public Law 2023, c. 138, ("An Act to Support Manufacturers Whose Products Contain Perfluoroalkyl and Polyfluoroalkyl Substances") (LD 217, 131st Legislature), Honeywell does not believe a state-based shared system would serve any material utility given the EPA's detailed process to collect product information pursuant to TSCA. Honeywell encourages MPCA to coordinate and share information with the EPA as the primary agency collecting PFAS product information at the federal level.[14]

V. There are specific portions of the reporting process that should not be defined through guidance.

It would be more appropriate to define the reporting process through rulemaking rather than guidance. Though a guidance document to accompany the final rule may be a useful tool for providing illustrative examples for reporting nuances, its value is otherwise limited. Guidance is not binding nor determinative.[15] Thus, reporting obligations, including clear and concise expectations and procedures, should be set forth in regulation. No regulatory obligation dictated by a "shall" statement should be left to guidance. Such requirements must be articulated in regulation.

VI. Other comments relating to the PFAS reporting process

a. MPCA should explicitly identify certain exemptions in the Planned Rule.

i. Certain products should be exempted from reporting due to national security considerations.

Honeywell manufactures certain components of International Traffic in Arms Regulations (ITAR)-controlled Department of Defense programs in Minnesota. Due to the sensitive nature of materials that, if disclosed, could be considered a threat to national security, the MPCA should also expressly provide exclusionary language for any federally classified, controlled unclassified, or export-controlled information from its PFAS reporting requirements. This will ensure compliance with federal statutes and regulations applicable to products having United States Government end use (including but not limited to those in the Federal Acquisition Regulation and Department of Defense Federal Acquisition Regulation Supplement), and to avoid any unnecessary risk to national security.

[14] As detailed below, there are data security reasons why EPA would be the ideal agency to collect and store sensitive and expansive product information related to PFAS.

[15] As aptly stated by the federal Government Accountability Office, "Agencies rely on guidance to clarify regulatory text or statutes, to respond to the questions of affected parties in a timely way, and to inform the public about complex policy implementation topics. Unlike regulations, guidance is not legally binding." GAO-15-368, pub. May 18, 2015.

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ii. MPCA should explicitly identify types of federal reporting that preempt application of the Minnesota Statute.

Subdivision 8(a) of the Minnesota Statute exempts from its requirements "a product for which federal law governs the presence of PFAS in the product in a manner that preempts state authority[.]" The MPCA should explicitly identify which products this exemption applies to. Honeywell recommends that MPCA include at least these categories:

- A product for which federal law or regulation requires the authorization or approval of the product's content of performance characteristics, such as, but not limited to, materials subject to Department of Defense (DoD) or similar military specifications, materials required to meet Federal Aviation Administration (FAA) or National Aeronautics and Space Administration (NASA) standards, products regulated as drugs, dietary supplements, and medical devices as well as their packaging, products intended for animals that are regulated as animal drugs, biologics, parasiticides, medical devices, and diagnostics used to treat or administer to animals under the Federal Food, Drug, and Cosmetic Act (FDA) (21 U.S.C. § 301, *et seq.*), the federal Virus-Serum-Toxin Act (21 U.S.C. § 151, *et seq.*), or the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) Act (7 U.S.C. § 136, *et seq.*), substances manufactured or imported pursuant to administrative orders issued or exemptions granted pursuant to Section 5 of the Toxic Substances Control Act (TSCA).
- A product which has been approved under the EPA's SNAP program which implements section 612 of the amended Clean Air Act of 1990 and includes evaluation of overall risk to human health and the environment. SNAP already generates lists of acceptable and unacceptable substitutes for major industrial use sectors and provides smooth transitions to safer alternatives.

***b. Definition of* "Medical Application"**

Honeywell requests that the MPCA clarify the meaning of "medical application" in Subdivision 8(b) of the Minnesota Statute. This definition should include medical device and pharmaceutical packaging because both undergo similar scrutiny under the Federal Drug Administration 501k process and Drug Master File process. Packaging materials used in these applications are meant to provide moisture/chemical barrier and clarity properties, that are essential for preserving the quality, safety, and efficiency of drugs and medical devices over a range of temperatures as well as cryogenic conditions.

In other states such as California and Colorado they have exempted articles that met the following criteria:

- A product regulated as a drug, medical device, or dietary supplement by the United States Food and Drug Administration.
- A medical equipment or product used in medical settings that is regulated by the United States Food and Drug Administration.
- A product intended for animals that regulated as animal drugs, biologics, parasiticides, medical devices, and diagnostics used to treat or are administered to animals under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) , the federal Virus-Serum-Toxin Act (21 U.S.C. Sec. 151 et seq.), or the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 136 et seq.).

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The MPCA should consider whether an adoption of this language pursuant to Subdivision 8(b) would be a clearer way to define these applications and materials.

c. Prohibition Prioritization in Subdivision 5(b)

Honeywell supports using MPCA's upcoming rulemaking to ensure that the regulated community and MCPA have a common understanding of the processes and criteria that MPCA will be using for purposes of prioritizing for potential prohibitions under Subdivision 5 of the Minnesota statute (products and product categories that, "in the commissioner's judgment, are most likely to contaminate or harm the state's environment and natural resources if they contain intentionally added PFAS.").

Honeywell recommends that a risk-based determination process be structured and applied, taking into consideration factors affecting exposures (e.g., production volumes, nature and conditions of manufacture and use) and hazard (e.g., toxicity, bioaccumulation, persistence). The process established should enable potentially affected entities to apply for and provide technical support for essential use determination. The process for applicants seeking such determination should also establish deadlines for application submission, and definitive points in the application consideration processes. This should include a timeline for when MPCA will reach a determination (e.g., no later than a certain number of days following receipt of the application). Honeywell considers the following risk matrix to be an example of some of the criteria that could be established for applicants.

	Known Low Production/Emissions	Unknown Production/Emissions	Known High Production/Emissions	
Known High PBT Risk				High priority regulatory targets; decreasing priority to the left
Unknown Risk				High priority for risk studies to identify or eliminate additional substances of concern; decreasing priority to the left
Known Low PBT Risk				Lower priority for both regulations and additional research
	Candidates to monitor for change in production/emissions volume; increasing priority toward the top	Candidates for more research on production/emissions; increasing priority toward the top	Candidates for research on emissions profiles & environmental fate; increasing priority toward the top	

d. Reporting database and cyber security concerns

As the MPCA is certainly aware, it will receive notifications for hundreds of thousands of products (if not more) from all sectors of the economy. Honeywell is concerned about the ability of any reporting tool being developed and administered by MPCA or a third-party vendor to manage this task since, as MPCA and common third-party vendors in this space, such as IC2, have not developed a reporting system of this scope and magnitude. Consequently, it will be essential that MPCA take whatever measures are necessary to build in a beta testing phase to ensure that the reporting tool is sufficiently robust to manage and protect the number of users and volume of information anticipated and sufficiently flexible to allow for reporting of information that may not conform to a particular format contemplated by MPCA.

Given the volume and corporate trade secret sensitivity of collected data, it will be essential that comprehensive steps are taken to protect collected information from cyberattack or other malicious efforts to obtain or compromise the data. Coordination with and deference to EPA on data collection and storage given its significant experience in this area and even more expansive data collection and storage efforts related to the TSCA PFAS reporting rule would be advised.

e. Compliance evidence related to enforcement

The MPCA should provide defined examples of information it will accept as proof of compliance to the MPCA pursuant to Subdivision 7(b) of the Minnesota Statute.

f. The Reporting deadline should provide sufficient time for collection of the required information.

Allowing for more time between promulgation of a final rule and the reporting deadline makes it more likely that the data generated will be more complete and accurate, since reporting stakeholders would have more time to gather the required data using already familiar systems. Similar to federal obligations, MPCA should also take into account how long it will take regulated manufacturers to comply with the reporting requirements of the Planned Rule and work to make that burden as minimal as possible.[16] As an example, a manufacturer of a product with many components will have to go to each of the manufacturers of those components to determine whether any of the materials used in those products qualify under the rule. That is a lengthy process, as some products involve hundreds or thousands of components from many different suppliers, some of which will have even more sub-suppliers. Additionally, not all of these suppliers will respond to requests right away, especially if they are outside of the United States and unaware or unconcerned with a U.S. reporting requirement. Adequate time must be allowed for these processes to be conducted, especially if the state decides to vary its requirements from those of EPA where companies are already putting compliance systems in place.

Minnesota PCA should strive to afford companies a reporting timeframe of four years, similar to that established by the Environmental Protection Agency (EPA) for the Chemical Data Reporting (CDR) system, ensuring sufficient time for accurate and comprehensive submissions.

g. Considerations regarding fees

On September 11, 2023, the MPCA also sought comments regarding related planned rulemaking related to fees to implement the reporting requirements of the Minnesota Statute.[17] Subdivision 6 authorizes the MPCA to establish fees payable by reporting manufacturers to cover the MPCA's "reasonable costs to implement" the Minnesota Statute. Honeywell incorporates and provides its comments to that separate but related rulemaking process here.

[16] The Paperwork Reduction Act (PRA) was enacted to minimize the paperwork burden for individuals; small businesses; educational and nonprofit institutions; Federal contractors; State, local and tribal governments; and other persons resulting from the collection of information by or for the federal government. *See* 44 USC §3501, *et seq*.
[17] *See* Minnesota OAH Docket No. 71-9003-39506.

i. MPCA should not consider tiered fees for different sizes of manufacturers.

Honeywell does not support tiered fees based on the size of the manufacturer's business. Manufacturers with a small number of reporting obligations due to limited use of intentionally added PFAS should not (effectively) subsidize the fees of manufacturers with relatively larger reporting obligations that may therefore incur relatively larger agency costs related to program administration. Likewise, manufacturers with relatively larger reporting obligations should not pay less than their equitable share for expenses related to program administration.

Honeywell assumes that the number of reports will be the primary cost driver for the MPCA. Therefore, tiered fees based on the size of business should not be the basis for fees. Said differently, a manufacturer should not be disproportionately burdened or subsidized by virtue of the size of the business.

ii. MPCA should not consider a per-product or per-company fee.

Honeywell does not believe a per-company fee is equitable for the reasons articulated in the response to question 1 above. Honeywell suggests that a more equitable approach could be an initial, relatively higher fee for a manufacturer's first three submissions and a reduced fee for any additional filings. Such an approach would appear to align with what is likely to be the most significant, on-going cost to the MPCA, namely reviewing submissions. Honeywell would expect that a single submission for a group of products in a category-based submission would be treated as a single submission for the purpose of calculating fees.

iii. MPCA should not consider a per-PFAS or PFAS amount fee.

Honeywell does not support a per-PFAS or PFAS amount fee and does not understand how either the number of PFAS in a product or the amount of PFAS in a product would drive program administration costs. Should the MPCA choose to explore these options further, it should clarify that the fee basis would be for intentionally added PFAS only.

iv. MPCA should use caution considering other state program fee structures.

Honeywell does not have a recommendation in response to this question at this time. However, because the product notification requirement is unprecedented in scope and size, Honeywell urges caution in considering the use of other state fee structures as a model for this program.

v. MPCA should not consider a fee to be paid when updates to information on previously reported products are submitted.

Without a more thorough explanation of what costs the MPCA would incur as a result of a manufacturer providing an update, Honeywell would not support the MPCA levying a new fee when a manufacturer provides an update. An update concerning an increased amount of intentionally PFAS in a previously reported product would appear to create marginal, if any, new work. Honeywell does not support an additional fee in either case.

vi. Other issues related to reporting or fees

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The MPCA should not promulgate a fee rule until the cost of administering the program and the size and scope is better understood. The rationale for setting fees should be transparent about revenue generated by fees and how the fees will be used to manage the program. Fees should be calibrated appropriately such that the MPCA is not collecting more in fees than what is needed to administer the program. To this end, Honeywell suggests that the MPCA publish a publicly available annual audit of fees collected and program administration costs that it incurs. Where possible, the MPCA should cap fees.

Conclusion

Honeywell appreciates MPCA's consideration of these suggestions and would be glad to participate in further discussions about these comments. We look forward to reviewing and commenting on the Planned Rule.

Sincerely,

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RECEIVED
By: OAH on 11/27/2023

General Comments to Section 116.963 from JP4EE

Name of the associations which make this input:

The Japanese electric and electronic industrial associations:

JEITA (Japan Electronics and Information Technology Industries Association)
CIAJ (Communications and Information Network Association of Japan)
JBMIA (Japan Business Machine and Information System Industries Association)
JEMA (Japan Electrical Manufacturers' Association)

The Japanese electric and electronic industrial associations, JEITA, CIAJ, JBMIA and JEMA (hereinafter JP4EE), hereby express gratitude to the Minnesota Pollution Control Agency (MPCA) for inviting comments on PFAS in products.
https://www.pca.state.mn.us/get-engaged/pfas-in-products-reporting

We are the manufacturers of electric and electronic equipment (hereinafter EEE) and have consistently supported the ambitious attempt to reduce the risk caused from the hazardous substances and taken practical measures for that. In such spirit, we have carefully and conscientiously examined the law and questions and would like to submit the following comments towards making the proposed PFAS management scheme more practical, feasible and permanent.

We would very much appreciate if you would give our comments your careful consideration.

(1) **The regulation should be examined based on the risk evaluation, and the scope of the measures should be adequately defined.**

We have sincerely and diligently taken actual measures to meet the requirements under the ambitious attempt of many States, countries and regions to reduce the risk caused from the hazardous substances. However, it is unfeasible to legislate the PFAS restrictions uniformly, and we are deeply concerned that, if enforced, they will not only hollow out the Minnesota industry, but also make existing infrastructure unsustainable.

(a) About the risk assessment of the substances themselves.

PFAS are a huge group of substances that include many different substances with varying levels of risk. Nevertheless, we believe that a blanket restriction on all PFAS may lack a risk-benefit balance and is not scientifically or socio-economically sound.

Highly hazardous PFAS such as PFOS and PFOA are already restricted under the Stockholm Convention on Persistent Organic Pollutants (POPs). If other PFAS for which a hazard classification has not yet been identified are to be restricted, a proper risk assessment should be conducted and the regulation should focus on applications with high exposure potential and well-established alternative technologies.

Especially for the risk of fluoropolymers, chemical industry explains as follows: *Fluoropolymers do not pose a risk to human health or the environment as they are non-toxic, not bioavailable, non-water soluble, non-mobile and do not bio accumulate*. If MPCA would not be able to provide more reasonable justifications, it would be appropriate for MPCA to reconsider the proposed measures for fluoropolymers.

For PFAS which does not have a hazard classification and whose detailed information on contents are confidential or trade secret of the chemical industry, we, the finished products manufacturers located at the end of the supply chain, are not able to provide accurate information on exact use of PFAS in the complex articles. What we can do is only estimate the PFAS group used in many applications in EEE, and the range of its concentration in products. (We will explain about the difficulties in survey of substances in the complex articles in other paper in detail.)

(b) About the assessment of the risk caused by the substances in the articles.

During the use of articles like EEE, it is presumed that an exposure amount of PFAS is generally negligibly low compared with the exposure from the PFAS as chemicals own. The blanket restriction on PFAS will affect many industries. We hope that MPCA will consider our recommendations and information in the following sections and make a scientific and technical decision about the need for and feasibility of regulation.

(c) The effective date of the restriction of PFAS in the article should be set more later than that for the chemicals.

If the restriction of PFAS in the articles is really planned by MPCA after the proper risk assessment, all the issues described in our comments should be carefully considered for establishing the feasible and enforceable measures.

In addition, we consider that the separate effective date of the restriction of the articles should be set as a date later than that for chemicals. For complex articles like EEE, possible substitution would be able to be examined only after the feasible substitutes are available on the market as substances or

mixtures. Therefore, the timing for getting substitutes available for the articles would be far later than that for chemicals.

(2) With conducting socio-economic impact assessment, EEE should be excluded from the subject to Section 116.943.

As we stated in the above, the articles and the chemicals should not be managed uniformly, as the possibilities of exposure are so different between them. The possible risk caused from the articles should be properly considered, and convincing justification should be provided to show why the uniform restriction of PFAS in the articles is the most appropriate measure to address the identified risks.

We believe that PFAS emissions relating to EEE are quite well managed and are quite limited. If there are any concerns on the end-of-life stage of EEE, requirements for separate treatment under the legislations on recycling and treatment of the waste or occupational safety regulations would be more effective ways to manage them with better cost-benefit than uniform ban of PFAS.

In addition, there are following serious issues in applying uniform ban of PFAS in EEE.

PFAS are the only materials that can simultaneously provide and exhibit multiple functions, such as low dielectric constant, low dielectric loss tangent, low refractive index, oil repellency, electrical insulation, water repellency, heat resistance, chemical resistance, weather resistance, mold releasability, flame resistance, separability, wear resistance, surface properties (friction coefficient), bending strength, stretching properties, non-flammability, etc. which are necessary for electrical and electronic devices.

We recognize that such characteristics of PFAS are made use of in the following functions of EEE:
Optical function; high speed communication and transmission function; piezoelectric function; sliding function in mechanical section; display function (Liquid crystal display / LCD); Safety and safety functions; functional surface; semiconductor; thin-film device manufacturing process; energy supply (battery); cooling function (Refrigerant).
(However, please note that we cannot get accurate information on exact name of the substances or concentration from the upper stream of the supply chain.)

Cost of the uniform elimination of PFAS would be huge not only for the industry but also socio-economically, but it cannot be calculated because the whole effect on society cannot be estimated. For the cost to the industry, we may refer to the case of the EU RoHS Directive (2011/65/EU) which restricts substances in the EEE and are well-recognized internationally as precedent example of such kind of regulations. For the RoHS, where four heavy metal elements and two groups of the flame retardants were regulated and some feasible alternatives for actual use in EEE is established, the threshold was from 100ppm to 1,000ppm, and necessary derogations and grace period were set, the average cost per company was $2,640,000 to achieve initial RoHS compliance and another $482,000 for annual maintenance. (According to a study conducted for the U.S. Consumer Electronics Association (currently,

CTA) by researcher Technology Forecasters Inc. (TFI).) The study found that the RoHS Directive costs the global electronics industry more than $32 billion for initial compliance and about $3 billion annually to maintain compliance. However, the cost for restriction of PFAS would be far higher because there are so many PFAS to be restricted and the necessary derogations (waivers) have not been established.

PFAS is widely contained in many critical components such as semiconductors horizontally used in EEE, regardless of the type, but in very small volume. Therefore, if intentionally added PFAS were prohibited in all applications, all the semiconductors and almost all the EEE would not be able to be made and used in the State of Minnesota. Such uniform restriction of PFAS may lead to defective substitution which cannot attain necessary performances but also ensure safety, reliability, and durability of the whole products. The end-users will be affected most seriously. This may lead collapse of the whole social infrastructure based on IT and semiconductor technologies in the State of Minnesota.

Considering the potential impact at the uncountable level as mentioned above, we believe that the essential PFAS applications should be kept usable under the reasonable management and that the society had better to keep obtaining the benefit from it. Even if MPCA concludes that some PFAS should be restricted in the articles, widely used industrial chemicals in articles should be restricted only when they can be replaced by substitutes or alternative technologies with less negative environmental impact, according to the results of technical and socioeconomic impact assessment.

About the issues relating to the reporting requirement for EEE, please see our comments (3) to (5) in this document.

(3) The purpose of reporting requirement should be clearly described and the information fitting for the purpose should be gathered. (Please refer to our comment (6)-1 in our comments to the reporting rule)

MPCA describes the purpose of the rulemaking as follows, but there is no clarification on why the PFAS information shall be gathered in the first place. The purpose of the legislation should be stated at first, then, the rulemaking should be considered for the necessary information in order to meet the purpose.

> *The Minnesota Pollution Control Agency (MPCA) is planning new rules governing reporting of per- and polyfluoroalkyl substances (PFAS) in products. The main purpose of this rulemaking is to establish a program for the MPCA to collect information about products containing intentionally added PFAS as directed by Minnesota Session Law - 2023, Chapter 60, H.F. No. 2310.*

If MPCA requires information because of the concern on the possible risk caused by the emission of PFAS, EEE should be out of the scope of the requirement. We believe that PFAS emissions relating to EEE are quite well managed and are quite limited. In the first place, at design and manufacturing stages, the use of PFAS in EEE is limited to the places where the functions of PFAS are really necessary,

because PFAS materials are more expensive in exchange for high-performance than non-PFAS low-performance ones.
In addition, in use phase, EEE must keep their quality and performance in their durable life. The PFASs used in products have a very low vapour pressure and therefore do not volatilise at room temperature, and are designed to remain where they are applied to in order to provide the required function during the product lifetime, and to perform well under more severe conditions than the rated operating conditions. We therefore believe that it is unlikely that PFASs will be released into the atmosphere from the products during the use phase.
Or, if MPCA would like to research “currently unavoidable use” based on the result of PFAS reporting, like the State of Maine, submission of the list of the essential uses of PFAS should be required to the industry, not PFAS reporting. Although the information on the contents of PFAS in the complex articles are difficult to be communicated, we, article manufacturers, have comprehensive information of PFAS applications which are currently substitutable, based on our technical expertise.

In anyway, PFAS reporting in EEE would not contribute so much for attaining the estimated purposes. If enforced, we are afraid that the cost and resources may be used in vain also for MPCA.

(4) If PFAS reporting applies articles including EEE, the scope of reporting should be “reasonably ascertainable information” and simple reporting as well as the one required under the section 705.18 of PFAS reporting rule of TSCA Article 8(a)(7). (Please refer to comment(2)-2 in our comments to the reporting rule)

Firstly, it is difficult to conduct an investigation of substances contained in EEE. For complex articles like EEE, the industry must take actions as a whole supply chain which is multiply tiered and spreading globally even when only one substance is subject to the investigation.

Most of our members have established and are implementing extensive chemical management programs. These chemical management programs are designed to ban or restrict the presence of chemical substances throughout the complex global supply chain in conformance with global laws and regulations applicable to EEE. However, the companies operating such management programs do not require their suppliers to identify the presence and amount of each and every chemical substance contained in every article. However, since most PFAS have not been classified as hazardous and are not covered by reporting requirements in countries and regions. Furthermore, as accurate information (PFAS identification and amount) is CBI for actors on supply chain who intentionally added PFAS (e.g. chemicals manufacturer, component manufacturer etc.), such CBI would not been transmitted to EEE manufacturers placed on the bottom of supply chain. Therefore, EEE manufactures cannot estimate an accurate amount or impact on PFAS. Under such a situation, it is rarely possible to obtain and report reliable information even if MPCA would require PFAS information to product manufacturers who distribute products in the State of Minnesota. So, It is not possible to obtain information more than

“reasonably ascertainable” and report PFAS information which fulfils current legal requirements. Please refer to the attachment ”3. Explanation of Difficulties in Obtaining Information on Chemical Substances Contained in EEE” for details.

(5) Although we think PFAS reporting should not be required to complex articles like EEE, fee should not be imposed to the reporting even if MPCA would eventually impose simple reporting.

As stated above, it is not possible to obtain detailed and accurate PFAS information contained in complex articles, therefore it is not possible to submit a report per model or material or PFAS amount. What is possible is a simple reporting as a result of estimation for PFAS contained in products the manufacturer is handling, based on “reasonably ascertainable reporting” standard. Therefore, the number of reporting is expected to be limited and it is reportable only when such information can be obtained from its supply chain. We have serious concern about the justification on taking such actions which impose both MPCA and industries huge cost and resources in order to obtain such a poor information. There is no other country or region including US to imposing fee for detailed reporting for chemical substances contained in articles.

(6) The system and period of “waiver” should be well considered. The criteria of waiver for essential use of complex articles should be similar to those under EU RoHS Directive.

(a) About the criteria for setting a waiver for the essential use for the complex articles. (Please refer to Comment(4)-1 in our comments to the reporting rule)

As PFAS is the huge group of the industrial chemicals taking indispensable uses on complex articles at present, the conditions set in the Article 5(1)(a) of EU RoHS Directive 2011/65/EU, which is a precedent of the restriction of the substances in EEE, should be considered in determining appropriate derogations for the PFAS in the complex articles as follows:

- *their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II (note: restricted substances) is scientifically or technically impracticable,*
- *the reliability of substitutes is not ensured,*
- *the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.*

(b) Waiver application from not only an individual company but also a trade association should be accepted. (Please refer to Comment(4)-2 in our comments to the reporting rule)

(c) As stated in (2) above, we believe EEE should be exempted from the scope of Section 116.943.

However, if MPCA intends not to exclude EEE and to set waiver for specific PFAS applications which are currently unavoidable, we are concerned that loopholes might be generated if it depends on the PFAS information which are not easily gathered. Instead, we can provide MPCA with the list of essential PFAS contained in EEE based on our knowledge, which is the one JP4EE submitted to European Chemicals Agency (ECHA). Please contact us if necessary.

(7) Effective date should be based on manufacture date (Please refer to Comment(2)-1 of our comments to the reporting rule)

Since final products manufacturers cannot control products which have already been in the stock of the distributors/retailers, effective date should be based on the manufacture date so that manufacturers can control their product distribution.

(8) Excluding spare parts for articles manufactured prior to the effective date (Please refer to Comments(1)-2 in our comments to the reporting rule)

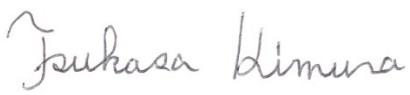
Products (that contain intentionally-added PFAS) that were manufactured prior to the prohibition of sales may require the use of PFAS-containing parts for their proper use and repair, and the exclusion of spare parts allows such products to be repaired and used for a longer period of time, thereby reducing unnecessary waste.

(9) No analytical method for PFAS contained in complex articles has been established and testing requirements should not be imposed. (Please refer to Comment(2)-3 in our comments to the reporting rules)

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 the methods that can be used to analyze the PFAS content in articles.

Even in the case of measuring the total organic fluorine when individual PFASs cannot be identified, there are few analysis methods known as available for articles. For example, Combustion-Ion Chromatography (CIC), the commonly known analytical method to detect fluorine, detects both organic and inorganic fluorine. Therefore, it is not possible to detect only total organic fluorine.

Sincerely yours,



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About Japanese electric and electronic (E&E) industrial associations (JP4EE):

About JEITA

The objective of the Japan Electronics and Information Technology Industries Association (JEITA) is to promote the healthy manufacturing, international trade and consumption of electronics products and components in order to contribute to the overall development of the electronics and information technology (IT) industries, and thereby further Japan's economic development and cultural prosperity.

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.

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.

About JEMA

The Japan Electrical Manufacturers' Association (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. The products handled by JEMA cover a wide spectrum; from boilers and turbines for power generation to home electrical appliances. Membership of 291 companies, http://www.jema-net.or.jp/English/

JP4EE comments to the REQUEST FOR COMMENTS
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

1) Are there definitions in subdivision 1 for which clarification would be useful to understanding reporting responsibilities?

Comment(1)-1: EEE should be excluded from the scope of Section 116.943

In relation to the definition (q) product, electrical and electronic equipment (EEE) should be excluded from the definition of "product". It is not explicitly mentioned in the legal text but we understand that the legal objective of this law is to minimize adverse effect to human and environment caused by PFAS. As we mentioned in our comments 6), exposure of PFAS from article including EEE is considered small under intended use conditions and the adverse effect on human and environment would be negligible. Also, it is extremely difficult to obtain information on PFAS contained in EEE and only a few benefits will be gained for achievement of the legal objective despite the huge burden for EEE industries.

At present, most of EEE (including those used as component of other products) uses semiconductors. Also, to our best knowledge, PFAS used in semiconductors are impossible to substitute. Therefore, if the State of Minnesota would enforce the uniform PFAS prohibition in the future, all equipment using EEE including automobiles, aviation equipment and infrastructures might not be able to be distributed in the State of Minnesota. In such case, citizens of Minnesota would be limited to using antiquated technology, and would not benefit from new innovative products. If MPCA would receive waiver application for individual product or use in order to avoid such situation, it would occur huge administrative burden. We would strongly recommend assessing risk-profit of the restriction and to exclude EEE from the scope of Section 116.943.

Proposed amendments:

Following definition should be added:

> *'electrical and electronic equipment' or 'EEE' means a product or component which is needing electric currents or electromagnetic fields to fulfil at least one intended function in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a designated voltage. This definition also covers electrical and electronic parts and components used in other products such as transportation equipment, aviation equipment or automobiles, because almost all the industrial products make use of EEE as their components.*

Following exclusion should be added:

(q) "Product" means an item manufactured, assembled, packaged, or otherwise prepared for sale to consumers, including but not limited to its product components, sold or distributed for personal, residential, commercial, or industrial use, including for use in making other products. The term "product" does not cover electrical and electronic equipment.

Or, subd. 8. Exemptions should be amended as follows.

Subd. 8. 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 325072 or 325075;

(3) electrical and electronic equipment.

(4) the sale or resale of a used product; or

(…)

Comment(1)-2: Spare parts should be excluded from the scope of Section 116.943

In relation to the definitions for "(q)product" and "(r)product component", we request that spare (repair/replacement) parts for existing products manufactured prior to the sales prohibition date be excluded from the definition and excluded from the scope of the Section 116.943. Products (that contain intentionally-added PFAS) that were manufactured prior to the prohibition of sales may require the use of PFAS-containing parts for their proper use and repair, and the exclusion of spare parts allows such products to be repaired and used for a longer period of time, thereby reducing unnecessary waste.

Proposed amendments:

(q) "Product" means an item manufactured, assembled, packaged, or otherwise prepared for sale to consumers, including but not limited to its product components, sold or distributed for personal, residential, commercial, or industrial use, including for use in making other products. The term "product" does not cover spare or repair parts for products manufacture on or before January 1, 2026, for reporting, and on or before January 1, 2032, for prohibition of the sale.

(r) "Product component" means an identifiable component of a product, regardless of whether the manufacturer of the product is the manufacturer of the component. The term "product component" does not cover spare or repair parts for products manufacture on or before January 1, 2026, for reporting, and on or before January 1, 2032, for prohibition of the sale.

Or, amending subd. 8. Exemptions as follows.

Subd. 8. 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 325072 or 325075;

(3) the sale or resale of a used product; or

(4) spare or repair parts for products manufacture on or before January 1, 2026, for reporting, and on or before January 1, 2032, for prohibition of the sale.

Comment(1)-3: Targeted substances

PFAS subject to Section 116.943 should be prioritized based on their risk assessments and limited only to high priority substances. Specifically, we propose that PFAS that have been internationally-recognized to be harmful to be targeted first, and then those that have been determined to be harmful be subsequently added as regulated substances. In addition, the list of target substances with identifiers such as CAS RN should be specifically identified to allow for accurate transmission of information throughout the supply chain.

Most of PFAS which were proven to be hazardous are already covered by the Stockholm Convention on POPs based on the risk assessment. For example, the indicative list of PFOA-related compounds which are restricted as hazardous are available at the following website.

https://chm.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC17/Overview/tabid/8900/Default.aspx

Corresponding document: POPRC-17/9 Indicative list of substances covered by the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds.

Also, chemicals industry explains the risk of fluoropolymers as follows[1]:

"*Fluoropolymers have been categorized as PFAS when based solely on their molecular structure. However, their environmental and toxicological profiles are distinctly different to the majority of other lower molecular weight PFAS:*

- *In general, the properties of many fluoropolymers (fluoroplastics and fluoroelastomers) are such that they do not show the environmental and toxicological profiles associated with some PFAS that could be considered of concern;*
- *Specifically, recent studies[2] have shown that 16 unique families of commercially popular*

[1] Joint statement of the European Industry on planned PFAS restriction under EU REACH Regulation: https://fluoropolymers.plasticseurope.org/application/files/7116/7334/1071/Fluoropolymer_Letter_5_January_2023_-_PFAS_REACH_Restriction_2.pdf

[2] A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and Fluoroelastomers, Stephen H. Korzeniowski et al, 2022.

fluoropolymers meet the OECD Polymer of Low Concern criteria[3]*.*

- *They are chemically stable, non-toxic, non-bioavailable, non-water soluble and non-mobile materials and they are deemed to have no significant environmental and human health impacts."*

If MPCA would not be able to provide reasonable justification, it would be appropriate to re-consider targeted PFAS subject to Section 116.943.

Comment (1)-4: Currently unavoidable use

In Section 116.943, the definition of "currently unavoidable use" exists in subdivision 1.(j) but it is not clear the conditions and procedure to determine it. If MPCA considers that currently unavoidable use is determined based on collected data, it would not be possible for complex articles like EEE to gather sufficient information along with supply chain, and what is only possible is to assume the use of PFAS based on technical knowledge. However, such PFAS would be used with a tiny amount at the upstream supply chain and it is not possible to gather the data to be reported, therefore we have concerns not to determine such uses as currently unavoidable use. It would be appreciated if MPCA refers an attached document which explains the difficulties of transmitting chemical substance information contained in products along the supply chain.

"Currently unavoidable uses" that the industries think at the moment are indicated in the comments to the draft PFAS restriction proposed by ECHA (European Chemicals Agency).

https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term

In the middle of this page, the list of documents in the row "Comments submitted to date on restriction report" are comments submitted to the draft and eventually more than 5,600 comments were submitted. We believe that the similar number of waiver application would be submitted if the State of Minnesota will enforce this uniform PFAS prohibition as they are. Also, since PFAS, especially fluoropolymers, are inevitable for the state-of-the-art technologies, we are concerned that the uniform prohibition of PFAS would end up for people in the State of Minnesota not being able to benefit the products using the state-of-the-art technologies.

2) Are there terms or processes in subdivision 2 for which clarifications will help reporting entities determine reporting status or data-gathering process?

Comment(2)-1: Effective date should be "manufacture date"

https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4646?af=R
A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers, Barbara Henry et al, 2018.
https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4035

[3] Data Analysis of the identification of correlations between polymer characteristics and potential for health or ecotoxicological concern, OECD 2009.
https://www.oecd.org/env/ehs/risk-assessment/42081261.pdf

Since final products manufacturers cannot control products which have already been in the stock of the distributors/retailers, effective date should be based on the manufacture date so that manufacturers can control their product distribution.
Proposed amendment:

> *(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 and were manufactured on and after mm dd, yyyy, must submit to the commissioner information that includes:*

Comment(2)-2: Accept "Known to or Reasonably Ascertainable by" reporting standard and simplified reporting for articles.
For example, in many cases, specific chemical composition of functional materials is considered as CBI (Confidential Business Information) and is not communicated to downstream users beyond the information necessary for its safe use. For impurities originated during the manufacturing process, such information is not going to be transmitted to downstream entities due to confidentiality. Therefore, such CBI should be exempted from notification as information beyond "Known to or Reasonably Ascertainable" standard since finished goods manufacturers (i.e. EEE manufacturers) are unable to obtain such information.

On October 11, 2023, US EPA published "Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, (TSCA PFAS Reporting Rule)" in the Federal Register.
https://www.govinfo.gov/content/pkg/FR-2023-10-11/pdf/2023-22094.pdf
The "Known to or Reasonably Ascertainable by" reporting standard is accepted under this TSCA PFAS Reporting rule.
The EPA acknowledges the difficulties of gathering information on PFAS contained in articles in case of imported articles and accepts simplified reporting in 40 CFR Part 705 Section 705.18 (a) Article reporting. The same difficulties can apply to the Section 116.943 and therefore we request MPCA to accept the simplified reporting which is similar to it under 40 CFR Part 705 Section 705.18 (a) Article reporting.
For your information, the State of Maine allows the following simplified reporting by H.P. 138 - L.D. 217 *"An Act to Support Manufacturers Whose Products Contain Perfluoroalkyl and Polyfluoroalkyl Substances"* (Approved on June 8, 2023)[4]:

> *2.A.(1) A brief description of the product, including an estimate of the total number of units of the product sold annually in the State or nationally;*
> *(…)*
> *(3) The amount of each of the PFAS, identified by its chemical abstracts service registry*

[4] http://www.mainelegislature.org/legis/bills/display_ps.asp?paper=HP0138&snum=131&PID=1456

number or in the absence of this number a description approved by the department, in the product, reported as an exact quantity, or as the amount of total organic fluorine if the amount of each PFAS compound is not known, determined using commercially available analytical methods or based on information provided by a supplier as falling within a range approved for reporting purposes by the department;

Comment (2)-3: MPCA should not require analysis results described in Subd. 4 "Testing required and certificate of compliance" as mandatory.

This Act requires reporting the concentration of each PFAS in a product or product component, as identified by its CAS RN. There is no description on testing in Subd. 2. and such description is only mentioned in Subd. 4. However, since no question relating to Subd.4. is provided in this Request for Comment, we would like to comment here as those related to reporting.

Even if we were to try to analyze the amount of PFAS contained in articles, to the best of our knowledge, there is no internationally-recognized analytical method that can quantify the amount and identify PFAS at a CAS RN level (except for certain types of PFAS in water or soil). Therefore, EEE manufacturers are unable to obtain precise information of PFAS contained in articles through scientific analysis.

The first step in performing targeted analysis on article is a process called extraction, in which PFAS is dissolved into a fluid, such as water or organic solvent, which is suitable for the analytical method to be used. For PFAS in articles, such extraction process is not established at all. More concretely, it is necessary to establish an extraction method by optimizing the organic solvent used, extraction time, extraction temperature, etc., according to the type of materials that constitutes the molded product and the type of PFAS to be analyzed.

Establishing this extraction method has the following difficulties.

(1) There are many types of PFAS, and it is not easy to cover all PFAS.

(2) It is necessary to examine the extraction conditions for each material that uses PFAS.

(3) A material containing a predetermined amount of PAFS to be used for the study must be prepared.

(4) At low concentrations, the influence of adsorption during pretreatment on the analysis results is relatively large.

These difficulties cannot be easily solved in a short period of time and it is not feasible to identify the substance and amount of PFAS in articles.

Also, as referenced below, the European Chemical Agency (ECHA) recommends in their Guidance (on requirements for substance in articles) that analysis not be conducted for articles, and also mentions the difficulties associated with assigning suitable analytical methods for unidentified substances.

Guidance on requirements for substances in articles (version 4.0)

https://echa.europa.eu/documents/10162/2324906/articles_en.pdf

5.2 Chemical analysis of substances in articles

…

It is to be noted that chemical analyses may yield ambiguous results and/or be very costly and are thus not recommended as the preferred instrument for obtaining information.

5.2.1 Challenges of chemical analyses

…

If the identity of the substances of potential concern is not known, it may be difficult to assign suitable analytical methods.

3) How should the MPCA balance public availability of data and trade secrecy as part of the reporting requirements?

Comment(3)-1: About Subd.3(s), especially for the complex articles, all the intelligence-based information on PFAS application has been already published on EU ECHA website. The listed essential uses of PFAS should be waived. Our comment (1)-4 referenced the ECHA website and we would be able to provide our list of PFAS applications which are publicly available at the ECHA website. Also, Similar law will be effective in the State of Maine from January 1, 2025, which is one year earlier than Minnesota law. Information which is already reported under the Maine law should be considered as “publicly available information” and be exempted from the reporting requirements under the Minnesota law. Likewise, if the information required under TSCA PFAS reporting rule becomes publicly available, it should be exempted, too.

Comment(3)-2: As mentioned in the comment to our comment(2)-2, “Known to or Reasonably Ascertainable by" reporting standard should be accepted and information which cannot be obtained due to CBI should be exempted from the scope of reporting requirements.

4) Are there any terms used in subdivision 3 that should be further defined or where examples would be helpful?

Comment(4)-1: The reasonable and feasible criteria for setting a waiver should be provided.

As PFAS is the huge group of the industrial chemicals taking indispensable uses on complex articles at present, for example, the following conditions set in the Article 5(1)(a) of RoHS DIRECTIVE 2011/65/EU should be considered in determining waiver as follows:

- their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II (note: restricted substances) is scientifically or technically impracticable,

- the reliability of substitutes is not ensured,
- the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

At present, to our best knowledge, there is no available PFAS alternative which can fulfill necessary characterizations for EEE in many uses at the same time.

Comment(4)-2: Waiver application from not only an individual company but also a trade association should be accepted.

5) Are there specific portions of the reporting process that should not be defined through guidance or the development of an application form?

Comment(5)-1: MPCA should not require analysis results described in Subd. 4 "Testing required and certificate of compliance" as mandatory. Please see our comment (2)-3.

6) Other questions or comments relating to reporting or the process of reporting.

Comment (6)-1 The purpose of PFAS reporting should be clearly stated.

Although MPCA states the purpose of the rulemaking as follows, it is not clearly stated the reason to gather PFAS information in the first place. MPCA should clarify the objective of the law at first, then rulemaking to gather necessary information which can fulfill the objectives should be initiated .

> *The Minnesota Pollution Control Agency (MPCA) is planning new rules governing reporting of per- and polyfluoroalkyl substances (PFAS) in products. The main purpose of this rulemaking is to establish a program for the MPCA to collect information about products containing intentionally added PFAS as directed by Minnesota Session Law - 2023, Chapter 60, H.F. No. 2310.*

If MPCA wants to know PFAS information because of concerns of the risk from PFAS release, we believe EEE can be excluded from the scope of reporting. We believe that PFAS release from EEE are quite well managed and are quite limited. In the first place, at design and manufacturing stages, the use of PFAS in EEE is limited to the places where the functions of PFAS are inevitable, because PFAS materials are more expensive in exchange for high-performance than non-PFAS low-performance ones. In addition, during product usage, EEE must keep their quality and performance in their lifetime. The PFAS used in products have a very low vapor pressure and therefore do not volatilize at room temperature, and are designed to remain where they are applied to in order to provide the required function during the product lifetime, and to perform well under more severe conditions than the rated operating conditions. We therefore believe that it is unlikely that PFAS will be released into the atmosphere from the products during the product usage.

Or, if MPCA would like to examine "currently unavoidable use" based on the results of PFAS information reported in accordance with the reporting requirements, MPCA should request industries for providing the list of PFAS essential uses. Although PFAS information contained in complex articles is unlikely

transmitted, articles manufacturers have information on PFAS applications which cannot be substituted based on their technical knowledge.

Comment(6)-2: The handling of chemical products and the articles (manufactured items should be differentiated.)

We believe the fundamental issue is that MPCA seems to treat chemical products and articles (or manufactured items) the same. Examples of articles include devices that utilize the physical properties of chemical substances and set equipment that function by combining different devices. PFASs, as defined in the law, consist of a broad scope of substances, and PFASs may be contained in many electric and electronic equipment (EEE) because of their functional and indispensable qualities (e.g. water repellency, oil repellency, heat resistance, chemical resistance, reflexibility, etc.). In contrast, the current requirements under the law exceed the EEE industry's current best practices, thereby increasing our concerns about the feasibility of complying with the requirements. Even if articles were in the scope, we do not believe that regulating articles would contribute to fulfilling the objectives of the law of reducing the negative impact to human health and the environment. Additionally, we are concerned that the citizens, as well as the economy, of Minnesota would be negatively impacted due to the restriction of the sale and distribution of essential EEE that are found to be noncompliant to this PFAS law.

Comment(6)-3: As we stated in our comment(1)-1, EEE and components used in EEE should be excluded from the scope of Section 116.943.

Comment(6)-4: As we stated in our comment(1)-4, we attached the explanation of the difficulties of transmitting chemical substance information contained in products along the supply chain in EEE. This explanation was submitted to the Maine Department of Environment Protection (DEP) as a part of comments to the preceding Maine PFAS law and was positively acknowledged as a good explanation on issues of complex products and complex supply chain. Currently, further revision of the Maine PFAS regulation is under discussion in the Maine Legislature and this document was referenced at its Environment and Natural Resources Committee. A LIVE video clip of the first committee meeting held on 10/2 is available on the Maine Legislature's website at https://legislature.maine.gov/committee/#Committees/ENR

Comment(6)-5: On 23 October 2023, European Chemicals Agency (ECHA) published advice on enforceability of REACH PFAS restriction proposal as follows. The Forum consists of members of enforcement authorities in EU, Norway, Iceland and Liechtenstein, and may advice to the proposed restriction under EU REACH Regulation from enforceability perspective. The advice from the Forum will be taken into account when compiling the ECHA opinion to be eventually sent to the European Commission.

Opinion of RAC (and minority positions) and Forum Enforceability Advice (as of September 2023) in following URL.
https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b#msdynttrid=OIbf7bRXcLIU-8Ibydy7Z32gfZV1ZeQXbQOGWlSKQSc
Or
https://echa.europa.eu/documents/10162/c77815fb-d3b8-38f3-ca2d-de7fdd155e60

In this document, the Forum proposed as follows (Issues pointed out by the Forum can be found in the bottom of this comment).

PFAS restriction in EU is similar to the Minnesota PFAS law in the following points.
1. defining PFAS by structure
2. identifying PFAS amount by analytical testing is necessary since threshold is set for certain type of PFAS (like polymeric PFAS)
Therefore, we believe these proposals can also be applicable to the Minnesota PFAS law.

3.3 Recommendations on the wording to improve the enforceability

Definition of PFAS

To help enforcement authorities, the Forum suggests the developing of an indicative list of PFAS in a future guidance (with the chemical structure) covered by the restriction.

3.4 Practicability/Enforceability/Enforcement costs

3.4.1 Enforceability

The Forum considers that the proposal in its current form will be challenging to enforce. Significant improvements are needed in the availability of standardised analytical methods and in supplying additional guidance. …
Analytical methodologies used for monitoring programs are in a high number of cases not sufficient. Especially with the broad field of polymeric PFAS on the horizon this issue marks a serious challenge to enforcement.

Issues pointed out by the Forum are as follows.
Issues for enforceability related to the proposed scope
Substance identification
substance identification is based on structural criteria only. There is no reference to a list of substances or CAS numbers. The Forum considers this proposal challenging for enforcement authorities.

3.2.1 Sampling and sample preparation

General remarks on sampling

Since this is a very broad restriction proposal that covers a large range of articles and many chemical products, it is hard to say if specific sampling and preparation methods are necessary and available. … As a high number of polymeric analytes on articles can be expected, it remains unclear if proper sample preparation could be achieved to enforce the current restriction proposal effectively.

Standardised analytical methods necessary and available?

In Appendix E4 of the dossier, very few of the listed methods are standardised ones. Even for the total fluorine analysis, for the application of the limit value of 2(iii), there are currently no standardised methods available.

There is a strong need for developing standardised methods, certainly for TF in different types of matrices. Also, for targeted PFAS analysis more standards are required. … Analytical methods to analyse various forms of TF content (inorganic, organic, adsorbable, extractable) are available but the restriction needs to clearly define which method or methods are acceptable for which type of sample, to ensure comparable results for this generic parameter.

Certain problems with analytical methods are not addressed in the dossier:

- Reference materials are not commonly available or may require special techniques of analysis (e.g., headspace gas chromatography–mass spectrometry (GC-MS) for e.g., F-gases).

- The TF content may be measured after combustion. However, especially polymeric PFAS may require very high to extreme temperatures to fully combust, which may exceed the technical limitations of conventional combustion equipment in laboratories.

- Extraction methods for the differentiation of the organic and inorganic fluorine may be very cumbersome and difficult in the case of some polymers and require special chemicals.

For the targeted analyses only approximately 100 PFAS can be determined, ca 1% of the estimated 10 000 PFAS covered by the proposed restriction. … It is also unclear how the sum of PFAS via targeted analysis (polymeric PFAS excluded) should be determined for compliance check, due to the lack of standardised analytical methods.

<u>Available analytical methods carried out by conventional equipment?</u>

Most of the methods mentioned in Appendix E4 of the dossier are using chromatography and/or spectrometry (such as GC-MS, LC-MS, GC-MS/MS, LC-MS/MS, HRMS, LC-HRMS, SFC-MS/MS, PIGE, XPS, CIC, FTIR), which is usual laboratory equipment. But even though this is usual laboratory equipment, a substantial set of such equipment will be required to carry out all these tests.

Nevertheless, these techniques refer to the identification of single substances or measure HF. This leads to the point that the analysis method is limited to the availability of reference materials (single substance analysis) or requires in many cases sample preparation. Coming back to polymeric PFAS, the sample preparation itself may demonstrate the actual problem as many of the restricted compounds/polymers are extremely stable (which is one or the main reason for the restriction).

EOF

Explanation of Difficulties in Obtaining Information on Chemical Substances Contained in EEE (Electrical and Electronic Equipment)

1. Framework on Investigating Chemical Substances Contained in Products within the EEE Industry

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

Even if the CASRNs are identified, it would take at least months (or potentially years) if EEE manufacturers need to survey the supply chain for the presence of numerous chemical substances. This is due to the fact that EEE manufacturers are placed towards the bottom of the supply chain, and the inquiry on the presence of chemical substances may need to be transmitted to the top of the supply chain (the chemical manufacturers), and the results must then be transmitted back to the EEE manufacturers.

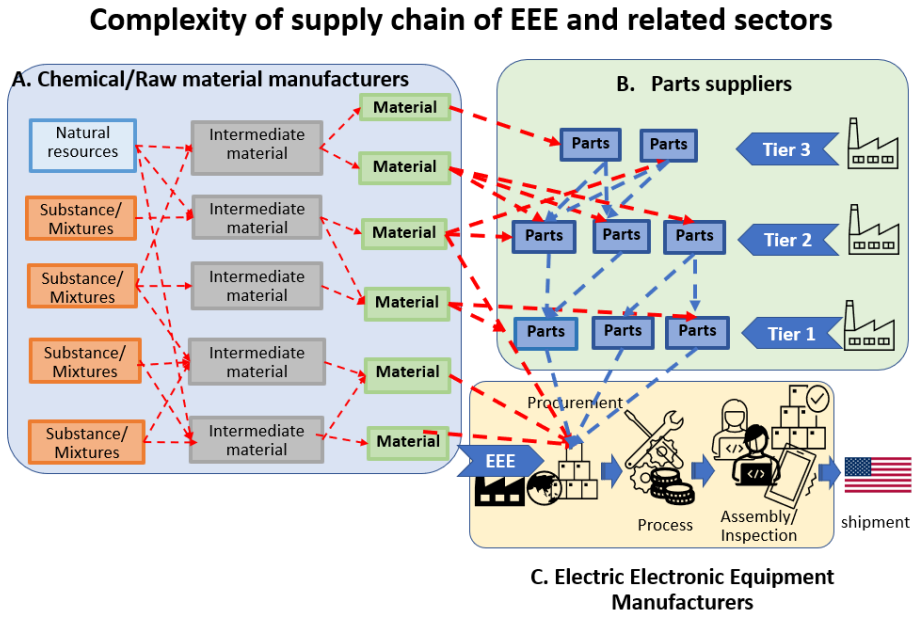
2. Adding PFASs to the DSL

The EEE industry has begun to take certain actions to PFAS laws which have been proposed or introduced so far. Although most PFASs have not been found to be hazardous, "PFAS" was recently added to the DSL on January 17, 2023. Nevertheless, since the most PFAS laws do not specify the CAS numbers of the specific PFAS substances, the DSL does not identify the specific PFAS substances. Instead, a non-exhaustive list of 629 PFAS substances (selected based on expert knowledge) was added to the Reference Substance List (RSL).

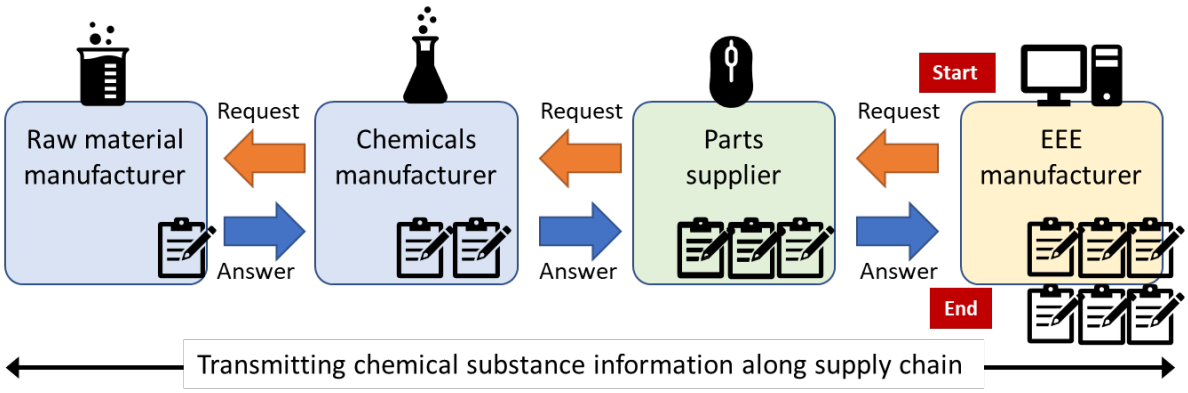
This will enable the future survey of the listed PFASs across the supply chain, but there are many obstacles to conducting such surveys, as described below.

3. Conducting Surveys

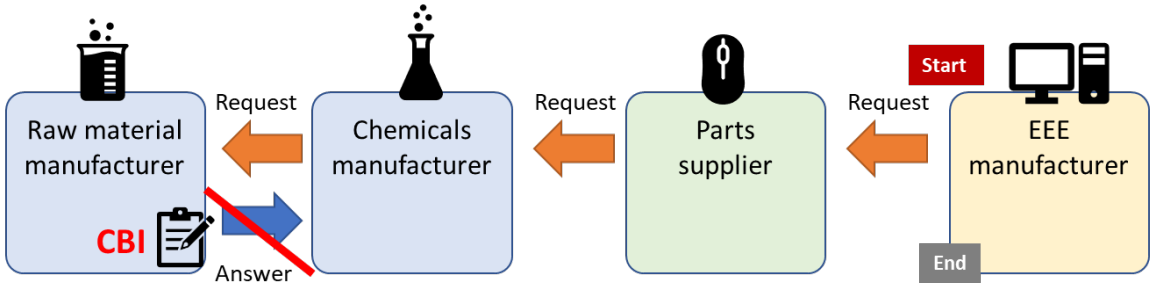
For complex articles such as EEE, the supply chain is multi-layered and complex, and operates on a global scale.



For the final EEE manufacturers (placed downstream in the supply chain) to obtain information about the chemicals contained in each part of component of the product, it is necessary to communicate the need for information upstream in the supply chain one tier at a time. Generally, the final EEE manufacturers are only capable of directly communicating with suppliers that are two-tiers upstream, at best.



The detailed chemical composition of the functional material (in which PFAS may be used) is often considered a trade secret and is not communicated to the downstream entity 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 upstream chemicals manufacturer may not know the information unless a highly accurate analysis is conducted. For example, one of our members was unable to obtain from its suppliers the specific chemical names of PFOA-related substances covered under the PFOA exemptions under the Stockholm Convention.



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

The more complex the supply chain and the larger the number of substances surveyed, the longer the time that is needed to obtain responses (ranging from months to years).

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

Additionally, 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 EEE manufacturer to know whether or not they are PFAS.

EEE manufacturers have hundreds or thousands of tier 1 suppliers, and it is not possible to estimate how much time and effort it would take to obtain information on the use of potentially more than 10,000 PFAS substances throughout the entire supply chain.

The EEE manufacturer specifies the necessary specifications of the main material or finished product to its suppliers, but rarely specifies the use of each substance in each article (except for legally restricted substances). Also, in most cases, finished article manufacturers themselves rarely use PFAS substances or PFAS-containing mixtures. Furthermore, in the supply chain, the users of the PFAS chemicals themselves are not the "first or second tier" suppliers, but are often the material manufacturers that are further upstream.

Therefore, the EEE manufacturer has no choice but to rely on information communicated through their direct channels. The information that the EEE manufacturer ultimately receives from these direct channels may consist of information from suppliers further upstream.

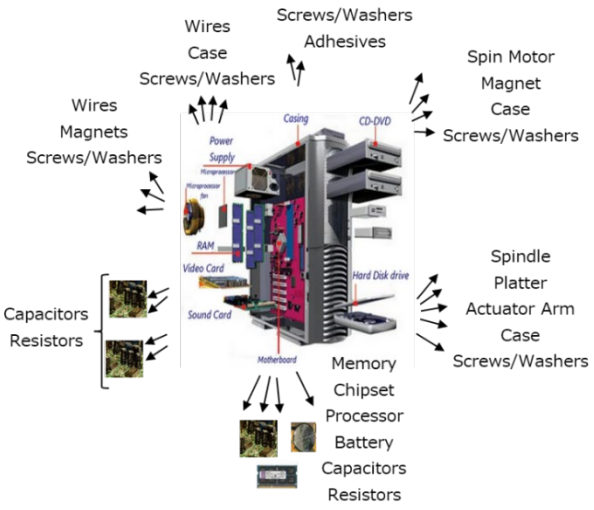
Although a list of certain PFAS substances were added to the DSL to initiative the investigation of their use in the supply chain, the information may be transmitted to EEE manufacturers years later. There is also no certainty that the EEE manufacturers would obtain information on all of the PFAS substances used in their articles even if substantial time is used to conduct these investigations.

4. Difficulty of analyzing 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 the methods that can be used to analyze the PFAS content in articles.

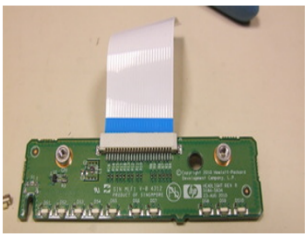
Even in the case of measuring the total organic fluorine when individual PFASs cannot be identified, there are few analysis methods known as available for articles. For example, Combustion-Ion Chromatography (CIC), the commonly known analytical method to detect fluorine, detects both organic and inorganic fluorine. Therefore, it is not possible to detect only total organic fluorine. Even if an EEE manufacturer were capable of conducting analytical testing, EEE consists of tens of thousands of parts. It would be impractical for companies to expend significant resources to analyze each of these parts to determine PFAS content.

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



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

Small circuit board unit



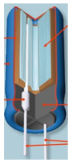
Simple BoM

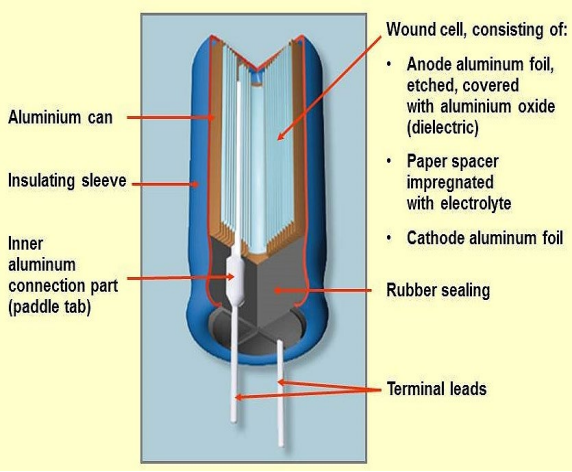
Qty	Component
1	PCB FR4 (88mm x 23mm x 2.5mm)
2	Ceramic Capacitor 0.1 uF (0603 size)
15	Ceramic Capacitor 100 pF (0402 size)
1	Ceramic Capacitor 2.2 uF (0603 size)
2	Al Electrolytic Capacitor (SMD)
4	Ceramic Resistor 0 ohm (0402 size)
24	22AWG wire (7cm)
15	Ceramic Resistor 82.5k ohm (0402 size)
2	Label 45mm x 6mm
1	Cermic Resistor 56k ohm (0603 size)
1	IC CMOS Inverter (SOT23 size)
1	IC PLD (64L TQFP)
2	Transistor MOSFET (SOT-23 size)
1	24 pin connector
1	Pushbutton switch 12 V
2	Clinch Nut (PEM Nut)
10	LED lamp Orange SMT

Parts of Al capacitor

Qty	Component	Sub-Component
2	Al Electrolytic Capacitor(SMD)	Aluminum can Insulating sleeve Al anode & cathode Paper spacer Electrolyte solution Seal ring Terminal leads

To be analyzed in this level





To conduct a PFAS analysis, it would be necessary to analyze at a material level of the tiny components. Even these components may consist of multiple material, making it difficult to estimate the time, effort, and cost to conduct analyses for each component of every EEE subject to the law.

Based on the above, it is not practical for an EEE manufacturer (as downstream entity of the supply chain) to analyze and identify the type and content of the PFASs contained in their products.

5. Conclusion

To the best extent possible, the EEE industry is conducting efforts to comply with the PFAS reporting requirements. However, due to the difficulties explained in this document, the industry will not be able to obtain the sufficient information to fully satisfy the PFAS reporting requirements.

EOF

MedicalAlley

11/27/23

RE: Request for Comment on PFAS in Products Reporting Rule

Commissioner Kessler,

Medical Alley and our network of more than 800 partners represent one of the most diverse and influential healthcare communities in the world. We are a critical partner and connection point between companies, talent, and the broader Medical Alley community, which employs more than half a million Minnesotans.

Based on the feedback of our partners, we are responding to the Minnesota Pollution Control Agency's Request for Comment on the PFAS in Products Reporting Rule.

As the MPCA approaches regulation of the reporting of medical device PFAS, the agency must preserve patient access to healthcare and protect the medical device supply chain.

For ease of reporting to prevent such disruption, the MPCA needs to establish a uniform process for reporting in consultation with the medical device manufacturing industry.

- Without a uniform system, compliance for each product will be very costly and time-consuming. It will likely require the services of dedicated labs for several years to work through all of a manufacturer's products.
- Additionally, the MPCA needs to offer guidance on how a manufacturer is to collect PFAS component information from third-party suppliers, including in situations where the supplier will not provide the information to the manufacturer.

As the MPCA develops a standard for reporting, Medical Alley encourages agency officials to understand that a complex process for data collection slows down access to patient care through a restricted supply chain, thereby increasing costs that will most certainly be pushed down to the patient. A complicated process for reporting will add significantly to the price of a medical device, thus reducing its cost effectiveness while decreasing patient access due to cost and supply chain impact. Such reporting requirements will force third-party payers to adjust and transfer the additional cost to the patient and overall health system, having the potential to cause financial distress to the patients with chronic disease seeking these devices for diagnosis and treatment.

Public Comments on PFAS in Products Reporting Rule

1. Are there definitions in subdivision 1 for which clarification would be useful to understanding reporting responsibilities?

    - The definition of PFAS should be based on a list of Chemical Abstracts Service (CAS) Registry numbers.

- Rulemaking should further require that for PFAS to have been "intentionally added" to a product, PFAS must be explicitly specified in the device manufacturing record for the product under Subdivision 1(l).
    - This is consistent with Subdivision 2(a)(2), which requires the manufacturer to indicate in reporting "the purpose for which PFAS are used in the product."
    - This is also consistent with the definition of "product component" as an "identifiable component of a product" under Subdivision 1(r).
    - Without such limitation, it could prove impossible for a manufacturer to report "the amount of each PFAS…reported as an exact quantity determined using commercially available analytical methods" under Subdivision 2(a)(3).
    - This is a reasonable limitation given that these PFAS are not capable of escaping into the air or leaching into the water.
- Rulemaking should clarify that prescription medical devices are not contemplated in the definition of "juvenile product" regardless of pediatric indication under Subdivision 1(m).
- Rulemaking should narrow the definition of PFAS to focus on the most harmful classes of PFAS under Subdivision 1(p).

2. Are there terms or processes in subdivision 2 for which clarifications will help reporting entities determine reporting status or data-gathering process?

- Under Subdivision 2(a)(2):
    - The reasons for using PFAS in any medical device falls into a few categories – lubricity, dielectric strength, mechanical properties, or epithelial response. Will it be sufficient for a medical device manufacturer to state that the purpose is for one of these four categories as the reason?
        - These categories would be helpful to explain why PFAS is required.
        - The aim would be to have common purpose language for every product manufactured, then make a single submission for every UPN (UPC or SKU) and only update said submission when a new product is launched in Minnesota.
    - Final manufacturers are not the actors making the decision to include PFAS in products. Often this is done by sub-suppliers of subcomponents and unknown to the final manufacturer. Final manufacturers are limited, in a best-case scenario, to gather information based on the international standard. Due to the complexity of the supply chain, it is not feasible to request additional information outside of the standard.
    - To facilitate information exchange across the supply chain, international standards such as IEC 62474 have been developed. This includes disclosure of the occurrence of substances above a certain threshold for a limited set of regulated substances. However, for complex medical

systems, it does not contain all PFAS, does not contain the exact amount of PFAS, and does not contain the reason for including PFAS.
    - Complex medical systems like an MRI device requires nearly 120,000 components to be assembled. In many instances, those 120,000 components could have sub-components needed to operate the device. The supply chain runs seven-to-ten layers deep to obtain these components from other countries. It would take an enormous amount of time to track each supplier to disclose their product chemistries because they would have to detect over 12000 chemistries for each component.
    - The MPCA needs to explain how a manufacturer is to retrieve PFAS data from suppliers. How is a manufacturer to proceed in compliance if the supplier will not provide that data?
- Under Subdivision 2(a)(3):
    - Testing is not a feasible alternative to identify the occurrence of PFAS. The number of manufactured individual medical systems is low. Its complexity and number of subcomponents is very high. Costs of testing is prohibitive for the low volume high complexity sector of medical systems.
    - PFAS content in a medical device will be miniscule. Can a medical device manufacturer measure a single product with the highest PFAS content (as defined by numerical methods) within their portfolio and assert that all other products within their portfolio do not exceed that measured PFAS content?
    - The MPCA needs to provide guidance on minimum content reporting thresholds. There may be situation where PFAS is intentionally added and desired to be present in the finished device but is unmeasurable through commercially available analytical methods.
    - The MPCA needs to provide direction on the analytical methods required, since the statute did not provide that.
    - For manufacturers, complying with each product will be very costly and time-consuming. It will likely require the services of dedicated labs for several years to work through all of a manufacturer's products. Requirements like this would result in significant delays in delivering medical devices to health systems, clinics, etc., resulting in delayed patient care. In addition, it would significantly harm rural hospitals already facing closures due to reduced revenue.
    - In accordance with the language of Subdivision 8(b), which exempts medical devices from the requirements of Subdivisions 4 (Testing required and certificate of compliance), it is Medical Alley's interpretation that testing is not required of medical devices.
- Under Subdivision 2(a)(4), how is a manufacturer to retrieve this data from a supplier's supplier and other sub-suppliers? How is a manufacturer to proceed in compliance if the supplier will not provide that data?
- Under Subdivision 2(c):

    - How is a manufacturer to retrieve this data from suppliers? How is a manufacturer to proceed in compliance if the supplier will not provide that data?
    - Where information is available from the supplier, can a manufacturer report product information on an annual basis following the initial disclosure process, even when new products are launched where there is not significant increase in PFAS content for said new product relative to an incumbent product portfolio?
- Without a reasonable approach to medical device PFAS regulation, industry will not be able to meet the reporting timeline of January 1, 2026.

3. How should the MPCA balance public availability of data and trade secrecy as part of the reporting requirements?

    - The disclosure requirements raise significant intellectual property concerns. When a company is both the manufacturer and design owner, there still would be many instances where a component material supplier would 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 company manufacturing the final product.
        - The MPCA must develop something similar if the desire is full disclosure. Otherwise, no manufacturer will be able to achieve 100% disclosure.

4. Are there any terms used in subdivision 3 that should be further defined or where examples would be helpful?

    - “substantially equivalent information” needs to be further defined under Subdivision 3(a).
    - “publicly available” needs to be further defined under Subdivision 3(a).
    - “if the commissioner determines that more time is needed by the manufacturer to comply with the submission requirement” needs an example under Subdivision 3(d).

5. Are there specific portions of the reporting process that should not be defined through guidance or development of an application form?

    - Disclosure through a manual reporting form will require too much overhead for companies of medical products due to its wide portfolio and low sales volume per type of medical system (e.g. prohibitive overhead costs as compared to high volume goods). Reporting should be limited to what is feasible based on information in the supply chain.

6. Other questions or comments relating to reporting or the process of reporting.

   The MPCA needs to consider the use of representative products for medical devices containing PFAS (i.e. products that are considered to be representative of a logical grouping of products with respect to PFAS content). This would mean that a group of products with a similar end function, similar purposes for use of PFAS, and similar PFAS content can be grouped together. A single example from said grouping can then be tested by commercially available analytical methods and reported upon as an analogue for all products within that grouping.

   Further, Medical Alley encourages the MPCA to consider the relevance of reporting the use of fluoropolymers in healthcare products sold in the State of Minnesota. Fluoropolymers have been used in implantable medical device applications for over 50 years. They are inherently safe; are chemically, biologically and thermally stable; are insoluble in water, solvents and biological liquids; are non-mobile, non-bioavailable, non-bio accumulative and non-toxic; do not degrade to low molecular weight PFAS; and are internationally recognized as OECD Polymers of Low Concern.

   The US EPA White Paper on Fluoropolymers (*Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS?* Lohmann et al. 2020 https://doi.org/10.1021/acs.est.0c03244) outlines various issues related to the release of PFAS of Concern during the manufacturing processes of fluoropolymers, even though fluoropolymers in themselves are considered non-toxic. Arguments are made that releases related to such substances are of concern for human and environmental health. That paper was written before the fluoropolymers industry started communicating advances in processes technologies that eliminate the need for use of Fluorinated Processing Aids (FPAs), which cause potential releases of PFAS of Concern. Advances since 2020 mean that Non-Fluorinated Processing Aids (NFPAs) are now available for the manufacture of fluoropolymers and are becoming more widespread. The MPCA is requested to eliminate the need for reporting of fluoropolymer usage in products where such fluoropolymers are made using NFPAs and where said manufacturers can provide evidence to support such claims.

   The whitepaper also deals with inadequate disposal of fluoropolymers, which may lead to unintended releases of PFAS of Concern. The use of fluoropolymers in medical devices are invariably in healthcare settings, where the chief disposal concern post-use is biohazard contamination, meaning that disposal is already well controlled. Associated disposal techniques mean that the post-use disposal concerns outlined in the whitepaper are not relevant to the medical device industry. For this reason, the MPCA is again requested to eliminate medical devices containing fluoropolymers manufactured using NFPAs from the scope of reporting, as there are no PFAS of Concern releases related to the manufacture, use, or disposal of said medical devices.

Medical Alley appreciates the time and consideration of MPCA officials working toward protecting our environment and public health while balancing the needs of the healthcare industry, preserving patient access to healthcare, and protecting the medical device supply chain.

Please reach out to Medical Alley Senior Director of Policy and Advocacy Peter Glessing (PGlessing@medicalalley.org) with any questions.

Sincerely,

Roberta Antoine Dressen
President/CEO Medical Alley

POLAR semiconductor

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November 28, 2023

Submitted via Minnesota Office of Administrative Hearings eComments Website

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

Re: MPCA Request for Comments regarding *PFAS in Products Reporting Rule* (Revisor ID No. R-4828) and *PFAS in Products Fee Rule* (Revisor ID No. R-4827)

Dear Ms. Kessler,

Polar Semiconductor (Polar) offers the following comments on the PFAS regulations being developed by the Minnesota Pollution Control Agency (MPCA) as authorized in Chapter 60 of H.F. 2310. The MPCA has requested comments on planned new rules for the *PFAS in Products Reporting Rule* (Revisor ID No. R-4828) and the *PFAS in Products Fee Rule* (Revisor ID No. R-4827). The MPCA also stated that it is interested in comments on the phaseout and ban of intentionally added PFAS in products in 2032.

Polar wholeheartedly supports the goal of limiting the release of harmful PFAS substances into the environment. Polar is concerned, however, about the incompatibility of PFAS regulations with the State's goal to expand its semiconductor industry. In these comments, Polar offers recommendations on how the rules should be drafted to protect the environment while simultaneously allowing semiconductor manufacturing to thrive in the State. Polar also reiterates its support for the comments submitted by the semiconductor industry association SEMI in response to the MPCA's request for comments.

POLAR AS AN ECONOMIC DRIVER AND ENVIRONMENTAL STEWARD

Polar is a Minnesota-based company that produces integrated circuits (IC) and discrete semiconductor devices on 8-inch wafers at its fabrication facility in Bloomington. Polar's processes start with a bare silicon substrate and end with a finished wafer containing functional devices. Polar is the largest semiconductor chip manufacturing facility in Minnesota. Semiconductors are a necessary part of all electronic devices, controlling and managing the flow of electric current and enabling advances in communications, computers, transportation, military systems, and clean energy. Polar supplies products to a diverse group of end market users, with approximately 60% of its manufactured wafers dedicated to the automotive sector. The remaining share of Polar's wafers cater to industrial, commercial, and defense customers. Demand for semiconductors is projected to increase with the electrification of nearly every part of the economy and society.

Polar is in the midst of an exciting transformation. With help from the Minnesota Investment Fund, Job Creation Fund, Minnesota Forward Fund and potentially, federal CHIPS Act funding, Polar plans to

expand within its current footprint and increase manufacturing capacity by 85%. This expansion will create 74 construction jobs and 98 new full time Minnesota-based jobs at Polar's Bloomington facility.

PFAS-containing materials are essential components to semiconductor manufacturing. While completed semiconductor devices do not contain intentionally added PFAS, liquid chemicals and fluorinated gases with PFAS components are used in the manufacturing process. For example, fluorocarbon gases are used in plasma etch processes, fluorinated chemicals are used in photolithography, and fluorinated chemicals are used as refrigerants and heat transfer fluids. The carbon-fluorine chemistry of these PFAS-containing materials alters surface tension, thermal stability, and chemical compatibility in ways essential to the semiconductor manufacturing process. Despite years of extensive research, there have been no viable PFAS-free alternatives identified. In short, the semiconductor manufacturing process is enormously dependent on PFAS, for which there are currently no viable alternatives.[1]

Polar prioritizes sustainability at its facility and is committed to reducing or mitigating its environmental impact. It maintains an ISO 14001 certified Environmental Management System (EMS) and has established environmental improvements goals related to hazardous waste reductions, water conservation, and greenhouse gas emission reductions. For example, Polar recently transitioned operations to be powered 100% by renewable energy through purchased Renewable Energy Certificates.[2]

Polar recognizes that PFAS can have impacts to human health and the environment, and is committed to finding alternatives to PFAS-containing materials. In the meantime, Polar is actively investigating various technologies including ion exchange to mitigate potential PFAS in discharged treated wastewater. However, during the period of transition, Polar believes the State should balance its dual priorities of environmental protection and creating a thriving semiconductor manufacturing ecosystem in Minnesota.

COMMENTS ON THE *PFAS IN PRODUCTS REPORTING RULE*

(1) Are there definitions in subdivision 1 for which clarification would be useful to understanding reporting responsibilities?

Polar does not have comments on this issue at this time.

(2) Are there terms or processes in subdivision 2 for which clarifications will help reporting entities determine reporting status or data-gathering process?

The authorizing statute empowers the MPCA to determine a PFAS concentration range for the purposes of fulfilling reporting requirements. Polar supports this approach because there is no commercially available methodology for identifying an exact quantity of PFAS. As part of this rulemaking, the MPCA should specify concentration ranges for all PFAS or groups of PFAS subject to reporting (product group). Doing so will provide adequate data on PFAS use without burdensome reporting obligations on the regulated community. The MPCA should determine and add the notification ranges to the draft before the rulemaking process is finalized. These concentration ranges should be harmonized with those enacted by EPA

[1] Semiconductor Industry Association (SIA) Background on Semiconductor Manufacturing and PFAS (May 17, 2023).

[2] Xcel Energy Renewable*Connect

under its PFAS reporting rule for articles (but with an exclusion for products containing less than 0.1% PFAS).

(3) How should the MPCA balance public availability of data and trade secrecy as part of the reporting requirements?

The semiconductor industry, as well as the technology sector in general, treats the chemical composition of materials as proprietary information that is carefully protected and of significant commercial value. Any proposed rules, therefore, should address how entities can designate reports or portions thereof as confidential business information (CBI) and trade secrets, how the MPCA will protect the information or decide what non-CBI elements will be made publicly available, and how CBI and trade secrets in the MPCA's possession will be protected from disclosure.

To the extent information about PFAS use and concentration is made available to the public, the MPCA should permit the use of generic chemical names or ranges instead of CAS numbers.

(4) Are there any terms used in subdivision 3 that should be further defined or where examples would be helpful?

Polar does not have comments on this issue at this time.

(5) Are there specific portions of the reporting process that should not be defined through guidance or the development of an application form?

Polar does not have comments on this issue at this time.

(6) Other questions or comments relating to reporting or the process of reporting.

Polar supports SEMI's recommendation to incorporate the EPA's "known to or reasonably ascertainable by" standard:

> *SEMI also recommends that the MPCA expressly incorporate EPA's "known to or reasonably ascertainable by" standard that allows notifying entities to rely on supplier declarations, and to limit the scope of investigation that manufacturers would be expected to undertake with respect to upstream suppliers. EPA has applied this standard for years in its Toxic Substances Control Act Chemical Data Reporting Rule and recently extended its use to the agency's PFAS reporting rule. See, e.g., 40 C.F.R. § 711.15; 88 Fed. Reg. 70516. The MPCA should mirror this standard to prevent a reporting scheme that is broader than EPA's PFAS reporting rule and is therefore more expensive to implement than EPA's $843 million estimate for the compliance costs associated with its rule. See 88 Fed. Reg. 70516. In addition, companies that manufacture semiconductors and semiconductor equipment and materials, including those operating in Minnesota, share numerous common chemical suppliers. There is a significant efficiency advantage to limiting the scope of due diligence to EPA's "known to or reasonably ascertainable" standard in order to prevent burdensome and duplicative outreach by manufacturers to these suppliers.*

COMMENTS ON THE *PFAS IN PRODUCTS FEE RULE*

(1) Should the Agency consider tiered fees for different sizes of business?

Polar does not have comments on this issue at this time.

(2) Should the Agency consider a per-product or per-company fee?

If the MPCA allows reporting by product group and assesses per-product fees, it should assess fees by PFAS product group instead of individual product.

(3) Should the Agency consider a per-PFAS or PFAS amount fee?

Polar supports SEMI's comments on per-PFAS or PFAS amount fees.

(4) Are there other state program fee structures on which the Agency should model the fees?

Polar does not have comments on this issue at this time.

(5) Should the Agency consider a fee to be paid when updates to information on previously reported products are submitted? (e.g., decreased amounts or elimination of one or more PFAS)

Polar does not have comments on this issue at this time.

COMMENTS ON THE PFAS PROHIBITION AND EXEMPTIONS

Because the MPCA has also invited comment on any other aspect of potential PFAS rulemaking, Polar emphasizes the importance of exempting products, product components, materials, or equipment used in semiconductor manufacturing under a "currently unavoidable use" exemption or establishing a simple, straightforward process for obtaining a "currently unavoidable use" exemption.

The legislature empowered the commissioner to specify products or product categories for which PFAS use is currently unavoidable, and exempt those products from the upcoming 2032 ban on sale or distribution of products with intentionally added PFAS. The statute defines "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."

To the extent that materials used in semiconductor manufacturing contain PFAS, they satisfy the statutory standard for a currently unavoidable use exemption. (Note: final semiconductor products generally do not contain intentionally added PFAS). Semiconductors (and the raw materials needed for their manufacture) are necessary components of everyday life; an average person will interact with dozens to hundreds of semiconductors each day. The United States has declared domestic manufacturing of semiconductors a national and economic security priority, and the State has made spurring local growth of semiconductor manufacturing a priority, setting aside $250 million for investment in the semiconductor industry.

At present, there are no known alternatives to using PFAS-containing material in semiconductor manufacturing. The semiconductor industry is developing strategies to identify alternatives and reduce dependence on PFAS. If PFAS alternatives are identified, however, the implementation timeline could be 15 or more years. Given the necessity of semiconductors for a functioning society and the lack of feasible alternatives, the 2032 ban should not apply to products necessary for semiconductor manufacturing. Any rule should allow the semiconductor industry to obtain currently unavoidable use exemptions for necessary products.

CONCLUSION

Polar is proud to be the largest semiconductor chip manufacturing facility in Minnesota. Without carefully crafted regulations or a currently unavoidable use exemption for semiconductor manufacturing products, the PFAS prohibition will have a profound impact on Polar's short-term expansion, Polar's long-term viability, and the semiconductor manufacturing industry in the State.

Thank you for the opportunity to provide comments to the MPCA on upcoming PFAS reporting, fee, and other regulations. Polar welcomes further discussion with the MPCA on the role of PFAS in semiconductor manufacturing and mitigation measures underway.

Sincerely,

Surya Iyer
President and Chief Operating Officer
Polar Semiconductor LLC

Rosanna Imholte
Facilities Manager - EHS
Polar Semiconductor LLC

RECEIVED
By: OAH on 11/28/2023
Andrew Bemus Attachment

SUSTAINABLE PFAS ACTION NETWORK

November 28, 2023

Response to Minnesota PFAS in Products Reporting Rules and Product Prohibitions
Revisor's ID Number R-4828; Minnesota Statutes 116.943
Attention: May H. Lynn
Minnesota Pollution Control Agency
520 Lafayette Road North
St. Paul, Minnesota 55155-4194

Copy submitted electronically to:
Office of Administrative Hearings
600 North Robert Street
P. O. Box 64620
St. Paul, Minnesota 55164-0620

The Sustainable PFAS Action Network (SPAN) is pleased to submit the following comments concerning the planned rulemaking governing reporting for products containing per- and polyfluoroalkyl substances (PFAS).

Background

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. In a recent study by INFORUM, a Washington-based economic consulting firm, it was reported that critical PFAS-using industries (e.g., automotive, aerospace, air conditioning and refrigeration, medical device and pharmaceutical, battery, and semiconductor industries) contribute more than $1 trillion to the U.S. gross domestic product each year, accounting for more than six million U.S. jobs, while providing annual wages estimated to exceed $600 billion. In Minnesota alone, the industries in which SPAN members participate (specifically aerospace, semiconductor, and air conditioning and refrigeration), contribute more than $8 billion in annual economic output, employ more than 42,000 Minnesotans directly and indirectly, and generate greater than $2.5 billion in annual wages. 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.

Brief Summary of Comments

SPAN encourages MPCA to prepare proposed regulations for public comment that will establish

clear and practical reporting obligations for PFAS-containing consumer products, under Subdivisions 2 and 3 of the law, which will provide information of value to MPCA and its stakeholders, while ensuring any prohibitions and an exemptions processes that are implemented pursuant to Subdivision 5 and 8 of the law are reasonable, and risk-based and accommodate essential PFAS uses and products that provide important societal benefits. The information gathered under the reporting requirements should be considered and evaluated and inform any risk-based product restrictions issued by MPCA.

SPAN also recommends that the reporting fees be modest, that reporting should be done using an online platform that has been tested and is efficient, and entities filing reports should be able to assert claims of confidentiality for information that is a trade secret or protected for national security reasons.

SPAN further recommends that MCPA make every effort to benefit from and to avoid duplicating EPA's ongoing PFAS information collections efforts.

In the interest of brevity, the following addresses specific points on which comments are being solicited by MPCA that are of greatest importance to SPAN members. SPAN reserves the opportunity to comment in greater detail and on additional topics when a proposed regulation is made available by MPCA.

Reporting Requirements

SPAN recommends that the MCPA consider imposing the reporting requirements incrementally. MCPA would analyze different product categories for likelihood to cause contamination of the environment in Minnesota. The categories most likely to cause such contamination would be subject to reporting first. Once an initial round of reporting has been completed, MCPA can then move to the next group. Such a phased approach will permit both MCPA and the regulated community to adjust the new requirements and address any practical issues that may arise. MCPA can then make any adjustments to reporting requirements if needed. A phased-in approach also can reduce the reporting burdens on the entities subject to the final regulations and administrative burdens on MCPA and its personnel.

SPAN recommends that the information required for reporting be simplified and streamlined to ensure MPCA is focused on gathering the information of greatest interest to PFAS exposures and releases that are likely to occur within the state. SPAN recommends minimizing reporting requirements specifically asking for information on PFAS content in finished products (or finished component parts) that are "articles" (i.e., manufactured finished products that are not in a solution or dry mixture or other physical form that will undergo further shaping or processing), and that greater emphasis be placed on gathering information on PFAS-containing substances, formulations, and other chemical mixtures that are produced in the state, and will undergo further processing and use in the state in a manner that will provide an opportunity for releases

and exposures to occur within Minnesota.

SPAN members also request that the reporting format enable entities submitting information to claim certain data and information to be confidential. Such information must be kept secure and protected from public disclosure or unintended disclosure, including through hacking efforts and commercial espionage. MPCA should consider whether it should permit two or more parties to provide their own (confidential) portions of a joint submission system. This might allow manufacturers of complex articles and unique formulations to submit their suppliers' contact information when such suppliers are unwilling to provide chemical substance information to the customers due to confidentiality concerns. The reporting tool should permit the supplier to submit the needed information directly to the state. The reporting obligation would be fulfilled by the separate entities in the value chain who have a role in the production of a complex product that contains PFAS.

SPAN requests that MPCA provide guidance on the requirement that the notification contain the amount of each PFAS by name and CAS number. This requirement presumes that it is possible to identify all PFAS in a product; this is not correct in all cases. Testing is not currently available to specifically identify all PFAS. The only other way to ascertain PFAS content is from information provided by suppliers. However, if the needed PFAS content information cannot be obtained from others, for example due to intellectual property concerns or simply refusal to cooperate, a manufacturer may be unable to fulfill the notification requirement. SPAN therefore suggests that MCPA embrace a "reasonably ascertainable" due diligence standard for manufacturers who are attempting to fulfill their compliance obligations. MPCA should make clear that manufacturers may reasonably rely on information provided by the suppliers, provided that they can provide documentation of inquiries made to suppliers and the efforts made to obtain information regarding the use of PFAS.

SPAN requests that MPCA clarify how it will expect manufacturers that report to calculate ranges for the amount of PFAS that will be reported for products, and what such ranges will be.

In the course of reporting, it is likely that some data and information elements will be confidential business information. SPAN reiterates its recommendation that MCPA include guidance and regulatory provisions that govern how claims of confidential business information can be asserted at the time of reporting and how such information will indeed be handled in a confidential manner. The procedures must be in place to maintain the security and confidentiality of the information collected before the reporting period commences; MCPA's data storage systems must be hardened again unwanted intrusions by third parties and competitors.

Fees

SPAN recommends that fees be established on a "per report" basis, or on a per-company basis, and in a manner that enables a single company filing reports for multiple products to avoid paying reporting fees on a per-product basis. Thus, multiple products produced by a single company

should be reported within the same report, perhaps permitting similar products to be grouped for reporting purposes (e.g., all wrist watch models manufactured by the same entity filing a report).

Fees should be established at a level that does not discourage reporting and at a level which supports the reporting program.

Clarification of Definitions

SPAN requests that MPCA address the definition of "Intentionally added" PFAS. Specifically, MPCA should clarify that the definition does not include the following: manufacturing byproducts and impurities that might be unintentionally present in a product in commerce, and PFAS degradants that might be formed during product manufacturing but also be considered unintended components or contaminants.

SPAN requests MPCA clarify in the regulatory proposal that the definition in the statute of "product" is, as was intended by the legislature, limited to those products made available to consumers for their personal use. The inclusion in the definition of products that are also made available to consumers for "commercial, or industrial use" or "for use in making other products" unintentionally expands the scope of the products on which the focus should remain. MPCA should include language in the proposal to make clear that PFAS-containing products that are used in commercial settings (e.g., office equipment) and in industrial and manufacturing applications (e.g., industrial and commercial devices, such as mechanized systems and robotics) are excluded from the reporting and the prohibitions requirements under the law.

MCPA should be certain any proposed rule clearly defines who must report. The term "Manufacturer" under the statute is 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 a circumstance, it is not clear who the "manufacturer" is and therefore which entity has the reporting requirement. SPAN recommends that MPCA clarify how the notification requirements apply to multiple businesses in the supply chain for finished products that will be distributed with multiple PFAS containing components. The proposed regulation must make clear whether the responsibility falls upon the maker of the PFAS-containing components, the brand owner, a brand licensee, an importer, or the company that is distributing the finished product when multiple parties fit into the definition of manufacturer.

The Department should clarify which entity has the primary obligation to report.

Reducing Burdens by Aligning with Federal EPA Reporting Rules; Waiving Certain Reporting Requirements

Subdivision 3 of the reporting program gives the Commissioner the authority to waive all or part of the information requirement under subdivision 2 if the Commissioner determines that substantially equivalent information is already publicly available. SPAN recommends MPCA ensure its reporting requirements do not duplicate and take into consideration information being collected by the U.S. government, and that will be collected in other states. For example, on October 11, 2023, the U.S. Environmental Protection Agency (EPA) codified its final rules for PFAS reporting pursuant to Section 8(a)(7) of the Toxic Substances Control Act (TSCA).[1] EPA is requiring any person that manufactures or has manufactured (including imported) PFAS (as a substance or as a chemical in a formulation or mixture) or PFAS-containing articles in any year since January 1, 2011, to electronically report information regarding PFAS uses, production volumes, disposal, exposures, and hazards. EPA is initiating this reporting program to gather additional data on the production, use, exposure, and environmental and health effects of PFAS in the United States, to enable the Agency to more effectively determine what further measures concerning PFAS might be appropriate. SPAN recommends MPCA make reasonable efforts to recognize and benefit from information being gathered by EPA and other states and provide mechanisms that will permit businesses preparing information for submittal to EPA (and to other states) to avoid duplicative requirements.

For the sake of regulatory consistency and clarity, MPCA should align its regulatory definition of PFAS (which currently is the overly-inclusive "single fully-fluorinated carbon atom" definition) with the U.S. EPA's more constrained definition[2] (a structural definition approach that relies on the presence of at least two fluorinated carbons). EPA states that this definition covers approximately 1,500 compounds believed to be active in U.S. commerce during the pertinent period. This is significantly fewer than the estimated 14,000 substances that would be covered using Minnesota's "one fully fluorinated carbon" definition. EPA's more modest approach to defining PFAS is intended to capture reporting on the various PFAS moieties of potential concern without being overly inclusive. Unlike the Minnesota statue, EPA's reporting program will gather information on PFAS in chemical formulations and mixtures, as well as imported articles containing PFAS; the EPA program is not focused on PFAS-containing consumer products *per se*.

As discussed above, SPAN recommends, as a resource-saving measure, that MPCA consider adopting an incremental reporting approach. The January 2026 reporting requirement would apply initially only to PFAS-containing consumer products. As a further resource saving measure, MPCA could consider omitting any requirement to report initially on fluoropolymer content in

[1] 88 Fed. Reg. 70516; Oct. 11, 2023. Codified as 40 CFR Part 705.

[2] EPA's reporting rules at 40 CFR 705.3 define *Per- and polyfluoroalkyl substances* or *PFAS as* any chemical substance or mixture containing a chemical substance that structurally contains at least one of the following three sub-structures: (1) R-(CF_2)-CF(R□)R□, where both the CF_2 and CF moieties are saturated carbons; (2) R-CF_2OCF_2-R□, where R and R 2□can either be F, O, or saturated carbons; (3) $CF_3C(CF_3)$R□R□, where R 2□and R□ can either be F or saturated carbons.

products given that fluoropolymers are believed to present fewer risks and to be unlikely to be readily released from a manufactured article during routine uses.

A phased (or narrowed) approach will permit MPCA to focus its attention and resources first on a category of products to which a Minnesota resident likely has the greatest exposure. Once these initial rounds of reporting has been completed, MCPA can them move to other category of products. This "staggered" approach will permit both MCPA and the regulated community to adjust the new requirements and learn from any implementation issues that arise. MCPA can then make any adjustments to reporting requirements needed. This also will provide time for reporting under the federal program to be compiled, and provide an opportunity for states, such as Minnesota, to assess the information collected and made public through the federal program. Such a delay will also provide MPCA the opportunity to use information gathered under the federal program, as well as the state's own program, to effectively guide the state's program under Subdivision 5 of the statute for considering ways to prioritize products or uses that may warrant future restrictions. This approach will ultimately reduce the burdens on both the entities subject to the final regulations and MCPA personnel. It will also allow for more orderly and responsive reporting

Currently Unavoidable Uses Exemptions & Essential Use Considerations

In the course of developing regulations to implement the statute, MPCA may conduct rulemaking to prohibit intentionally added PFAS in additional product categories. Simultaneously, MPCA is expected to identify "currently unavoidable uses," which will be exempted from the general PFAS-containing products 2032 ban. SPAN recommends MPCA identify as "currently unavoidable" critical PFAS and certain uses that have undergone federal authorizations for specific uses pursuant to programs such as (but not limited to) the significant new alternatives program (SNAP) under the Clean Air Act, the EPA's new chemical review program under Section 5 of the Toxic Substances Control Act, the Food and Drug Act, the Federal Insecticide, Fungicide, and Rodenticide Act, and other federal programs whereby either the PFAS, or products containing them, have been deemed acceptable for their intended use by federal government agencies. PFAS-containing products that are subject to, or necessary for, meeting federal specifications (e.g., military specifications, FAA-issued standards, NASA requirements) also should be considered currently unavoidable. Such an approach will help MPCA concentrate its efforts on non-essential consumer products.

SPAN recognizes that certain PFAS uses have only implicit "federal approvals", such as authorizations granted by EPA under the SNAP Program, FDA, TSCA, and FIFRA, and these may not fully satisfy the statutory provision that refers to "a product for which federal law governs the presence of PFAS in a manner that preempts state authority." This is because specific federal preemption is not provided for in these Federal statutes. Nevertheless, fairness and market stability should be assured to businesses that have successfully completed federal reviews for their PFAS-containing products under these statutes, or provide products that must meet military or similar government specifications. SPAN suggests that, at a minimum, MPCA's upcoming

rulemaking should enable members of the regulated community to request "currently unavoidable use" classification for these products and provide information that was the basis for the federal review and approval.

Furthermore, SPAN recommends the rulemaking also establish both a clear-cut process and criteria whereby any PFAS containing product producer may seek a "currently unavoidable use" determination. MPCA may want to exercise its authority to issue such determinations carefully and with conditions. For example, exemptions from a prohibition might be granted subject to an appropriate time limitation (with the ability to seek extensions), or be contingent on commitments from the product producer to minimize human exposures to retain the currently unavoidable use designation. Periodic reporting by the exemption recipient also could be a condition of the currently unavoidable use designation.

Prioritization

SPAN supports using MPCA's upcoming rulemaking as a means to ensure the regulated community and MCPA have a common understanding of the processes and criteria that MPCA will be using for purposes of prioritizing for potential prohibitions, under Subdivision 5 of the statute, products and product categories that, "in the commissioner's judgment, are most likely to contaminate or harm the state's environment and natural resources if they contain intentionally added PFAS."

SPAN recommends that a risk-based determination process be structured and applied, taking into consideration factors affecting exposures (e.g., production volumes, nature and conditions of manufacture and use) and hazard (e.g., toxicity, bioaccumulation, persistence). The process established should enable potentially affected entities to apply for, and provide technical support for, an essential use determination. The process established for applicants seeking such determination should also establish deadlines for application submission and definitive points in the application consideration processes; this should include a timeline for when MPCA will reach a determination (e.g., no later than 90 days following receipt of the application). SPAN considers the following matrix to be an example of some of the criteria that could be established for applicants.

	Known Low Production/Emissions	Unknown Production/Emissions	Known High Production/Emissions	
Known High PBT Risk				*High priority regulatory targets; decreasing priority to the left.*
Unknown Risk				*High priority for risk studies to identify or eliminate additional substances of concern; decreasing priority to the left.*
Known Low PBT Risk				*Lower priority for both regulations and additional research.*
	Candidates to monitor for change in production/emissions volume; increasing priority toward the top.	*Candidates for more research on production/emissions; increasing priority toward the top.*	*Candidates for research on emission profiles & environmental fate; increasing priority toward the top.*	

Conclusion

SPAN appreciates the opportunity to provide input in advance of the proposed rules being issued for consideration. Please contact SPAN with any comments or questions.

Sincerely,

Kevin Fay
Executive Director
Sustainable PFAS Action Network (SPAN)

RECEIVED
By: OAH on 11/28/2023
Avonna Starck Attachment

CLEAN WATER ACTION
PEOPLE • ACTION • JUSTICE

November 27, 2023

Thank you for the opportunity to comment on the "Possible 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".

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.

1. **PFAS definition:**

It is vital that the definition of PFAS in the law be protected. "Perfluoroalkyl and polyfluoroalkyl substances" or "PFAS" means a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom. This definition has now been adopted by twenty-two states. The definition includes polymers and fluorinated gases like hydrofluoroolefins (HFOs). Consistency across states is important.

Furthermore, polymers and HFOs must continue to be included in the definition because they are PFAS, and they contribute to overall PFAS and other toxic pollution. The production of PFAS polymers results in PFAS pollution during their production, use, and disposal. In addition, a recent investigation showed that one U.S. chemical manufacturing facility released a potent climate pollutant equivalent to one billion pounds of carbon dioxide in one year.

2. **PFAS Reporting:**

The definition of PFAS in the law is clear and encompasses all PFAS. The law also states a manufacturer must report:

> ***"(a)(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"***

The rule should provide clarification so that the manufacturer is required to: 1) report if any PFAS are intentionally added to a product component; 2) conduct testing for total fluorine; and 3) report concentrations of individual PFAS identified by CAS numbers using commercially available analytical methods or based on information provided by a supplier as falling within a range approved for reporting purposes by the department.

It is important for manufacturers to conduct total fluorine testing because most PFAS are not detected using standard analytical methods and total fluorine testing can screen for the total concentration of PFAS in a product. The analytical methods for testing individual PFAS are not adequate to capture all of the PFAS. Individual CAS numbers for PFAS number in the thousands; reporting on a subset of them may not reflect the total PFAS concentration, especially for those that may come into use or be developed subsequent to promulgation of this regulation. Naming a short list of individual PFAS by CAS number creates an incentive for a market shift away from those specific compounds to whatever is not on the list, including other PFAS.

3. Confidential Business Information (CBI):

The use of PFAS in a product should not be considered confidential business information. Other laws in OR and WA have required manufacturers of children's products to report certain toxic chemicals, including PFOS and PFOA, in products for many years. This information is available in a publicly accessible database. There should be nothing secret about toxic chemicals used in products that are having serious adverse impacts on health and the environment.

We urge the Agency to adopt an approach to protect the public's right to know about which products PFAS are present in and prioritize public health and the ability of the agency staff to achieve the goals of this law in the consideration of any such claim.

4. Feasibility of Reporting:

It is the responsibility of the manufacturer to know whether PFAS is in their product and it is feasible to do so. As mentioned above, children's products manufacturers have reported the intentional use of certain toxic chemicals to the state of Washington for many years. Nearly 100 chemicals, including some PFAS, are required to be reported in product components. Manufacturers have been able to get this information from suppliers or obtain it through other means. There should be no exemptions for products given the magnitude of the PFAS problem and the need to understand where and how the chemicals are being used.

It will be argued by opponents of this law that compliance with this law, including the information disclosure portion, is too difficult to comply with. We encourage the MPCA to acknowledge that it is industry's responsibility to know that if intentionally added PFAS is in their product, it must be for a reason essential to the function of the product. And if PFAS is essential to the function of the product, it is industry's responsibility to understand the supply chain and where/how/when the PFAS was added to the product. If PFAS is not intentionally added, it is not required to be disclosed under Amara's Law.

In Maine, industry requested that they be allowed to disclose the EPA number applied to chemicals in order to keep them confidential, rather than disclosing the chemical itself. We expect the same request will be made in Minnesota. This request undermines the spirit

and intention of Amara's law. It's vital that consumers are properly and fully informed of intentionally added PFAS in a transparent, truthful way.

5. <u>Early Reporting</u>

Industry will ask to apply early to be exempted as an essential product in their comments. This removes industry's motivation to find safe alternatives to toxic PFAS. While industry can't avoid using PFAS for an essential use in 2024, holding them accountable in the future to identify safe alternatives is vital. Early exemptions are extremely detrimental to the goal of replacing dangerous PFAS with safer options.

Sincerely,

Avonna Starck
Clean Water Action
Minnesota State Director

Arnold & Porter

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November 28, 2023

ELECTRONICALLY FILED VIA MINNESOTA OAH PORTAL

ALJ Ann O'Reilly
Minnesota Office of Administrative Hearings
600 North Robert Street
PO Box 64620
St. Paul, MN 55164-0620

Re: **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**

Dear Judge O'Reilly:

The Chemical Users Coalition ("CUC") is providing the enclosed comments in response to the Minnesota Pollution Control Agency's Request for Comments on planned new rules for PFAS reporting.

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.[1] 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.

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

Sincerely,

Judah Prero

Enclosure

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

Before the
Minnesota Pollution Control Agency
Request for Comments
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

Comments of the Chemical Users Coalition

The Chemical Users Coalition ("CUC") appreciates the opportunity to provide our comments on the Planned New Rules Governing Reporting by Manufacturers Upon Submission of Required information about Products concerning PFAS (the "Planned Rule") that will be promulgated by the Minnesota Pollution Control Agency (the "MPCA" or the "Agency") pursuant to Minnesota Statutes 116.943, subdivision 2 ("Amara's Law"). 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.[1] 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.

The MPCA, in the Request for Comments, specifically requested comments on the following questions:

1) Are there definitions in subdivision 1 for which clarification would be useful to understanding reporting responsibilities?
2) Are there terms or processes in subdivision 2 for which clarifications will help reporting entities determine reporting status or data-gathering process?
3) How should the MPCA balance public availability of data and trade secrecy as part of the reporting requirements?
4) Are there any terms used in subdivision 3 that should be further defined or where examples would be helpful?
5) Are there specific portions of the reporting process that should not be defined through guidance or the development of an application form?
6) Other questions or comments relating to reporting or the process of reporting.

CUC appreciates the MPCA's efforts to gather information and identify issues on reporting prior to issuing a draft rule implementing the reporting requirements. We are providing comments on a question-by-question basis in the more detailed comments below. We also have these general comments as well.

CUC recommends that the MPCA consider a "phased in" approach whereby different product categories are considered for initial reporting on the basis of the category's likelihood to cause contamination of the environment in Minnesota. This "staggered reporting" approach will allow for both MPCA and the regulated

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

community to adjust to the new requirements and learn from any implementation issues that arise. It will reduce reporting and administrative burdens on both the entities subject to the final regulations and MPCA personnel. It will also allow for more orderly and complete reporting.

CUC recommends that the MPCA consider collaborating with agencies in other states where similar PFAS reporting requirements are being implemented. Subdivision 3 of Amara's Law clearly grants MPCA that ability, and to consider information and technology sharing efforts to do so. When states have laws and regulations which are harmonized, it ensures a level playing field and consistency across different regions. If each state has drastically different laws, it can create barriers to trade and increase costs for businesses operating across state lines. By regulating in a similar fashion, states can facilitate the smooth flow of data and regulated goods, services, and investments between different regions. Furthermore, when regulations are consistent, it becomes easier for businesses to comply with them, as they do not have to navigate a complex web of varying rules and requirements in different states. It also simplifies enforcement efforts for regulatory agencies, allowing them to allocate resources more effectively. Lastly, when states regulate in a similar fashion, it promotes collaboration and learning among policymakers. States can share best practices, lessons learned, and successful regulatory approaches, leading to better-informed decision-making. This collaboration can enhance regulatory effectiveness, foster innovation, and create a collective knowledge base that benefits all states.

CUC therefore requests that the MPCA carefully consider the importance of maintaining uniformity of regulation from state to state. Specifically, the MPCA should carefully learn from the experience with Maine's Act To Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution. Collaboration with Maine is encouraged, so that Maine's experience can aid the MPCA in crafting a rule that is workable and achieves stated policy objectives.

In addition, although the MPCA current solicitation of comments relates solely to Amara's Law reporting requirements, CUC urges the MPCA to initiate as soon as possible its planning for how it will determine whether the use of PFAS in a product is a "currently unavoidable use" that will be exempt from the 2032 prohibition on any product containing intentionally added PFAS. It is important that stakeholders have an opportunity to provide input on this aspect of Amara's Law and for the MPCA to provide clear guidance on the procedures that will be followed and the substantive criteria that will be applied.

The following are CUC's responses to the specific topics on which the MPCA requested input.

1) **Are there definitions in subdivision 1 for which clarification would be useful to understanding reporting responsibilities?**

- Amara's Law currently 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." CUC recommends that the MPCA clarify that the definition does not include manufacturing byproducts and impurities that might be unintentionally present in a product in commerce, PFAS degradants that might be formed during product manufacturing but also be considered unintended components, and PFAS that is reasonably believed to be present in the final product as a contaminant.

- Amara's Law defines "Manufacturer" as "the person that creates or produces a product or whose brand name is affixed to the product." 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 notification requirement. The Agency should clarify which entity has the primary obligation to report.

- Amara's Law defines "product component" as "an identifiable component of a product, regardless of whether the manufacturer of the product is the manufacturer of the component." The MPCA needs to clarify the intent behind the "identifiable components." In a complex manufactured item, such as a fabricated product known as an 'article', many components are not visible due the manner in which the product is assembled. Additionally, often individual components are assembled from other distinct components. It is not clear as to what "identifiable" means in this context. Articles are particularly challenging as downstream users are often removed by multiple layers in the supply chain, thus may not be aware of the presence of PFAS-containing parts or components. Given the broad definition of PFAS in the law, [predicated on a structural definition,] it will be imperative that downstream users of articles are protected against the undisclosed presence of PFAS by an upstream supplier. CUC strongly recommends that *safe harbor* provisions be granted to downstream users of articles and sufficient time be granted in the event of subsequent discovery of PFAS.

2) Are there terms or processes in subdivision 2 for which clarifications will help reporting entities determine reporting status or data-gathering process?

- Many companies provide products to downstream distributors/resellers, in which case the companies have ultimately no control as to when and where the products ultimately are distributed/sold. Consequently, CUC requests the effective date for reporting be based on the manufacture date so that previously manufactured products are exempt from the reporting (and prohibition) requirements.

- CUC recommends that the MPCA clarify how the notification requirements apply to multiple businesses in the supply chain for finished products that will be distributed with multiple PFAS-containing components. The MPCA must make it sufficiently clear whether the responsibility falls upon the maker of the PFAS-containing components, the brand owner, a brand licensee, an importer, or the company that is distributing the finished product when multiple parties fit into the definition of manufacturer.

- Amara's Law provides that the notification must include a description of the product. CUC requests greater clarity as to what is meant by "a description." Does it refer to common distinctions such as consumer use vs. commercial use; or for retail distribution vs. for wholesale distribution; or into product categories such as toy/consumer electronic/furniture etc.? Would it also include (as a requirement) the principal intended uses of the product? CUC recommends some level of standardization for the elements of the "description."

- Amara's Law provides that a description of the product, including a UPC, should be reported. The MPCA should take into consideration the amount of time/resources required to report based on UPC. A more generic classifier (such as those based on product category) is preferable. The MPCA should consider use of alternative code systems, including the Harmonized Tariff Schedule ("HTS"), which is widely used around the world. HTS will not, however, be an adequate replacement for all products since it is not required for products shipped domestically within the US and manufacturers therefore may not have this data readily available. An HTS determination is a complex process that requires detailed knowledge of both product and tariff schedule.

- The MPCA must recognize that manufacturers may not know if PFAS is contained in the products they sell. Testing all products to determine if PFAS is in the product is not viable or even possible. Consequently, many manufacturers will be turning to component suppliers (who will in turn also ask their upstream suppliers) for information concerning PFAS content. First, CUC asks that the MPCA adopt a reasonability standard for determining if any obligation to report exists. If a manufacturer can

reasonably ascertain, via documentation or supplier communications, that PFAS is present in the product, they have an obligation to report. If a manufacturer cannot reasonably ascertain whether or not a product contains PFAS, the rule should state that a manufacturer has no obligation to report. Furthermore, even with due diligence, manufacturers may only be notified concerning the presence of PFAS in their products after the notification deadline has passed. CUC recommends that the MPCA adopt a safe harbor provision (or equivalent) to protect downstream users against post-deadline discovery of PFAS. CUC asks that manufacturers not be penalized in such cases as long as the manufacturers have made a good faith effort to reasonably ascertain the use of PFAS prior to selling the product into Minnesota after the effective date. Further, CUC members seek protection for the sell-through of OEM parts for use as replacement and spare parts, of original design and origin. Article manufacturers work within complex supply chains composed of potentially thousands of suppliers, and it is anticipated that some time and resources will be needed for upstream suppliers to become aware of the use of PFAS. Additionally, certain upstream suppliers may claim that information related to the specific type and amount of PFAS substance(s) used are trade secrets and cannot be disclosed.

- Similar to the above, manufacturers may not know the purpose for which PFAS is added, and therefore would not be able to report on such information. CUC recommends that the "reasonability" standard discussed above apply as well to this reporting element.

- Amara's Law provides that notifications are required for products sold, offered for sale, or distributed in the state. CUC recommends that the MPCA exempt previously manufactured products (existing stocks produced before the final rule's effective date), and spare/replacement parts for 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 in Minnesota to ascertain PFAS content due to the lapse of time since manufacture. The availability of spare/replacement parts would also allow for the continued use and maintenance of existing products, thereby preventing the accumulation of unnecessary waste including e-waste.

- Amara's Law requires that the notification contain the amount of each PFAS by name and CAS number. CUC has significant concern with this requirement. Amara's Law presumes that it is possible to identify all PFAS in a product. At this time, testing is not available to specifically identify all PFAS. Consequently, the only other way to ascertain PFAS content is from suppliers. However, if PFAS content information – such as the CAS number of the specific PFAS in the product and the amount contained – cannot be obtained from others, due to trade secret concerns or simply refusal to cooperate, a manufacturer will not be able to provide the required notification. CUC recommends that the MPCA address this extremely likely scenario. Utilizing a "reasonability" standard, as discussed earlier, is an option the MPCA should seriously consider, and it should be within the MPCA's discretion to provide such clarification and guidance. Additionally, CUC suggests that the rule allow for reporting the amount of PFAS either by concentration or by weight. The same components which contain PFAS can be used in multiple products, and that would result in different PFAS concentrations in the overall product. To simplify reporting, we believe that both options be made available.

- Should the MPCA allow reporting by concentration, CUC suggests that the MPCA establish a concentration range for PFAS reporting, similar to that used by the IC2 High Priority Chemicals Data System (HPCDS) for Oregon Toxic-Free Kids Act (TFKA) and the Washington Children's Safe Products Act (CSPA). Using such a construct, all products that are the same type / model (under the

same Harmonized Tariff Schedule Code) containing the same PFAS within the same concentration range established by the MPCA could be grouped together for reporting instead of individual product reporting.

- CUC also recommends that manufacturers be allowed to report on PFAS content on the basis of information obtained from suppliers, as opposed to relying exclusively on analytical methods. CUC recommends that the MPCA make clear that manufacturers may reasonably rely on information provided by their suppliers, provided they can document that inquiries have been made to suppliers and reasonable efforts have been made to obtain information regarding the use of PFAS.

- Amara's Law sates that the quantity of PFAS be reported using "commercially available analytical methods." That term is not defined. CUC recommends that the term be clarified to only include methods that have been "validated" by at least one federal and state regulatory authority (e.g., US EPA) in addition to being commercially available.

- CUC recommends that the MPCA clarify how it will expect the reporting entities to calculate ranges for the amount of PFAS that will be reported for products.

- CUC recommends that PFAS content in packaging should not be subject to the reporting requirement. This adds another layer of complexity, as packaging may also be manufactured through multiple value chain layers and obtaining PFAS content information may prove to be challenging.

- Amara's Law provides that information submission is required whenever there is a "significant change in the information." CUC recommends that the MPCA define this term. Right now, the requirement could be read such that changes in company personnel or their contact information at a particular reporting entity could trigger a notification of a "significant change." The identity of corporate officers and directors, as well as their contact information, can change frequently, and requiring notification for each such occurrence is burdensome and should not be considered a "significant" change.

  In addition, the removal of a PFAS could also be a trigger for a "significant change" notification. These types of changes are not pertinent to what CUC understands to be the underlying policy objectives of the reporting requirements (i.e., to identify products that contain PFAS and to identify which PFAS are contained in products). CUC suggests that the MPCA should minimize unnecessary reporting such as these changes. Thus, CUC recommends that the definition of "significant change" should not include the removal of a specific PFAS or a change in responsible official or contact information. CUC recommends that there be an option to provide notification of the removal of PFAS, but that such notification should be voluntary. CUC recommends that a "significant change" should be defined as the addition of one or more PFAS not previously reported or the material increase (i.e., one which reflects an increase of at least 10% by weight or greater) in the concentration of a previously reported PFAS that is present in a product. Notification of the removal of PFAS content or an immaterial increase or decrease should not be required.

3) How should the MPCA balance public availability of data and trade secrecy as part of the reporting requirements?

- It is anticipated that the state of Maine will start receiving notifications on PFAS content in products in January 2025. CUC recommends that such information submitted in Maine should be considered publicly available information for purposes of waiving the information submission requirements.

- CUC asks that the MPCA recognize that PFAS content could be classified as "Confidential Business Information" ("CBI"). To address the situation where PFAS content information cannot be obtained from a supplier due to CBI, trade secret, or non-responsiveness concerns, CUC suggests that the MPCA authorize and implement an optional 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 notification obligation by providing the supplier contact information. Further, CBI protection may be necessary for national security interests and Department of Defense concerns.

4) Are there any terms used in subdivision 3 that should be further defined or where examples would be helpful?

- CUC requests additional clarification on the waiver process. First, the MPCA should provide guidance on what constitutes "substantially equivalent information." The MPCA should set forth in detail the procedures for requesting and issuing waivers, including expected timelines for the waiver processing, and the expected timing required for the MPCA to answer waiver requests. The regulations also should provide that information submission is not required during the period when a waiver request is being processed. CUC also requests that waivers not be limited to instances where "substantially equivalent information is publicly available." CUC also recommends that the MPCA exercise its discretion to issue procedural regulations to allow manufacturers to request full or partial waivers (or extensions of time for notification submission) for other reasons, including because manufacturers may not receive specific information in regards to the PFAS used in their products for a variety of reasons (including proprietary reasons, etc.).

- The waiver provision provides that the MPCA may waive requirements for reporting multiple products or a product category. CUC recommends that a rule contain details concerning the process for proposing a category for reporting multiple products. Aside from the procedural elements of how a manufacturer formally proposes a category, the MPCA should elaborate on the criteria the Agency will use to determine whether the proposed category is reasonable.

- Products used for national security, space exploration, and defense purposes for which PFAS may be added should be categorically excluded or waived. CUC members that build and sell into this sector, often do not own or control the design criteria for new, replacement and spare parts.

5) Are there specific portions of the reporting process that should not be defined through guidance or the development of an application form?

- CUC believes that detailed guidance is needed for all aspects of reporting to ensure the process is predictable, open, and transparent and compliance is achieved with the least burden possible.

6) Other questions or comments relating to reporting or the process of reporting.

- The definition of PFAS used in Amara's Law is expansive and inclusive of a significant number of substances. Consequently, compliance with the requirements can be challenging, as many substances are implicated and for most there are no testing methodologies that can be used to identify them. Therefore, CUC recommends that the MPCA create a list of specific PFAS that are of concern for

health or environmental effects and require reporting only on products containing the listed PFAS.[2] Such a list should include the Chemical Abstract Services Registry Number and the specific chemical identity using CAS nomenclature for each substance for which reporting is required. The use of CAS numbers enables businesses throughout the value chain and across global marketplaces to understand which substances must be entities for reporting purposes.

- Furthermore, CUC requests that the MPCA establish a threshold (e.g., de minimis) level for PFAS content in manufactured articles, beneath which level no reporting would be required (such as PFAS present at 0.1% by product weight or greater). The de minimis level of 0.1% is practical and is generally understood by the manufacturers and distributors of manufactured articles that move among various international markets because the level aligns with the level imposed in European Union for substances of very high concern when present in articles.

- Under Subdivision 4, the MPCA has the authority to require testing. If the MPCA does require companies to provide test results, the MPCA should specify the test method to use. There are no internationally recognized test methods for "PFAS" in complex articles; therefore, CUC anticipates it will be very difficult to provide test results to the MPCA. Only a select number of PFAS substances are capable of being tested.

- Amara's Law states that if testing demonstrates that a product contains intentionally added PFAS, testing results and information must be provided. It is not clear how testing demonstrates that the PFAS was indeed intentionally added. The MPCA must provide guidance on how MPCA will make a determination based on testing that a PFAS is intentionally added and how such determination can be challenged.

- Duplicative reporting (submitting the same report to multiple jurisdictions) should be avoided. CUC encourages the use of a single system (such as IC2) that can be used by multiple states for reporting purposes and to increase transparency among the states that have reporting requirements.

Fees

- CUC acknowledges that the MPCA has requested comments on proposed fees as well. CUC recommends that fees, if they must be imposed, should be assessed by each report or product group instead of by individual product.

Conclusion

CUC appreciates the opportunity to submit the foregoing comments and reserves its right to submit additional or modified comments at a later date. We would welcome the opportunity to meet with the MPCA staff to address our comments and to assist in crafting implementing rules.

[2] See, for example, The European Chemicals Agency Forum for Exchange of Information on Enforcement *"Advice on PFAS restriction proposal,"* "To help enforcement authorities, the Forum suggests the developing of an indicative list of PFAS in a future guidance (with the chemical structure) covered by the restriction."

RECEIVED
By: OAH on 11/28/2023
Riaz Zaman Attachment 1

AmericanCoatings ASSOCIATION℠

November 28, 2023

Katrina Kessler
Commissioner
Minnesota Pollution Control Agency
Office of Administrative Hearings
600 North Robert Street
St. Paul, MN 55164-0620

Re: Possible 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
(fee obligation)
OAH Docket No. 65-9003-39507
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 fees under 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 is commenting in response to MPCA's (Minnesota Pollution Control Agency's) request for information towards establishing fees for the PFAS reporting law. ACA is submitting separate comment regarding reporting requirements in the law.

MPCA must balance several considerations when developing fees to prevent inequity in fee payments. MPCA identifies considerations for small businesses, tiered fees by company size, per-product or per-company fees, etc. Any of the options MPCA identifies has the potential for inequitable fee payment and

[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.

disproportionate fee payments by company size. Rather, whichever option MPCA chooses, it must consider limiting fee amounts to encourage equity and proportionality between paying entities, while recovering a fair, but not excessive amount, of administrative costs.

I. Methods of fee payment.

MPCA may address these concerns with a fee levied per product grouping or product type, with a fee cap on the number of payments, with a separate fee reduction for small businesses. A fee cap is important to prevent inequity. Considering that even a small or medium sized company can manufacture over hundreds or thousands of formulated product types, costs can easily become excessive without a fee cap. A per company fee may also address concerns about equity, provided the fee is not excessive. ACA further recommends that MPCA not require a fee for updating information after the initial reporting period, since the online database and initial data input will be complete, minimizing administrative costs.

II. Considerations related to product grouping for registration and fee payment.

MPCA should further consider developing product categories or groupings for registration considering their effect on fees. Maine has suggested developing product categories for products with similar function using the same type of PFAS, although it has not finalized a viable reporting method. Maine further suggests that the quantity of PFAS used in products of a similar grouping must be proximate and within a certain range, although it has not clearly identified a range. The PFAS quantity requirement is unnecessary within a product category. A product category alone is sufficient, stipulating that companies are using a similar PFAS type within the category. With these specifications, manufacturers are likely to use proximate PFAS quantities. Specifying quantity amounts or a range can lead to inequitable fee payments for similar products that are near the cut-off thresholds for classification within a category.

MPCA must limit fee payment amounts to assure fees are proportionate to the cost of administering the program. MPCA has not provided any information related to program administrative costs that would justify uncapped fees. ACA suggests capping the fee amount after the first three notifications. MPCA's administrative costs will be mitigated by Maine's program, establishing the online database for use by Minnesota and other states. As such, these savings in costs should be passed down to reporting entities with lower fee amounts. A fee cap is necessary to prevent inequitable, excessive fees.

III. MPCA should provide lower fees for small businesses.

ACA further suggests providing an exemption or lower fees for small businesses. Such an exemption or at least lower fees are necessary to assure that small businesses, that cannot easily absorb costs, remain competitive. The U.S. Environmental Protection Agency (EPA) commonly allows lower fee amounts for small businesses, with a discount of about 80% for fees under the *Toxic Substances Control Act* (TSCA). EPA's TSCA definition of "small business concern" is based on employee size thresholds, modified from thresholds set by the Small Business Administration.

IV. Conclusion

ACA appreciates the opportunity to comment about MPCA's fees for PFAS reporting. ACA recommends that MPCA carefully consider equity and proportionality between payments from reporting entities

when considering a fee rule. These goals can be met through varying fee payment methods. Regardless of the fee payment system, ACA recommends implementing a fee cap to prevent excessive payments and lower fees or an exemption for small businesses. ACA also recommends a per product category fee, allowing one fee per product grouping.

Sincerely,

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RECEIVED
By: OAH on 11/28/2023
Riaz Zaman Attachment 2

AmericanCoatings ASSOCIATION℠

November 28, 2023

Katrina Kessler
Commissioner
Minnesota Pollution Control Agency
Office of Administrative Hearings
600 North Robert Street
St. Paul, MN 55164-0620

Re: Possible 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
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Dear Commissioner Kessler:

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I. DEP should allow use of alternative chemical identifiers to CAS numbers.

[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.

Minnesota's PFAS reporting law requires reporting of,

> "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."
>
> (Subdivision 2, paragraph 3)

The use of CAS numbers (chemical abstracts service registry numbers) for chemical tracking is problematic and will require additional explanations and exemptions in implementing rules. CAS numbers were never intended for regulatory use, and many PFAS do not have CAS numbers. CAS numbers are developed by the American Chemical Society's Chemical Abstracts Service to aid with identifying chemicals in literature. As such, they are not exhaustive, may represent broad categories of chemicals, or at the other extreme may be hyper-specific to a specific ion or even to a specific stereoisomer. Unfortunately, they also can overlap with one another (e.g., there can be a CAS number for a mixture of isomers as well as one for each individual isomer.)

U.S. EPA has had the same challenge of missing and overlapping CAS numbers in their efforts to track and regulate PFAS. To avoid these problems, U.S. EPA created its own system of unambiguous identifiers within the CompTox Chemicals Dashboard (https://www.epa.gov/chemical-research/comptox-chemicals-dashboard) called "DSSTox substance identifier (DTXSID)."

ACA suggests that MPCA:

1. Exclude any chemical not identified by CAS number on a Safety Data Sheet from reporting; or

2. Expand acceptable chemical identification to include alternative identification used by U.S. EPA, including: DSSTox substance identifier (DTXSID), TSCA accession number and generic name.

The second option is not as desirable as it may compromise confidentiality of chemical identity. Manufacturers of formulated products such as paints, adhesives, sealants, etc., rely on information provided by upstream chemical manufacturers. Often, chemicals in raw materials are not identified by CAS number to protect confidentiality of a formulation. Instead, chemicals may be identified by the TSCA accession number and/or generic name used for registration on the confidential portion of the TSCA Inventory. Typically, when a company proceeds with commercialization of a new chemical with a confidential identity, U.S. EPA assigns it a TSCA Accession Number for listing on the confidential inventory, with a generic name conforming to EPA requirements, such that the name conceals at least one structural element of the chemical.

To protect confidentiality, chemical manufacturers sometimes will not provide CAS numbers to downstream formulators, relying on alternative identifiers. Even the act of disclosing those CAS numbers can break confidentiality of a chemical, requiring disclosure of the complete chemical identity on the TSCA Inventory and in the market generally. Chemical manufactures spend millions of dollars to bring new chemicals to market. Maintaining confidentiality of specific chemical identity, by withholding a CAS number or several CAS numbers in a mixture, provides an important incentive supporting innovation of new products, including safer, "green" chemistries.

II. MPCA should establish a *de minimis* level for chemical identification and reporting of amounts.

Considering confidentiality of specific identities and inconsistency in CAS identification, manufacturers of formulated products cannot consistently identify fluorinated chemicals by CAS number but may be able to provide TSCA accession numbers or generic names for any chemicals in mixtures *in amounts above OSHA disclosure thresholds*. These thresholds, set at 0.1% and 1%, depending on hazard classification, compel an upstream manufacturer to list the chemical on a Safety Data Sheet, provided to a downstream formulator.

Manufacturers of formulated products rely on disclosures from upstream actors to identify fluorinated chemicals and their amounts in raw materials. Amounts below disclosure thresholds typically are not disclosed on Safety Data Sheets. ACA suggests that MPCA adopt a *de minimis* threshold for reporting of 1% in mixture, harmonizing with federal OSHA Safety Data Sheet disclosure requirements. ACA further suggests that MPCA clarify that downstream manufacturers can rely on disclosures made on an OSHA mandated Safety Data Sheet. Alternatively, MPCA could mandate that companies only need to report those PFAS chemicals identified on an OSHA mandated Safety Data Sheet. In effect, companies would not have to report chemicals in trace amounts below SDS disclosure thresholds.

Maine faced the same problem when implementing its PFAS reporting requirement. To address this issue, the legislature passed an amendment clarifying that product manufacturers can rely on information provided by suppliers. MPCA can issue a similar clarification in implementing rules. Minnesota's reporting law does not require reporting of *de minimis* levels, and as such, reliance on information provided by upstream actors is warranted.

Downstream formulators face significant barriers to identifying amounts in mixtures when not disclosed. Such information is not readily supplied to downstream users upon request. Because of complexities in the supply chain, suppliers often do not know this information or simply do not want to disclose information about small amounts, even when known. Downstream users often struggle to identify a point of inquiry from a supplier for reportable information. Even if inquiries are submitted, obtaining a response, where information is not compelled or required, is rare.

De minimis thresholds are common for federal chemical reporting rules. U.S. EPA's Chemical Data Reporting Rule (CDR), for example includes a *de minimis* threshold of 25,000 pounds per year or 2,500 pounds per year for certain regulated chemicals.

Exemptions based on concentration thresholds are common under international systems also. For example, under EU REACH,[2] the European chemicals management law, companies manufacturing or importing an amount below 0.1% are exempt from reporting requirements. The International Material Data System[3] used by the automotive industry also has a minimum 0.1% concentration tracking requirement.

[2] European Commission regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), EC 1907/2006.

[3] The International Material Data System (IMDS) has been adopted as the global standard for reporting material content throughout the automotive supply chain and for identifying which chemicals of concern are present in

III. Test methods for products are not reliable.

Absent further clarification about reliance on information from a supplier, a downstream product manufacturer would need to test its product to determine PFAS amounts, if possible. ACA is concerned that MPCA will not be able to identify viable test methods for detection and reporting of fluorinated chemicals in products, leading to disparity in reporting methods and inaccurate reports. Prior to legislative amendments, Maine suggested using a commercially available analytical method, including methods identified by U.S. EPA for PFAS identification.[4] 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, and it has not identified existing analytical methods for 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."[5]

If testing is required, MPCA's reporting requirement would inevitably require third-party testing with development of new analytical techniques. This can be prohibitively expensive, especially for small manufacturers.

Some states have suggested tests for 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."[6]

ACA requests MPCA to clearly identify analytical methods for reporting of PFAS in chemicals, formulated products, articles and other types of products.

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finished materials and components. Additional information is available online at: https://public.mdsystem.com/web/imds-public-pages.

[4] Maine DEP provides an explanation of acceptable "commercially available analytical method" in Section 2(D) of its Concept Draft towards developing implementing rules:

> "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 PFAS in a product. Commercially available analytical methods do not need to be performed at a third-party laboratory; however, they must remain unmodified. Commercially available analytical methods include methods approved by the U.S. Environmental Protection Agency (EPA) when used in accordance with that approval.

[5] See additional information here: PFAS Analytical Methods Development and Sampling Research | US EPA

[6] 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#

IV. MPCA should consider specifying the scope of due diligence.

Another approach to addressing problems with chemical identification and measurement of amounts is to specify the scope of due diligence for reporting entities. A due diligence standard provides a company with a pathway for identifying reportable information. It also provides an indicator of when failure to report is not a violation of the law, when a company has performed its due diligence and did not identify reportable information.

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. The standard does not require general surveys or external inquiries, unless internal review identifies an external source that may have reportable information. In certain cases, targeted external inquiries may be justified.

Adopting this standard of due diligence would assure that companies conduct a thorough search for reportable PFAS and amounts, while providing companies assurance against inconsistent enforcement or inadvertent violation after a good faith effort to comply.

V. A due diligence standard may also address challenges related to tracing product placement across complex distribution chains.

Downstream formulators cannot readily trace products being placed on the market in Minnesota, resulting in a tendency to over-report. This unnecessarily increases the administrative burden on MPCA. A clear due diligence standard would provide downstream formulators with steps to review and identify potential distribution in Minnesota. Under the "known to or reasonably ascertainable by" standard, a company would review its internal documentation for any indication of product distribution in Minnesota, while making targeted inquiries to distributors as necessary.

The difficulty in tracing products placed on the market in Minnesota is due to complex distribution chains. Product manufacturers often ship to a supplier, who may then ship to a regional warehouse, distributing across several states. Distribution chains are not state-specific. Some products may not be distributed into the state, due to market differences across states, but companies and suppliers do not track product distribution by state.

VI. MPCA should address product traceability in regulations.

Manufacturers in a variety of industries, including the paint and coatings industry, will likely fall subject to MPCA's reporting regulations, and it is important to be aware that distribution and sales of PFAS-containing products often occur through a distributor or in bulk to a retailer or warehouse located outside of the state where the products may ultimately be sold. In these instances, the manufacturers typically do not have visibility into which states their products may be offered to a final consumer.

ACA recommends that the agency consider one of several alternatives for how this information gap of sales data into Minnesota could be addressed. ACA notes the following regulatory options:

1) One option could be to allow reporting by a "responsible party," instead of the product manufacturer, to allow flexibility in who takes responsibility for reporting. Manufacturers could then work with their retailers/distributors to decide who should be reporting and remitting information to Minnesota.

2) Another option could be to provide a standard formula that manufacturers can use to calculate an estimated amount of products sold into Minnesota based on national sales if they cannot obtain specific data for sales into Minnesota by product.

3) Another option could be for very large retailers (colloquially referred to as "big box retailers") and distributors to share point-of-sale data with manufacturers so the responsibility of reporting remains with the manufacturer to report data, provided the most accurate data was supplied by the retailer.

ACA recommends that MPCA recognize the complexity of tracing product sales into Minnesota by addressing this issue in its proposed reporting requirements with one or more of the suggested regulatory options above.

VII. Reporting should be required on an annual basis or upon request.

ACA urges MPCA to consider requiring updates after initial reporting on a schedule that could be easily incorporated into a company's regulatory calendar. The Minnesota reporting law requires:

> "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."

The law provides flexibility in the timing of reporting upon a change in a product. Requiring updated reports or revised reports immediately upon changes in the formula is extremely difficult to track. Changes in a formula could occur every time a new shipment of raw materials is delivered to a manufacturing facility and could result in numerous reports required over the course of a year. Tracking and monitoring these changes as well as the required reporting data points will be very complex for the manufacturer and confusing for the MPCA. A reporting schedule is more likely to serve the Department's need as well as provide some efficiency for manufacturers.

VIII. Conclusion

ACA appreciates MPCA's willingness to interact with stakeholders in this preliminary stage of developing implementing rules for reporting. ACA hopes that MPCA will carefully consider the significant challenges to complying presented by barriers to identifying PFAS by CAS number, identifying PFAS amounts and tracing product distribution. ACA has suggested several methods of addressing these concerns, such as adopting EPA's standard of due diligence, allowing reliance on information provided by suppliers, clarifying that PFAS without CAS number are not subject to reporting, establishing *de minimis* levels for reporting and allowing flexibility in reporting to accommodate for estimation and/or identification of product sales into Minnesota.

These regulatory options can be used individually or together in some combination. ACA suggests that MPCA, at a minimum, adopt EPA's standard of due diligence. This would promote some consistency in how reporting entities identify PFAS chemicals, quantifiable amounts and trace distribution chains to

Minnesota. Further, a regular reporting schedule for changes to products would also encourage accuracy and consistency in reports.

Please feel free to contact me if I can provide any additional information.

Sincerely,

Riaz Zaman
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Personal Care Products Council
Committed to Safety, Quality & Innovation

November 28, 2023

Mary H. Lynn
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Submitted electronically via Minnesota OAH Portal

Re: Comments regarding 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

The Personal Care Products Council (PCPC)[1] respectfully submits the following comment to the Minnesota Pollution Control Agency (MPCA) in response to the Request for Comments regarding the PFAS in Products Reporting Rule.

PCPC and its member companies have long been supportive of commonsense laws and policies that protect both the consumer and the environment. For this reason, we have supported laws in other states that prohibit certain intentionally added PFAS from use in cosmetics. To that end, and in an effort to promote development of the most efficient and practical rule, we offer the following feedback.

RESPONSES TO MPCA QUESTIONS

1. **Are there definitions in subdivision 1 for which clarification would be useful to understanding reporting responsibilities?**

   Product and Product Component - We request that the definition(s) of "product" and/or "product component" be clarified to explicitly exempt packaging. We understand that the definition of "product" as written does establish an implied distinction between

[1] Based in Washington, D.C., the Personal Care Products Council (PCPC) is the leading national trade association representing global cosmetics and personal care products companies. Founded in 1894, PCPC's approximately 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the U.S. As the makers of a diverse range of products millions of consumers rely on and trust every day – from sunscreens, toothpaste, and shampoo to moisturizer, lipstick, and fragrance – personal care products companies are global leaders committed to product safety, quality, and innovation.

the item itself and the packaging, through the inclusion of the word "packaged" as a potential descriptor of the product, but we believe more explicit language to clarify this distinction would be useful.

2. **Are there terms or processes in subdivision 2 for which clarifications will help reporting entities determine reporting status or data-gathering process?**

   - **Commercially available analytical method** - This term is challenging for industry because today's commercially available methods are inadequate to detect specific PFAS in the complex matrices that exist for the wide range of products in the market today. Further, given the extremely low weight of PFAS, it is difficult to produce an exact measurement. As such, PCPC strongly urges MPCA to establish flexibility on the test methodology/ies used to measure PFAS in finished products and to allow for the reporting of an average or an established MPCA-approved range. There are several reasons for this:

     - PFAS are a highly complex chemical class of compounds with diverse functional groups attached to the fluoroalkyl moiety (e.g., Perfluoroalkyl acids, Polyfluoroalkyl acids, PFAA precursors, etc.). This could represent hundreds of targets that "commercial methods" will need to be able to target. Current Environmental Protection Agency (EPA) methods[2] generally test for PFAS *in soil and water* and are not specific to finished products. While there are available test methods that measure PFAS in consumer products/cosmetics, they are not necessarily considered "commercial methods" as defined.

     - Even established testing methods used for cosmetics products will need to be validated/verified for the corresponding product matrixes, meaning they will require modifications.

   - **Significant Changes** - We request clarification around the term "significant changes" in Subd.2(c), and the actions that would follow, including how a significant change would be determined.

[2] EPA PFAS Methods: (1) ASTM D7968: Standard Test Method for Determination of Perfluorinated Compounds in Soil by Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS) (PDF)(17 pp, 175 K) [ASTM may charge a fee for this document.] (2) ASTM D7979: Standard Test Method for Determination of Perfluorinated Compounds in Water, Sludge, Influent, Effluent and Wastewater by Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS) (PDF)(18 pp, 181 K) [ASTM may charge a fee for this document.]

- Further, we request clarification that products will be removed from the database if PFAS are no longer intentionally added.

- In addition to the included terms, PCPC requests the possibility for reporting a group of products under the same Global Product Brick category with the same PFAS under a single entry, for instance as established by Department of Environmental Protection in the state of Maine. This would apply to cosmetics that are essentially identical and differ only by shade, tint, or fragrance (e.g., lipsticks, nail polish, etc.).

3. **How should the MPCA balance public availability of data and trade secrecy as part of the reporting requirements?**

   PCPC supports the ability to claim certain information as Confidential Business Information (CBI) to be managed under the Uniform Trade Secrets Act. There must be clear and simple procedures for protecting CBI, and the final rule should ensure that CBI can be asserted for PFAS on the TSCA Confidential Inventory or protected under the Uniform Trade Secrets Act.

4. **Are there any terms used in subdivision 3 that should be further defined or where examples would be helpful?**

   PCPC appreciates that Subd.3(c) states that the state may utilize a shared system with other states. We encourage Minnesota to allow shared reporting services with other states and with the EPA.

5. **Are there specific portions of the reporting process that should not be defined through guidance or the development of an application form?**

   PCPC does not have guidance to offer on this topic at this time.

6. **Other questions or comments relating to reporting or the process of reporting.**

   - In the interest of efficiency and achieving maximum possible compliance across the cosmetics industry, PCPC supports alignment with existing state PFAS laws and requirements wherever possible.

   - PCPC is seeking express clarification that over-the-counter (OTC) drug products are exempt from the law.

     - OTC drugs are subject to a federal monograph, or "rule book", which sets forth precise conditions for each therapeutic category – active ingredients, uses, doses,

route of administration, labeling, and testing requirements – in order for an OTC drug to be considered generally recognized as safe and effective.

- PCPC believes that OTC drugs should be exempt under the provisions[3] of MPCA's final rule because such products must, by law, follow the federal monograph, which preempts state authority.

Thank you for the opportunity to provide these comments. Should you have any questions or wish to discuss any of the above points with us, please do not hesitate to contact me.

Sincerely,

Thomas F. Myers
EVP-Legal & General Counsel

[3] "*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."* Minnesota Session Law – 2023, Chapter 60, Article 3, Section 21, Subd.8(a).

RECEIVED
By: OAH on 11/28/2023

ASSOCIATION OF HOME APPLIANCE MANUFACTURERS

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t 202.872.5955 f 202.872.9354 www.aham.org

November 28, 2023

Katrina Kessler
Commissioner
Minnesota Pollution Control Agency
520 Lafeyette Road North
St. Paul, Minnesota 55155-4194

Re: 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

Dear Ms. Kessler,

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 with some discussion on the PFS in Products Fee 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 also are 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 firmly supports the appropriate use of PFAS chemicals in appliances. Together with industry design practices, test requirements, and redundant safety mechanisms, PFAS chemicals play an important role in the safety of household appliances.

AHAM conducted a member survey in a good faith effort to determine the extent to which PFAS is used in home appliances and the estimated time needed to phase out of PFAS in those use cases. To the best of AHAM members' knowledge, appliances contain PFAS chemicals but in low

amounts. PFAS are used for their self-lubricating properties and great resistance to high temperature, chemical aggression and pressure. They are often confined to internal components and parts, such as bolts, washers and gaskets, plastic brackets, and wire terminals. This material is added during the manufacturing process, which reduces the potential for any consumer exposure during use or transmission to the environment.

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. There are international standards of communicating chemical compositions in the supply chain. Knowing what is sold in Minnesota would be extremely difficult for many manufacturers because many appliances are sold through national and even US-Canada retailers. This complexity is likely to result in over or under-reporting or simply incorrect information with this requirement. 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:

1. Under Subd. 2 notification requirements, it is unclear if manufacturers need to report the concentration of PFAS, total amount, or range of PFAS chemicals. There are over 10,000 PFAS chemical compounds and the draft proposal continues to lack de minimis concentration level on what concentrations are reportable. Even for manufacturers who distribute products in Europe and are subject to E.U. REACH & POPs regulations are having trouble identifying all the PFAS chemicals required to be disclosed in this law and whether trace amounts of PFAS are "intentionally added" or not. Thus, we ask for a clear de minimis concentration level and further clarity on "intentionally added" to determine the trace amounts, which are required to be disclosed. Secondly, without a clear definition of "reason to believe" in Subd. 4, it opens the possibility that the authority could take the freedom to consider virtually any product as being in violation.

2. Under the notifications section, it requires the disclosure "of the purpose" for which PFAS are used in the product, including PFAS in any product component. For appliance manufacturers, most parts are purchased from a supplier with the purpose of a specific substance or material often not revealed and may fall under proprietary business/confidential information. As a result, this information may not be available to disclose.

3. We request to allow other internationally used product classification codes such as TARIC code (as used by EU SCIP database), as alternative to GPC brick code. Many companies use these other reporting codes and not GPC brick code. To ease reporting burden, companies should use an international product classification code but not be required to use one verses another. Without allowing currently used reporting systems, the reporting burden becomes even more immense on companies.

4. In regard to potential exemptions deemed "currently unavoidable use", what are manufacturers required to report if they receive an exemption? As mentioned in these comments, appliance manufacturers have a complex and global supply chain, and many may

seek exemption from these requirements. We request the MPCA delay compliance timeline until the exemption process is further established and adopted.

5. Finally, in regard to new rules governing fees payable by manufacturers, we seek clarity on Section 6 for Fees, would every SKU registered in Minnesota count as one notification? Will manufacturers be required to pay a baseline company fee, or a weighted fee based on the amount of PFAS or products containing PFAS the company reports? We request clear definitions of the fee structure for product changes that add, decrease, and or eliminate PFAS. For every manufacturer with thousands of SKU's that could amount to an enormous financial burden for manufacturers with no benefit for the implementation of this law.

Given the complexity of modern supply chains, appliance manufacturers reported that 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. The inclusion of CAS numbers in the regulation will make reporting more efficient and reasonable. On top of that, testing each product and product component is extremely costly and time consuming, especially for manufacturers that have thousands of products. Ultimately, the scope of MPCA PFAS reporting requirements is overly broad, burdensome on manufacturers, and will likely result in a flood of unnecessary information to MPCA. The Environmental Protection Agency[1], the Consumer Product Safety Commission, and ECC are currently working on national responses to PFAS. Specifically, the EPA has finalized reporting and recordkeeping requirements for Per- and Polyfluoroalkyl Substances (PFAS) under the Toxic Substances Control Act (TSCA). As other states consider implementing reporting plans, we need to have a firm principal position that manufacturers should be allowed to submit one set of data—to the EPA—to cover all U.S. reporting requirements, and states should work with EPA to access the manufacturer data to satisfy their individual reporting requirements. This will be critical to ensure manufacturers do not end up with the burden of reporting the same/similar data to 50 states and EPA in the future. This would also have the benefit of creating a more manageable process for MPCA, who have requested a volume of data far in excess of their resources to process.

The law also establishes prohibition on cookware with intentionally added PFAS within Minnesota by 2025. Although this is not part of the rulemaking process, we do want to ensure compliance with the law is clear and feasible. Two states- California[2] and Colorado[3] have instituted cookware labeling requirements, but no state has enacted an outright prohibition. Under Minnesota law:

> "Cookware" means durable houseware items used to prepare, dispense, or store food, foodstuffs, or beverages. Cookware includes but is not limited to pots, pans, skillets, grills, baking sheets, baking molds, trays, bowls, and cooking utensils.

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[1] 2023-22094.pdf (govinfo.gov)

[2] https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202120220AB1200

[3] https://leg.colorado.gov/bills/hb22-1345

With the "includes but not limited to" language, it opens the door to unclear product scope. In the deliberation around the California law, an amendment was adopted that removed "but is not limited to" language so that cookware is only the items listed in the bill. Minnesota should work with other states to clarify and harmonize the cookware definition to include only products that meet all the following criteria: Contain intentionally added PFAS; Intended for cooking because the product is "cookware"; and only surfaces that are in contact with food during the cooking process. With a very tight timeline for this cookware prohibition, manufacturers are still working to understand the law to ensure full compliance because products are sold to a national marketplace providing economies of scale resulting in lower costs and more product availability to consumers. We would request a meeting with you to discuss further.

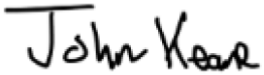
One category that falls under current definition of PFAS used in the home appliance industry is fluoropolymers. Fluoropolymers are used to make specific and critical components and parts of appliances, such as washers, plastic brackets, pipes, wire terminals, gaskets, and coatings; due to their unique combination of properties, e.g. non –stick, self-lubricating, resistance to high temperature, resistance to high pressure, durability, resistance to abrasion, and resistance to friction. There is no guarantee that alternatives can be found that will not compromise the high performance, durability and, functionality of household appliances and also the continuity of supply for spare parts. For this reason, we ask to remove polymers from the definition of PFAS.

Also under this law, effective 2032, products containing intentionally added PFAS may not be sold unless the use of PFAS in a product is specifically designated as a currently unavoidable use by the MPCA. Under this prohibition, hydrofluoroolefins (HFO's) would be included. These foam blowing agents are used in refrigeration and air conditioning. It is important for MPCA to work with stakeholders when the requirements could conflict with federal law (AIM Act[4]) which authorizes EPA to facilitate the next-generation of foam blowing agents, that are captured under the statutory definition, to combat climate change. HFOs are ultra-low Global warming, climate friendly alternatives for use as refrigerator insulation foam blowing agents. Other states have also acted to ban HFC use, and the U.S. Environmental Protection Agency (EPA) encouraged and effectively drove a transition to these and other low global warming potential (GWP) foam blowing agents through ozone depletion and climate focused phase-out's of CFC's, HCFC's, and HFC compounds. These HFO chemicals were approved under EPA's Significant New Alternatives Policy (SNAP) program, which included an environmental review. Prohibition or restriction of HFOs would require a total re-design of models and retooling of entire appliance manufacture facilities at significant cost. AHAM recommends that MPCA conduct stakeholder outreach to discuss these occurrences; otherwise, the regulated community will be unsure of how to proceed forward within Minnesota.

Thank you for considering our views and please contact me at jkeane@aham.org or 202-872-5955 if you would like to discuss in more detail.

[4] https://www.epa.gov/climate-hfcs-reduction/background-hfcs-and-aim-act

Respectfully submitted,



John Keane
Manager of Government Relations

SUBMITTED ELECTRONICALLY

November 28, 2023

Minnesota Pollution Control Agency
Resource Management and Assistance Division

RE: 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-482

To Whom It May Concern:
Contained within this submission are respectfully submitted responses by **DuPont de Nemours, Inc**, to address the request for comments by the Minnesota Pollution Control Agency on future PFAS rulemaking.

In contemplating the implementation of Minnesota Session Law – 2023, chapter 60, article 3, section 21, (Minnesota Statutes 116.943) subdivision 2, the MPCA has posed a number of questions to inform the rules for submission of required information about products containing PFAS. We respectfully submit the following comments for consideration.

1. Are there definitions in subdivision 1 for which clarification would be useful to understanding reporting responsibilities?

"Currently unavoidable use"
To ensure clarity and effective execution of "currently unavoidable use" designations, we suggest including guidance on required information such as: 1) segment of use, 2) societal benefit (how the PFAS specifically supports safety and critical functioning of society), 3) unintended consequences of a ban or restriction, 4) why alternatives do not exist including efforts to explore alternatives, 5) why the use of the PFAS does not impact human health and the environment and 6) information on disposal at end of life. This guidance should be provided in advance of the reporting deadline and would benefit from Agency-led public sessions for reporting entities, as has been done in other jurisdictions like the State of Maine. Additionally, the commission could provide high priority, currently unavoidable use exemptions in the implementation phase to reduce the scope and increase the focus on meeting the intent of the law which is to ban unavoidable uses that potentially pose the highest risk to human health and the environment. These unavoidable uses could include uses in military and defense, communications and navigation systems, energy recovery and distribution, energy efficiency systems supporting or protecting housing and construction, protection of human health, measurement and sensing systems, semiconductor manufacturing, electrification and safety of transport vehicles (including personal and public transport as

well as freight transport via rail and ocean), and high hazard manufacturing operations where the PFAS is instrumental in preventing catastrophic events, leaks or exposures.

“Intentionally added”
The definition of “intentionally added” should be changed to read "Intentionally added" means PFAS deliberately added as an ingredient 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”. This simple change may increase clarity.

"Perfluoroalkyl and polyfluoroalkyl substances" or "PFAS"
The Agency should consider adopting a less broad definition of perfluoroalkyl and polyfluoroalkyl substances in order to target those substances that are of the greatest concern. We suggest that the definition of PFAS be changed to: "Perfluoroalkyl and polyfluoroalkyl substances" or "PFAS” means, non-polymeric perfluoroalkyl and polyfluoroalkyl substances and side-chain fluorinated polymers that contain at least 2 fully fluorinated sequential carbon atoms, excluding gases and volatile liquids.

2. Are there terms or processes in subdivision 2 for which clarifications will help reporting entities determine reporting status or data-gathering process?

We respectfully request that a provision for reporting by product family be considered by the MPCA. Reporting by individual SKU or UPC will be complicated for companies and increase the complexity of analyses of the data without materially adding value to the purpose of this law, which is to protect human health and the environment. The State of Maine law includes provisions for reporting by product family that are reasonable and manageable. Additionally, if Minnesota includes a provision similar to the State of Maine, uniformity between the two states would support consistency and efficiency of the data collected. The State of Maine provision in H.P. 113 – L.D. 1503 Chapter 477 Section 1 38 MRSA 1612 2. Notification B. states: “With the approval of the department, a manufacturer may supply the information required in paragraph A for a category or type of product rather than for each individual product.” Having a provision to report by product family included in the implementation will reduce confusion and increase clarity of reporting. In addition to asking for product use type, the agency may also benefit by asking questions on how substances are handled and used (type of manufacturing setting or final use, i.e., industrial, professional or consumer use) and how the substances are controlled (emissions and waste handling, end of life disposal). The agency could also consider if the substance or use is adequately controlled, contained, and disposed of without risk to human health and the environment. If a PFAS is determined to be used and disposed of properly without risk to human health or the environment, there should be a provision for exemption when alternatives do not exist and when the use is unavoidable and contributes to safety and critical functioning of society. Additionally, the MPCA should consider thresholds that trigger reporting status such as the ECHA’s 1 ton threshold for reporting.

Subdivision 2 – Amount of each PFAS:

The agency should consider the use of multiple acceptable methods for quantifying the presence of PFAS in covered products. For example, by using the measurement of mass through a commercially available method for determination of exact quantity. If by formulation, the amount of PFAS is metered or weighed into the batch and included as an internal product specification or bill of materials, the mass as a weight percent should be considered an acceptable "commercially viable analytical method" by the agency.

Subdivision 2 – New Products:
Some industries are extremely dynamic with products created and discontinued at a high rate, along with products sold through distribution channels which add an additional level of complexity. Thus, MPCA should consider requiring updates at some agreed upon frequency (only every 2, 3 or 5 years) as defined in the future rulemaking.

3. Are there any terms used in subdivision 3 that should be further defined or where examples would be helpful?

Subdivision 3 – Substantially equivalent information:
MPCA should further define and clarify "substantially equivalent information that is already publicly available". Clear guidance on what is considered "substantially equivalent information is publicly available" and the process for being granted a waiver will be critical to responsible compliance in the implementation phase.

Subdivision 3 – Agreement with one or more states to collect information:
Currently there are two states or other agencies with PFAS reporting or data collection requirements: 1) The State of Maine and 2) the US EPA. Allowing for coordinated efforts with other agencies for similar reporting would be beneficial to companies in making efficient, timely and compliant reporting, downstream users who may place products on the market, consumers seeking consistent information and to the MPCA as it may reduce the level of resources needed to collect and interpret the data.

4. Are there specific portions of the reporting process that should not be defined through guidance or the development of an application form?

To support reporting, a portal should be developed to protect confidential company business information. Additionally, an application or guidance document would support efficient collection and reporting of information by companies. Having a clear reporting process, guidance and an application form will improve the overall quality of the data collected by companies and improve the management of data by the agency. For example, the ECHA PFAS restriction proposal request for information included a

portal and ten questions. Additionally, the EPA PFAS data gathering rule process has provided clear guidance, a data collection template, and a secure portal for submission.

We appreciate the opportunity to provide constructive input into this pre-rulemaking process and look forward to continued dialogue as the rule-making process advances. Should you have any questions about these comments or require additional information, please contact me at: lori.e.austino@dupont.com.

Sincerely,

LE Austino

Lori E. Austino
Global Technology Leader – Substances of Concern
lori.e.austino@dupont.com

Kindeva
DRUG DELIVERY
Manufacturing More Tomorrows™

November 27, 2023

Dr. Kami K. Thoen
Global Product Stewardship Senior Manager
Kindeva Drug Delivery L.P.
11200 Hudson Road
Woodbury, MN 55129

Dear Sir/Madam,

This letter is in response to the Minnesota Polluction Control Agency's planned new rules governing reporting of per- and polyfluoroalkyl substances (PFAS) in products. On September 25, 2023, the Minnesota Pollution Control Agency (MPCA) published a Request for Comments in the State Register. As a concerned Minnesota manufacturer of products that will be impacted by the proposed new rules, please see Kindeva's specific comments and questions below. These comments apply to both the "PFAS in Product: Fees" and the "PFAS in Products: Reporting" proposed rules.

Kindeva Drug Delivery is a global contract development manufacturing organization focused on drug-device combination products. Kindeva Drug Delivery develops and manufactures products across a broad range of complex drug-delivery formats, including injectables (autoinjector, intradermal, microneedle), pulmonary & nasal, and transdermal patches. Its service offering spans early-stage feasibility through commercial scale drug product fill-finish, container closure system manufacturing, and drug-device product assembly. Kindeva Drug Delivery serves a global client base from its nine manufacturing and research and development facilities located in the U.S. and U.K.

Comments from Kindeva Drug Delivery L.P, Regarding MPCA's Proposed Rules Regarding PFAS

PFAS in Products: Reporting

In developing the reporting rule, the MPCA would appreciate comments on the following questions:

1. Are there definitions in subdivision 1 for which clarification would be useful to understanding reporting responsibilities?

   In subdivision 1(p), "perfluoroalkyl and polyfluoroalkyl substances" or "PFAS" are defined as a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom. Kindeva Drug Delivery respectfully suggests that this definition be modified to include only those longer-chain PFAS currently recognized as "forever chemicals", substances known to cause harm to humans and/or the environment due to their slow breakdown over time.

   The primary concern with PFAS is their potential for buildup in humans, animals and/or the environment over time. However, this concern is related to the longer-chain PFAS already known to cause these issues, with perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS) being two key examples. In the EU, a number of PFAS are currently restricted by REACH Annex XVII Article 68, which places restrictions on the manufacture,

placing on the market and use of certain dangerous substances, mixtures and articles. This restriction is limited to those PFAS substances containing nine or more carbon atoms, as these are the chemicals known to persist in the environment.

There are numerous shorter-chain PFAS that have been shown to be nontoxic to humans and do not persist in the environment which are useful in many applications that are being needlessly included in the Minnesota Pollution Control Agency's proposed PFAS regulations. Kindeva Drug Delivery manufactures metered dose inhaler pharmaceutical drug products, which have been the subjects of numerous clinical studies and are approved by the FDA. These products use propellants to deliver the drugs into the lungs of patients, where they effectively treat many different acute and chronic respiratory diseases, including asthma and chronic obstructive pulmonary disease. These propellants are hydrofluorocarbons that are technically PFAS according to the proposed MPCA definition, even though they are proven to be nontoxic and do not persist in the environment. The main propellants currently used in metered dose inhalers are HFA-134a (1,1,1,2-tetrafluoroethane) and HFA-227 (1,1,1,2,3,3,3-heptafluoropropane). These two propellants are currently in the process of being phased out globally due to their high global warming potential. The replacements being developed are HFC-152a (1,1-difluoroethane) and HFO-1234ze (1,3,3,3-tetrafluoropropene)due to their significantly lower global warming potential, but HFO-1234ze would also still be considered a PFAS under the MPCA's definition despite the fact that it is both nontoxic and better for the environment in terms of global warming potential.

There are no other alternatives or substitutes being considered or developed that would not fall under the MPCA's definition of PFAS. Metered dose inhalers are complex devices and medical propellants must meet a specific range of technical performance characteristics to be safe and effectively deliver consistent doses of life-saving medicines for patients. A new propellant needs to have certain properties in terms of both human safety and physiochemical attributes and cannot simply be "dropped in", as reformulating existing drug products to use a new propellant requires the conduct of comprehensive preclinical and clinical studies, extensive product development studies inclusive of product stability and product characterisation tests as well as regulatory review and approval by the FDA.

PFAS are also used as coatings for the aluminum cans used in metered dose inhalers. This coating is critical to the proper, consistent function of the inhaler. These coatings, fluorinated ethylene propylene (FEP), are also shorter-chain hydrofluorocarbons that are nontoxic and do not persist in the environment.

These pharmaceutical drug products are necessary and must be accessible to patients for the treatment of their respiratory diseases, and the PFAS restrictions being proposed by MPCA would cause an undue burden on manufacturers working to provide these drugs to patients in need. If the definition of PFAS cannot be restricted to longer-chain hydrofluorocarbons, then at a minimum, an exemption for medical devices and pharmaceutical products should be included in the regulations. Inclusion of HFA-134a, HFA-227, HFO-1234ze and FEP in the MPCA definition of PFAS is inconsistent with the conclusions of the FDA, EMA and other regulatory agencies regarding the safety and benefits of these materials. It should be noted that this issue is being grappled with internationally and is currently being reviewed and discussed by numerous global health and regulatory agencies. Please see the following link for a comprehensive discussion of the scientific and clinical justifications for exempting MDI propellants from PFAS regulations. https://www.ipacinhaler.org/resource-hub

In subdivision 1(n), "manufacturer" is defined as the person that creates or produces a product or whose brand name is affixed to the product. This definition needs to be revised to clarify which party bears responsibility in a contract manufacturing arrangement. Many companies these days use contract manufacturers, such that the company that manufactures the product is not the same as the company whose brand name is affixed to the product. It is typically the company whose brand name is affixed to the product that is generally responsible for the marketing, distribution and sale of the product and, in the case of pharmaceutical products, is often the company that applies to the FDA for and holds the product's marketing authorization (NDA or ANDA). Kindeva Drug Delivery would thus suggest that the reporting and fee requirements proposed by MPCA should apply to the entity whose brand name is affixed to the product and who distributes the product in the state of Minnesota.

2. Are there terms or processes in subdivision 2 for which clarifications will help reporting entities determine reporting status or data-gathering process?

   No.

3. How should the MPCA balance public availability of data and trade secrecy as part of the reporting requirements?

   No.

4. Are there any terms used in subdivision 3 that should be further defined or where examples would be helpful?

No.

5. Are there specific portions of the reporting process that should not be defined through guidance or the development of an application form?

   No.

6. Other questions or comments relating to reporting or the process of reporting.

   None.

PFAS in Products: Fees

In developing the reporting rule, the MPCA would appreciate comments on the following questions:

1. Should the Agency consider tiered fees for different sizes of business?

   No. The amount of PFAS used by a business, and the necessity of using the PFAS substance, may not be related to the size of the business.

2. Should the Agency consider a per-product or per-company fee?

   Please see our comments above. Kindeva Drug Delivery L.P. believes that medical devices and pharmaceutical products should be exempted from all PFAS fees. The use of PFAS, as currently defined by the MPCA, in these products has been approved by the U.S. Food and Drug Administration (FDA) and other global health agencies, and the availability of these products is necessary for the health and safety of patients worldwide.

3. Should the Agency consider a per-PFAS or PFAS amount fee?

   Please see our comments above.

4. Are there other state program fee structures on which the Agency should model the fees?

   A similar program that could be used as a model is the MN Opiate Product Registration (OPR) Fee, administered by the MN Board of Pharmacy. This is a MN state law that establishes a product registration and fee collection program applicable to opiate manufacturers. This program provides funding for various opiate treatment, prevention and recovery programs. The key difference between this program and the PFAS reporting and fees proposed by the MPCA is the clarification that the MN

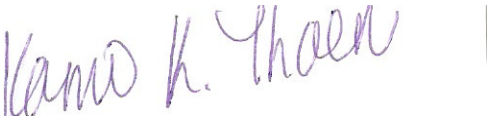
OPR reporting and fees only apply to opiate manufacturers and wholesalers that sell, deliver or distribute opiates to end users within the state of MN. This removes the reporting and fees requirements from contract manufacturers, who are not responsible for the sale, marketing or distribution of the product.

5. Should the Agency consider a fee to be paid when updates to information on previously reported products are submitted? (e.g., decreased amounts or elimination of one or more PFAS)

   No. Requiring a fee to be paid when reporting decreased amounts or elimination of one or more PFAS would discourage efforts to minimize their use in products. Product development efforts aimed at minimization of PFAS in products should be encouraged.

Thank you for your consideration of these comments, and please feel free to reach out if we can be of any assistance or provide any further information to MPCA.

Sincerely,



Kami K. Thoen, Ph.D.
Global Product Stewardship Senior Manager
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Tel.: (651) 335-1144

RECEIVED
By: OAH on 11/28/2023
Tony Kwilas Attachment

MINNESOTA CHAMBER OF COMMERCE
GROWING MINNESOTA

November 28, 2023

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

The Minnesota Chamber of Commerce (Chamber), a statewide organization representing more than 6,300 businesses and more than a half million employees throughout Minnesota, submits this letter in response to the Minnesota Pollution Control Agency's (MPCA or Agency) request for comments related to the Agency's planned rulemaking of reporting by manufacturers regarding products containing Per and Polyfluoroalkyl (PFAS).

As indicated below, the Chamber welcomes this opportunity to share its point of view regarding the proposed regulations. The Chamber recognizes, as we are sure the MPCA does, that these rules pose the possibility of a significant impact on the economic vitality of the businesses and manufacturers subject to the rules. Therefore, the Chamber urges MPCA to be deliberate and consultative in its approach.

Toward that end, and as a preliminary matter, the Chamber urges the creation of an advisory committee of all stakeholders (including representatives of the Chamber and other affected businesses) to consult with the Agency as it works to develop, and before publishing, draft rules. We believe such a process would help drive consensus around key issues and avoid unintended consequences.

We additionally encourage the Agency to coordinate with other states such as Maine and Washington, as well as on federal initiatives and with the Interstate Chemical Clearinghouse (ICC) to avoid duplication and confusion. As an example, the Environmental Protection Agency (EPA) has finalized PFAS reporting requirements under the Toxic Substances and Control Act (TSCA) that are estimated to include 1,462 chemical substances manufactured, processed or imported in the United States that will be required to report under the finalized rule. We encourage the MPCA to review this rule and coordinate where possible with the EPA and other reporting authorities to avoid a patchwork of related but distinct reporting requirements.

The Minnesota Session Law-2023, Chapter 60, Article 3, Section 21, contains definitions that need clarification to provide certainty to businesses that will be impacted by this law. The definition of PFAS that includes "one fully fluorinated carbon atom" will have the potential to include an estimated 9,000-12,000 chemicals. Not all of these chemicals have the same toxicological effect. Hazard and risk profiles are different for each chemical and use. The Agency should also consider a de minimis amount of PFAS not shown (or demonstrated) to have an adverse impact on human health or the environment. As mentioned previously, the EPA requires reporting of a specific list of chemicals. MPCA's reporting requirements should not duplicate requirements by EPA or other regulatory agencies. If a filing with the EPA or other regulatory agency is required, this should exempt a manufacturer from filing with the MPCA, subject to the MPCA's request for additional information.

380 St. Peter Street, Suite 1050, St. Paul, MN 55102
www.mnchamber.com

The definition of “manufacturer” is different from Minnesota Statutes 116.9401, as well as in conflict with other federal definitions used under Toxic Control Substances Act (TSCA) and CFR Title 21 used by the Food and Drug Administration (FDA). Significant confusion and duplicative reporting are likely to emerge from the current definition. Many products have components, sub-assemblies, and finished goods that do not have their brand name “affixed” to the product. Manufacturers may not be able to ascertain information, even after inquiry with suppliers, on whether their product contains PFAS or not. Additionally, the incredible complexity of the network of supply chains will further burden reporting entities attempting to obtain the required data. The definition of manufacturers needs to clearly and concisely identify who is impacted.

The definition of “currently unavoidable use” also requires clarification. The MPCA should include concepts on how “alternatives” will be determined, including functional equivalency, and technological and commercial feasibility. “Reasonably available” should include concepts of performance, safety, cost and supply chain considerations. The MPCA also must clarify how the Agency is going to determine what products are “essential to the health, safety and functioning of society” and what the process and criteria will be for the industry to follow. Products that are used in medical, recreational, automobile, aerospace, marine, defense and agricultural industries are just some of the businesses that need clear and workable definitions of these terms.

The MPCA should additionally clarify the definition of “product”. The interpretation of “item” within the product definition needs to be further evaluated as in other business transactions an “item” could be an article or a unit. The definition should also clarify that the product is for sale to “Minnesota” consumers.

Testing protocols and lab testing capabilities also need to be taken into account. Not all PFAS have testing protocols and analytical methods of testing need to be clarified. Adequate testing capacity needs to be assured and certified for impacted parties.

Data privacy and confidential business information (CBI) are also of concern. The MPCA should allow manufacturers to declare CBI and trade secrets/proprietary information on the reporting requirement and the ability to require that the data submitted be protected. The Agency must ensure through the rule, protection is provided under other state and federal data privacy laws along with Minnesota’s existing data privacy laws.

The Minnesota Chamber of Commerce appreciates the opportunity to provide our comments and looks forward to participating in further discussions on this critical matter to Minnesota businesses. Please do not hesitate to contact me with any questions.

Tony Kwilas
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Minnesota Chamber of Commerce
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ALLIANCE FOR AUTOMOTIVE INNOVATION

November 28, 2023

Submitted to Office of Administrative Hearings via Rulemaking eComments:
https://minnesotaoah.granicusideas.com/

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

Re: REQUEST FOR COMMENTS: 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

Dear Ms. Lynn:

The Alliance for Automotive Innovation[1] (Auto Innovators) appreciates the opportunity to provide comments on the Minnesota Pollution Control Agency's (MPCA's) Request for Comment on the Planned New Rules Governing Reporting by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS) (hereinafter "the Notice"). These rules will implement a statutory requirement that, 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 submit certain information to MPCA, and would establish a fee structure for required reporters.

We appreciate MPCA requesting input prior to the development of a proposed PFAS reporting rule and recommend that reflecting on the experiences of states like Maine and California will provide important insights into the challenges that this rulemaking may pose for Minnesota, its residents, and the regulated community. We have been actively engaged in the development of PFAS legislation and regulation at the federal and state levels; we believe our experience and recommendations will be beneficial to MPCA as it moves forward in drafting implementing regulations. Auto Innovators represents the auto manufacturing sector, including automakers that produce and sell approximately 95% of the new light-duty vehicles in the United States. The auto industry plays an important and critical role in our nation's economy, accounting for 10 million jobs and 5.5% of the annual Gross Domestic Product. Our mission is to work with policymakers to realize a future of cleaner, safer, and smarter personal transportation and to work together on policies that further these goals, increase U.S. competitiveness, and ensure sustainable, well-paying jobs for citizens throughout the country.

Our comments and recommendations reflect issues that we think will be critical for MPCA to consider. These are not knee-jerk reactions to the proposed definitions and procedures; rather, they

[1] From the manufacturers producing most vehicles sold in the U.S. to autonomous vehicle innovators to equipment suppliers, battery producers and semiconductor makers – Alliance for Automotive Innovation represents the full auto industry, a sector supporting 10 million American jobs and five percent of the economy. Active in Washington, D.C. and all 50 states, the association is committed to a cleaner, safer and smarter personal transportation future. www.autosinnovate.org.

reflect our in-depth assessment of this and other PFAS reporting approaches and regulations. Auto Innovators dedicated substantial time to identifying the challenges and obstacles that the PFAS proposals in this Notice would present to almost the entire U.S. auto manufacturing sector if adopted as drafted.

Our comments address some of the specific questions posed by MPCA. Below, we cover the following:

A. Definitions in subdivision 1 for which clarification would be useful to understanding reporting responsibilities.
B. Terms or processes in subdivision 2 for which clarifications will help reporting entities determine reporting status or data-gathering process.
C. Suggestions for balancing public availability of data and trade secrecy as part of the reporting requirements.
D. The unavoidable use exemption in subdivision 5.
E. The lack of available analytical methods.
F. Product bans.

A. Definitions in Subdivision 1 for Which Clarification Would Be Useful

Clarity of definitions is critical to ensuring that the regulated community understands exactly what data MPCA is seeking and of whom. We have reviewed the definitions in subdivision 1 and offer the following recommendations for clarity. Our comments here reflect our effort to have consistent definitions across federal and state PFAS reporting schemes. We have also identified terms which we believe need to be added and defined to further delineate the scope of any proposed rulemaking.

CURRENT DEFINITION	PROPOSED DEFINITION
"Air care product" means a chemically formulated consumer product labeled to indicate that the purpose of the product is to enhance or condition the indoor environment by eliminating odors or freshening the air.	**"Air care product"** means a chemically formulated consumer product labeled to indicate that the purpose of the product is to enhance or condition the ***household or business*** indoor environment by eliminating odors or freshening the air.
We suggest that specific mention of households and businesses be made to clarify that the intended target air care products are for use inside of buildings.	
"Automotive maintenance product" means a chemically formulated consumer product labeled to indicate that the purpose of the product is to maintain the appearance of a motor vehicle, including products for washing, waxing, polishing, cleaning, or treating the exterior or interior surfaces of motor vehicles. Automotive	**"Automotive maintenance product"** means a chemically formulated ***aftermarket*** consumer product labeled to indicate that the purpose of the product is to maintain the appearance of a motor vehicle, including products for washing, waxing, polishing, cleaning, or treating the exterior or interior surfaces of motor vehicles. Automotive

maintenance product does not include automotive paint or paint repair products.	maintenance product does not include automotive paint or paint repair products.
Similarly, we recommend including the word “aftermarket” here to clarify that MPCA is intending to target maintenance products that are utilized by consumers after the sale of the vehicle.	
“Carpet or rug” means a fabric marketed or intended for use as a floor covering.	**“Carpet or rug”** means a fabric marketed or intended for use as a floor covering ***for commercial, industrial, or residential buildings that contains intentionally added PFAS.***
We recommend that automotive mats be excluded from this definition. This would be consistent with Maine’s proposed definition and would identify car mats as significantly different from indoor floor coverings.	
“Cleaning product” means a finished product used primarily for domestic, commercial, or institutional cleaning purposes, including but not limited to an air care product, an automotive maintenance product, a general cleaning product, or a polish or floor maintenance product.	**“Cleaning product”** means an ***aftermarket*** finished product used for domestic, commercial, or institutional cleaning purposes, including but not limited to an air care product, an automotive maintenance product, a general cleaning product, or a polish or floor maintenance product.
We recommend including the word “aftermarket” here to clarify that MPCA is intending to target cleaning products that are utilized by consumers at home after the sale of the vehicle.	
“Fabric treatment” means a substance applied to fabric to give the fabric one or more characteristics, including but not limited to stain resistance or water resistance.	**“Fabric treatment”** means ***an aftermarket*** substance applied to fabric to give the fabric one or more characteristics, including but not limited to stain resistance or water resistance. ***Fabric treatment does not include processes or treatments applied during the manufacture of a product.***
We recommend including the word “aftermarket” and additional language here to clarify that MPCA is intending to target fabric treatments that are utilized by consumers after the sale of the vehicle.	
“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.	**“Intentionally added"** means PFAS deliberately added ***to a product or one of its product components to provide a specific characteristic, appearance, or quality or*** to perform a specific function. ***Intentionally added PFAS does not include degradation byproducts of PFAS within the product or its components. Products containing intentionally added***

	PFAS include products that consist solely of PFAS. Intentionally added PFAS does not include PFAS that is present in the final product as a contaminant.
We recommend adding the above text to the definition of "intentionally added." It addresses the potential reasons why a PFAS may be in a product, and PFAS present as a contaminant or as a degradation byproduct should not be included in the definition of "intentionally added." The recommended definition also makes the concept of "intentionally added" more consistent over multiple jurisdictions.	
"Juvenile product" means a product designed or marketed for use by infants and children under 12 years of age: (1) including but not limited to a baby or toddler foam pillow; bassinet; bedside sleeper; booster seat; changing pad; child restraint system for use in motor vehicles and aircraft; co-sleeper; crib mattress; highchair; highchair pad; infant bouncer; infant carrier; infant seat; infant sleep positioner; infant swing; infant travel bed; infant walker; nap cot; nursing pad; nursing pillow; play mat; playpen; play yard; polyurethane foam mat, pad, or pillow; portable foam nap mat; portable infant sleeper; portable hook-on chair; soft-sided portable crib; stroller; and toddler mattress; and (2) not including a children's electronic product such as a personal computer, audio and video equipment, calculator, wireless phone, game console, handheld device incorporating a video screen, or any associated peripheral such as a mouse, keyboard, power supply unit, or power cord; or an adult mattress.	**"Juvenile product"** means a product designed or marketed for use by infants and children under 12 years of age: (1) including but not limited to a baby or toddler foam pillow; bassinet; bedside sleeper; booster seat; changing pad; ~~**child restraint system for use in motor vehicles and aircraft**~~; co-sleeper; crib mattress; highchair; highchair pad; infant bouncer; infant carrier; infant seat; infant sleep positioner; infant swing; infant travel bed; infant walker; nap cot; nursing pad; nursing pillow; play mat; playpen; play yard; polyurethane foam mat, pad, or pillow; portable foam nap mat; portable infant sleeper; portable hook-on chair; soft-sided portable crib; stroller; and toddler mattress; and (2) not including a children's electronic product such as a personal computer, audio and video equipment, calculator, wireless phone, game console, handheld device incorporating a video screen, or any associated peripheral such as a mouse, keyboard, power supply unit, or power cord; or an adult mattress. ***(3) Juvenile product does not include any product that contains PFAS as necessary to meet international, federal, or state safety requirements.***
We recommend the above changes to the definition of "juvenile products." Vehicles and their restraint systems such as seatbelts must meet federal safety and performance requirements. "Child restraint systems" can include the seatbelts that are manufactured into the car, and these	

systems themselves are required to meet safety standards. We request their exclusion from this definition.	
"Perfluoroalkyl and polyfluoroalkyl substances" or "PFAS" means a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom.	**"Perfluoroalkyl and polyfluoroalkyl substances" or "PFAS"** means ***non-polymeric 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.***
We recommend that the definition of PFAS be revised to include substances that have two fully fluorinated carbon atoms, and that gases should be excluded as outlined above. We provide further explanation below. This more precise definition would ensure reporting of PFAS in products more narrowly targets PFAS substances that are known to cause harm and addresses the over-inclusiveness of the current definition.	
"Product" means an item manufactured, assembled, packaged, or otherwise prepared for sale to consumers, including but not limited to its product components, sold, or distributed for personal, residential, commercial, or industrial use, including for use in making other products.	**"Product"** means an item manufactured, assembled, packaged, or otherwise prepared for sale to consumers, including but not limited to its product components, sold, or distributed for personal, residential, commercial, or industrial use, including for use in making other products. ***For complex durable goods, "product" would encompass the complete product such as a complete vehicle.***
"Product component" means an identifiable component of a product, regardless of whether the manufacturer of the product is the manufacturer of the component.	**"Product component"** means an identifiable component of a product, regardless of whether the manufacturer of the product is the manufacturer of the component. ***"Product component" includes replacement and service parts necessary for the repair and maintenance of a "product."***
We recommend the above definitions for "product" and "product component." Vehicles (i.e., the "products") are made up of thousands of individual parts (i.e., the "product components"), and there is an essential market selling service and replacement parts to keep those vehicles in safe working order.	
"Textile furnishings" means textile goods of a type customarily used in households and businesses, including but not limited to	**"Textile furnishings"** means textile goods of a type customarily used in households and businesses, including but not limited to draperies, floor coverings, furnishings, bedding, towels, and tablecloths. ***Textile***

draperies, floor coverings, furnishings, bedding, towels, and tablecloths.	***furnishings do not include automotive textiles.***
We recommend a clear exclusion of automotive uses in the definition of "textile furnishings," which would be helpful to industry.	
"Upholstered furniture" means an article of furniture that is designed to be used for sitting, resting, or reclining and that is wholly or partly stuffed or filled with any filling material.	**"Upholstered furniture"** means an article of furniture that is designed to be used ***inside or outside of a building*** for sitting, resting, or reclining and that is wholly or partly stuffed or filled with any filling material.
The inclusion of a reference in the definition of "upholstered furniture" to use inside or outside of a building would make it clear that vehicular uses are not included.	

B. Terms or Processes Subdivision 2 for Which Clarifications Will Help Reporting Entities Determine Reporting Status or Data-Gathering Process

Subdivision 2 lays out a general description of the information required to be submitted, the ability to collect data on categories versus individual products, and specific use information as well as facility identification information. There are several critical issues that fall within the scope of this subdivision, each one linked to the basic issue of "meaningful data," the processes by which the regulated community will collect that data, approaches that MPCA will employ to interpret the data and use it in a constructive manner, and procedures integral to efficient data collection and data sharing.

We recommend that MPCA consider the following recommendations:

- Limit reporting requirements to PFAS chemicals of known concern.
- Define all applicable CAS numbers.
- Set a *de minimis* threshold value.
- Exempt impurities and byproducts.
- Exempt refrigerants and fluoropolymers.
- Exempt replacement and service parts for vehicles already manufactured prior to January 1, 2026, from notification and elimination requirements.
- Permit reporting at the total product level (vehicle) and include replacement, maintenance, and service parts in the vehicle reporting and within reporting ranges.
- Set a "reasonably ascertainable information" standard.

Limit Reporting Requirements to PFAS Chemicals of Known Concern

We have recommended a more precise definition of PFAS. "PFAS" should be defined, suggested above, as "non-polymeric 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." Within the boundaries of this more succinct definition, there are thousands of unique chemicals in the broad and diverse category of PFAS. With over

9,000 PFAS currently identified by the National Institute of Environmental Health Sciences,[2] failure to differentiate between those that may pose a risk and those that do not will result in an overly broad restriction with the unintended consequence of banning chemicals that pose no such threat. If MPCA chooses to move forward with this data collection effort, it is imperative that it focus its collection activities on those PFAS chemicals that are of high concern and exclude those that have been determined to be of low concern. For example, MPCA should exclude substances with low risk profiles. This would include fluoropolymers. These types of chemicals have high molecular weight, low levels of residual monomer, and do not degrade easily under normal conditions of use. Other categories to be excluded would be chemicals used for research and development, *de minimis* levels of PFAS chemicals, low volume service chemicals, refrigerants, and other categories identified as having low exposure potential.

Define All Applicable CAS Numbers

MPCA should define all regulated PFAS with a list of chemical names and Chemical Abstract Service (CAS) numbers. In doing so MPCA would clearly define the universe of chemicals that require notification and further clarify reporting requirements. CAS numbers are the universal identifier used to identify a chemical substance or molecular structure in an unambiguous manner and to discern between many possible systematic, generic, or proprietary chemicals. In the absence of CAS numbers, the automotive sector will be unable to search its Safety Data Sheets (SDSs) and use its International Material Data System (IMDS). IMDS is used throughout the global automotive supply chain to collect and analyze all parts and materials on the vehicle at the point of sale, including replacement parts. It provides analysis capabilities of the substances, tracked by CAS number, present in vehicles and vehicle components.

Set a De Minimis *Threshold Value*

We recommend that the notification requirement exclude products that contain PFAS equal to or less than 0.1% by weight. Products with *de minimis* levels of PFAS chemicals account for insignificant contributions to PFAS in the environment. A 0.1% by weight threshold is an appropriate threshold for MPCA to employ for purposes of the notification requirement. It would reasonably limit the volume of notifications, particularly for parts and components sold into Minnesota. Otherwise, MPCA could be burdened with literally hundreds of thousands of notifications related to parts and components that contain only trace concentrations of PFAS, which would be insignificant from a safety and health perspective.

IMDS utilizes a default *de minimis* 0.1% reporting threshold, unless otherwise specified, which is the level utilized for SDSs. The use of a 0.1% *de minimis* concentration will support the accuracy of the data provided by the supply chain to the material database. The 0.1% concentration is a threshold that has been almost universally adopted by international regulatory bodies and many states within the United States. Therefore, we recommend an exemption for PFAS levels at or below 0.1%.

In addition, promulgating a notification rule without a *de minimis* threshold would overly burden the supply chain. All end product manufacturers that sell any of their products into Minnesota would be

[2] *Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS)*, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES, https://www.niehs.nih.gov/health/topics/agents/pfc/index.cfm.

required, in the absence of a *de minimis* threshold, to spend considerable time and effort to attempt to determine whether any part or component, whether sourced locally or globally, that goes into their end products might contain a trace concentration of PFAS. Those manufacturers would also need to determine whether the PFAS was "intentionally added," which based on the current definition must likely be assumed, and the specific purpose and amount of PFAS. This expansive data gathering would place an enormous burden on manufacturers to try to obtain from their suppliers, some of which are second, third, etc. tier suppliers—information that would be difficult, if not impossible, to obtain.

Exempt Impurities and Byproducts

Byproducts and impurities would never be intentionally added to a product. Chemicals in these two categories are generally exempt from other regulatory schemes. For example, impurities and byproducts are exempt from EPA's Premanufacture Reporting Notification (PMN) reporting under 40 C.F.R. § 720.30(h). In addition, a byproduct that is not used for a commercial purpose after it is manufactured was not required to be listed on the TSCA Inventory (40 C.F.R. § 710.4(d)(2)). Requiring companies to gather information on impurities or byproducts to assure compliance with a data collection requirement would force producers, importers, and suppliers to expend substantial resources and a significant amount of time with very little, if any, environmental benefit. For this reason, we recommend above modifying the definition of "intentionally added" to clarify that PFAS present as an impurity or byproduct are not included.

Exempt Refrigerants and Fluoropolymers

The current definition of PFAS being considered by MPCA would include the refrigerants that are used in motor vehicle air conditioning (MVAC) applications. Those refrigerants are already the subject of regulations covering hydrofluorocarbons (HFCs) at both the state and federal levels; in fact, those regulations have resulted in the industry undertaking over the past several years the behemoth task of transitioning from one type of refrigerant to another that has a lower global warming potential. Banning use of the refrigerant now currently used in our vehicles, as the Minnesota PFAS law might do, would require OEMs to have an available alternative that is also approved by all those HFC regulations, and would result in OEMs having to significantly redesign and reengineer our recently revamped MVAC systems and vehicles, possibly even with a need to retrofit older vehicles. The definition of PFAS needs to be revised to exempt these substances.

Fluoropolymers satisfy widely accepted criteria to be considered polymers of low concern, indicating that they do not present a significant risk to human health or the environment. This is the reason why fluoropolymers should be regulated differently from PFOA and PFAS and should be exempted from these regulations.

Exempt Replacement and Service Parts for Vehicles Already Manufactured Prior To January 1, 2026, From Notification Requirements

Federal safety law requires auto manufacturers to have available replacement and service parts for 15 years after a vehicle is manufactured[3]; sensibly, those parts are often manufactured at the same

[3] *See* 49 U.S.C. § 30120(a), (g).

time as the original vehicle, and then held in storage. There are literally millions of replacement parts in commerce that are essential to maintain and repair in-service vehicles so that they remain safe and reliable; those parts are also manufactured according to the applicable laws and requirements in place when the vehicle was designed. For reference, there were 5,690,749 road vehicles registered in Minnesota in 2020.[4]

Reporting PFAS content for legacy replacement parts produced years ago but sold today would be a herculean task. Manufacturers may have changed suppliers and may no longer be working with a company, or companies may have folded; even if not, information requests for products produced several years ago would imaginably be particularly difficult, if not impossible to respond to. Because manufacturers are no longer selling as new the vehicles into which those replacement parts would be installed, reporting replacement parts for those past production vehicles would increase the number of reports received by MPCA by thousands.

Permit Reporting at the Total Product Level (Vehicle) and Include Replacement, Maintenance, and Service Parts in the Vehicle Reporting and Within Reporting Ranges

Each auto manufacturer has up to 100 vehicle models, and a single vehicle has tens of thousands of individual parts as single parts, subassemblies, and assemblies. Each automobile contains thousands of individual parts, as depicted in the adjacent graphic. Reporting on each one of those parts will not only overwhelm the data management system that MPCA is developing but will also place an unreasonable burden on automobile manufacturers. All other sectors that provide complex durable goods to consumers have the same profile—hundreds if not thousands of individual parts in the finished product. Investigating tens of thousands of parts in the automotive industry is costly and would result in fragmented and duplicative information going to the state of Minnesota that may overwhelm MPCA's database while providing little value. Reporting at the vehicle level would give an excellent and understandable measure of each car's PFAS content. Additionally, providing reporting ranges at the finished product level will simplify the reporting requirements and will still provide MPCA with the information that it needs to fulfill the requirements of the law.

[4] *Highway Statistics Series: State Motor-Vehicle Registrations – 2020*, U.S. Federal Highway Administration, https://www.fhwa.dot.gov/policyinformation/statistics/2020/mv1.cfm (last updated Feb. 16, 2023).

Adopt a Tiered Approach to Reporting

As enacted, the broad scope of coverage envisioned by this law is written as though it applies to simple consumer products rather than complex durable products. Moving along the spectrum from a simple product to a complex product, the challenges of identifying PFAS within the product multiply. MPCA should consider developing a phased-in reporting structure, with lower-complexity products reporting earlier and manufactures of complex products reporting later. We suggest that MPCA consider adopting a definition of complex durable goods similar to the Toxic Substances Control Act (TSCA) definition. This would permit MPCA to incorporate lessons learned into the reporting procedures and properly scale the required IT infrastructure for the online electronic portal. One option would be to allow manufacturers of complex goods to identify whether their product does or does not contain PFAS (a simple "yes" or "no") for the first two years, with more detailed reporting to follow in the subsequent years. This is not meant in any way to undercut the requirements of the law, but rather to find a feasible, practical way to implement the law in a manner consistent with industry's capabilities.

Set a "Known or Reasonably Ascertainable Information" Standard

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 contain intentionally added PFAS. If a supplier informs the manufacturer that the components, parts, or other elements 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 manufacturers by suppliers for parts, components, etc.

It would be unreasonable for the notification rule to require manufacturers to mount a burdensome due diligence effort essentially to prove what they already believe, i.e., 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 and parts 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.

We recommend that MPCA limit the notification requirement to instances where intentionally added PFAS is "known" to manufacturers. What is "known" to manufacturers should be limited to information provided by their component and parts suppliers without any requirement to perform additional due diligence or other information gathering up the supply chain.

Contact Person

We request that the contact person and the person of authority be separate people. The person responsible for supplying PFAS information to MPCA is not the same person who would have authority during a noncompliance situation.

C. Suggestions for Balancing Public Availability of Data and Trade Secrecy as Part of the Reporting Requirements

The data reporting system must allow manufacturers to claim certain data for products or components as CBI. This is especially important for manufacturers that have been required to put in place non-disclosure agreements with international suppliers. A well-defined CBI framework for all notification and future rulemaking (e.g., for future exemptions) will be essential for the protection of valuable intellectual property that might otherwise be jeopardized. Information that requires careful protection could include (for example) the identity of any PFAS present in a product, the volume and concentration of such a substance, and any information relating to sales volumes or production volumes. MPCA could look to the TSCA CBI framework as an example of an effective CBI program.[5]

D. The Unavoidable Use Exemption in Subdivision 5

If MPCA wishes to avoid the quandary that other states are facing regarding issuing unavoidable use exemptions, it should place a high priority on developing the rulemaking or technical guidance that is necessary for the regulated community to request such an exemption well before any final rule becomes effective and well in advance of the January 2032 restrictions that come into force. We are ready to work with MPCA and other manufacturers of complex durable goods on the implementing regulations for the unavoidable use provisions.

E. The Lack of Available Analytical Methods

There are no commercially available analytical methods to accurately quantify the presence and amount of PFAS in products and product components. EPA's PFAS website lists available analytical detection methods and, after reviewing the site and studying the six categories of analytical methods approved for measuring the concentration of a substance or pollutant, EPA has not identified or developed an appropriate test to determine the concentration of individual PFAS in a product or product component.

As recently as March 2023, the White House National Science and Technology Council issued a report on PFAS substances. The report acknowledges that only a limited number of analytical methods have been developed to detect PFAS, and that those focus predominantly on PFAS in various media (e.g., drinking water). No methods to detect PFAS chemicals in product or product components are referenced.

> All of the existing analytical methods, with the exception of EPA 162139, include a discrete list of PFAS target analytes with defined chemical structures for which the methods have been validated, which varies across methods… The number of PFAS

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[5] See 88 Fed. Reg. 37,155 (June 7, 2023), *available at* https://www.federalregister.gov/documents/2023/06/07/2023-12044/confidential-business-information-claims-under-the-toxic-substances-control-act-tsca.

> that can be quantified through targeted analysis is limited…. Additional PFAS standards will need to be developed in order for other PFAS to be added to these method lists.[6]

F. Product Bans

We have serious concerns about the timing of any product bans that may become effective in 2025 and in subsequent years at MPCA's discretion. The process for a complete ban two years after the passage of the Act is highly problematic. Two years is a very short amount of time to allow for the full accounting and identification of PFAS within a complex consumer product, let alone conduct the research necessary to develop viable alternative chemistries for those PFAS and test out their suitability for the product's functionality. Our industry's products, for example, often begin development five to seven years before their release and must meet all performance requirements, including those established by the National Highway Traffic Safety Administration (NHTSA) and Environmental Protection Agency (EPA). The iterative nature of developing substitutes that meet performance standards as well as health and safety standards is both complex and lengthy. This process can take 5 years or more and is essential to ensuring that an automobile performs as expected and meets all safety requirements.

We recognize that the law envisions the ability to apply for a currently unavoidable use exemption. However, within that same two years the agency will have to promulgate through a notice and comment rulemaking the criteria and requirements to apply for a currently unavoidable use exemption, affected industries will have to apply for that currently unavoidable use exemption, and then the agency will have to make a decision on each application, all to be able to avoid the product ban. This timeline is highly unlikely. For example, the state of Maine passed its PFAS law in July 2021, but the regulations just to implement the reporting element of that legislation are still not finalized and will likely not be finalized until 2024.

G. Conclusion

In conclusion, there are many significant issues to be addressed when developing such a massive data collection on a group of chemicals that exceed 9,000 individual substances. Perhaps the first and most relevant issue to be addressed is what is this data being collected for? As stated in the request for comment document, "[t]he main purpose of this rulemaking is to establish a program for the MPCA to collect information about products containing PFAS intentionally added to products sold, offered for sale, or distributed in Minnesota as required by Minnesota Session Law – 2023, chapter 60, article 3, section 21, (Minnesota Statutes 116.943) subdivision 2."[7]

This statement, however, gives very little insight into how MPCA will use this data to further any specific goals of environmental protection. If the goal is to look at impacts on human health, collecting data on articles, components, and products will provide very little meaningful information.

If, as is more likely, the goal is to determine how PFAS is entering the environment—air, water, waste streams, etc.—then collecting data from manufacturers and importers of products that contain

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[6] Per- And Polyfluoroalkyl Substances (PFAS) Report, Joint Subcommittee On Environment, Innovation, and Public Health and Per- And Polyfluoroalkyl Substances Strategy Team Of The National Science And Technology Council (Mar. 2023), *available at* https://www.whitehouse.gov/wp-content/uploads/2023/03/OSTP-March-2023-PFAS-Report.pdf.

[7] https://www.pca.state.mn.us/sites/default/files/c-pfas-rule1-01.pdf

PFAS will also lead to a dearth of truly meaningful information. To determine how PFAS is entering environmental media, the appropriate sources of data would be those facilities that handle waste streams including POTWs landfills, recyclers, and others. The federal Toxics Release Inventory (TRI) provides a good starting point for this type of data and over 300 PFAS chemicals have been added to the TRI.

Once the appropriate sectors that have relevant and useful information on PFAS sources in the environment have been identified, the many procedural and definitional issues that we have presented need to be addressed.

We thank MPCA for this opportunity and hope that our comments will be received in the manner that we intended; that is, to avoid the pitfalls other states have experienced and to invest valuable state resources in a meaningful and relevant program to address concerns with PFAS in the environment. We would welcome the opportunity to answer any questions that arise and discuss with you in greater detail.

Sincerely,

Catherine Palin
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PERFORMANCE FLUOROPOLYMER PARTNERSHIP

November 28, 2023

Re: 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[1]

Submitted via https://minnesotaoah.granicusideas.com/

On behalf of the American Chemistry Council's Performance Fluoropolymer Partnership,[2] thank you for the opportunity to submit comments on planned new rules for the reporting of the intentional use of per- and polyfluoroalkyl substances (PFAS) in products. The Partnership's members are some of the world's leading manufacturers, processors, and users of fluoropolymers, including fluoroelastomers, and polymeric perfluoropolyethers. 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 regulation. We hope the Minnesota Pollution Control Agency (hereafter "Agency") will find our comments useful in crafting proposed regulations. First, we provide general comments on the proposed regulation, followed by responses to the specific questions raised by the Agency.

General Comments

We request that the Agency exclude fluoropolymers and fluoropolymer-based products from the scope of the proposed regulations. Fluoropolymers are large, stable molecules that have been demonstrated[3,4] to meet criteria developed within chemical regulatory frameworks around the world to identify "polymers of low concern" for potential impacts on humans and the environment.[5,6] As demonstrated in our references provided here, fluoropolymers are insoluble substances and therefore do not present concerns about mobility in the environment, in contrast to certain highly water soluble PFAS substances. In addition, fluoropolymers are neither bioavailable nor bioaccumulative, are not long-chain non-polymer PFAS, such as PFOA and PFOS, and do not transform into non-polymer PFAS in the environment. Furthermore, because of

[1] https://www.pca.state.mn.us/sites/default/files/c-pfas-rule1-01.pdf
[2] https://fluoropolymerpartnership.com/
[3] 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, https://doi.org/10.1002/ieam.4035.
[4] 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, https://doi.org/10.1002/ieam.4646.
[5] Organisation for Economic Co-operation and Development. 2009. Data analysis of the identification of correlations between polymer characteristics and potential for health or ecotoxicological concern. Document ENV/JM/MONO(2009)1. Paris (FR).
[6] BIO by Deloitte. (2014). Technical assistance related to the review of REACH with regard to the registration requirements on polymers – Final report prepared for the European Commission (DG ENV), in collaboration with PIEP.

their chemical and heat resistance as well as their dielectric properties, fluoropolymers are often used in components such as gaskets, tubing, electrical wiring, and printed circuit boards, that are found in tens of thousands of different products, ranging from heating, ventilation and air conditioning (HVAC) systems to aerospace equipment. Compliance with the notification requirement will be exponentially more complex and burdensome if fluoropolymers are not excluded and, because of the benign nature of fluoropolymers, little useful information will be gained from their inclusion in the rule.

To avoid unnecessary and duplicative reporting, we urge the Agency to delay development and implementation of the reporting regulations until the data reported pursuant to the United States Environmental Protection Agency's (EPA) recently finalized reporting and record keeping regulation become available.[7] The rule requires comprehensive reporting on all PFAS substances manufactured or imported into the United States since 2011, including PFAS substances imported as part of articles. Reporting under this regulation will be completed in 2025, and much of the information reported is expected to be made available to the public. Even if the data collected by EPA do not completely address all of Minnesota's information needs, the EPA data should allow the Agency to more carefully tailor the reporting requirements so that manufacturers are not saddled with unnecessarily burdensome reporting obligations.

Finally, the overly broad definition of PFAS in the authorizing legislation creates an overwhelming task for the Agency. We suggest that the Agency reconsider the working definition of the program to focus on non-polymeric PFAS that contain at least two fully fluorinated sequential carbon atoms, excluding gasses and volatile liquids. This definition of PFAS would focus on smaller, lower molecular weight, soluble PFAS that may move between environmental media, may be more bioavailable and bioaccumulative, and should be of higher regulatory priority. It would allow the Agency to focus its limited resources and more quickly identify sources of PFAS that may be potentially of concern to human or environmental health.

Responses to Specific Questions Raised by MPCA

1. Are there definitions in subdivision 1 for which clarification would be useful to understanding reporting responsibilities?

There are several definitions in subdivision 1 for which clarification would be necessary or useful to understand reporting responsibilities. We address those definitions below in the order in which they appear in subdivision 1.

Air care product. The regulations should clarify that the term "air care product" is limited to formulated chemical products and does not include air filters, air purifying devices, or similar articles.

Durable houseware items. The Agency should provide a definition for "durable houseware items" or otherwise clarify the definition of "cookware." In particular, the regulations should

[7] *See* 88 Fed. Reg. 70516 (October 11, 2023).

clarify that the term "cookware" does not include household appliances such as refrigerators, ranges, microwaves, air fryers, and other types of countertop electrical appliances. More generally, the regulations should include a complete list of articles that are "cookware" rather than providing only an illustrative list of covered products. These clarifications are necessary to help ensure that the scope of the prohibition is clear and unambiguous.

Carpet or rug. The Agency should clarify in regulation that "carpet or rug" means a fabric floor covering "intended for use in a building." Carpeting used in automobiles, airplanes, and non-building applications should not be included.

Currently unavoidable use. Clarification is needed for several of the concepts embedded within the definition of "currently unavoidable use" as described below.

> **Essential for health, safety, or the functioning of society.** An "essentiality" assessment should only be initiated when there is deemed to be a risk to human health or the environment from the use of an intentionally added PFAS in a product. On this point, we reiterate that fluoropolymers have been demonstrated to satisfy internationally accepted criteria for being polymers of low concern.[8] If there is no concern about risk during the use of an intentionally added PFAS in a product, such as a fluoropolymer, valuable Agency time and resources should not be wasted on an essentiality analysis. Neither should residents of Minnesota be denied access to a myriad of products important to their daily lives simply because those products contain polymers of low concern.
>
> More generally, as illustrated by the following examples, the concept of essentiality must be interpreted broadly in order to be workable. Under a narrow interpretation of "essentiality" it may be argued that products such as cell phones, laptop computers, or automobiles are not "essential to the functioning of society" since society can continue to function without these conveniences. But this narrow, and in our view inappropriate, interpretation fails to properly account for the fact that these types of products are highly beneficial and are an ***essential feature*** of our society. Similarly, under a narrow interpretation of "essentiality" it could be argued that products such as refrigeration units are not "essential to health" since people can live healthy lives without refrigeration. However, this narrow interpretation ignores the critical role that refrigeration plays in supporting good health by preventing food spoilage and preserving pharmaceuticals. These are a few examples of the types of products that, if they became unavailable, would cause massive social and economic dislocation. To avoid this type of disruption we strongly urge the Agency to adopt a broader interpretation of essentiality.
>
> Finally, we urge the Agency to take notice of a report recently issued by the Department of Defense (DOD), highlighting the criticality of certain PFAS chemistries across a broad

[8] *See* notes 3 and 4.

swath of applications of strategic and national importance.[9] Based on an extensive survey of known uses of PFAS chemistries, DOD concluded as follows (emphases added):

> ***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**. DoD relies on an innovative, diverse U.S. industrial economy. **Most of the structurally defined PFAS are critical to the national security of the United States, not because they are used exclusively in military applications (although a few are) but because of the civil-military commonality and the potentially broad civilian impact**.[10]*

DOD went on to warn that:

> *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.*[11]

In developing regulations interpreting the concept of "currently unavoidable use" the Agency should heed DOD's warning and ensure that the term is interpreted broadly enough to encompass uses of PFAS that are critical to national infrastructure and supply chains.

Alternatives. The Agency should clarify that an "alternative" to PFAS means a chemical or non-chemical substitute that: (i) provides performance at least equivalent to the performance of the PFAS to be substituted; (ii) has been demonstrated to present lower risks to health and the environment than the product manufactured with PFAS; and (iii) is both technologically and commercially feasible.

Reasonably available. The Agency should provide a detailed definition of "reasonably available" that specifies the types of criteria that will be assessed to determine reasonable availability. In particular, the definition should help ensure that alternatives

[9] US Department of Defense. Report on Critical Per- and Polyfluoroalkyl Substance Uses. August 2023. *Available at* https://www.acq.osd.mil/eie/eer/ecc/pfas/docs/reports/Report-on-Critical-PFAS-Substance-Uses.pdf
[10] Id. at 15.
[11] Id.

are considered to be "reasonably available" only if they can be implemented at scale, at a cost that is comparable to the substance or product being replaced. The definition should also account for performance, safety, and supply chain considerations as well as regulatory restrictions or requirements that may otherwise impede availability.

Manufacturer. We are concerned that the definition of "Manufacturer" does not account for the way goods are bought, sold, and distributed, either through traditional or on-line markets. 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. 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.

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 statutory definition, both Company A (the brand owner) and Company B (the producer of the product) would be "manufacturers" with reporting obligations for the same product.

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 the State of Minnesota. Company A may not sell its product to purchasers in Minnesota, but, unbeknownst to Company A, the out-of-state distributor may sell 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 statutory definition, even though Company A has no idea that its product is being sold in the State. This is not an uncommon scenario. The same is true for sales made through on-line platforms where the original manufacturer is not the entity fulfilling the sale of the product into Minnesota. Products sold to members of the public through on-line platforms can come from anywhere, and the original manufacturer has little to no control over that sale or the ability to get sales information through such channels.

As these examples illustrate, the definition in the statute 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 a manufacturer that does not know its product is being sold in Minnesota. To address this concern, the regulations 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 ensure that there will be no "double counting" of products sold or offered for

sale. To further improve the accuracy of the information reported, the Agency should consider allowing joint submissions by the entity that first sells a product (or offers to sell a product) in Minnesota (i.e., the entity that knows the product is sold or offered for sale in Minnesota) and the entity that produces the product (i.e., the entity that may be more familiar with the chemical composition of the product).

Product. The Agency should clarify that the scope of products covered by the reporting requirement is limited to items intended for use by consumers and does not extend to products intended solely for industrial or commercial use. Also, the Agency should clarify that the definition applies to "items . . . for sale to consumers **in Minnesota.**"

2. Are there terms or processes in subdivision 2 for which clarifications will help reporting entities determine reporting status or data-gathering process?

There are terms or processes in subdivision 2 for which clarification will help reporting entities determine reporting status or the data-gathering process. We address those terms and processes below in the order in which they appear in subdivision 2.

Amount of each PFAS. Subdivision 2 calls for reporting of "the amount of each PFAS, identified by its chemical abstracts service registry number." Substances listed on the TSCA Inventory should be reported using the same identifier listed on the non-confidential Inventory. The Agency should allow the use of EPA-assigned Accession numbers, which are used for proprietary chemicals with CAS numbers that are federally protected as confidential business information and for which the manufacture can substantiate both the need for ongoing protection to sustain a commercial advantage and steps the manufacturer takes to maintain confidentiality. Pre-manufacture notice (PMN) numbers should also be an option. Also, some fluoropolymers do not have CAS numbers, and the Agency should clarify how manufacturers should report PFAS that do not have a CAS number, if at all.

Commercially available analytical method. Analytical methods must be appropriate for the specific PFAS compounds that are the target of the analysis and for the physical form of the product (e.g., gas, liquid, or solid). To create an even playing field, the Agency should elaborate in proposed regulations its intention regarding baseline criteria or performance standards for acceptable analytical methods. It would be inappropriate in our view for the Agency to allow the use of any method that any commercial lab says it can perform on any product matrix without due consideration of whether the method is fit for purpose, has undergone standard multi-laboratory validation, or has otherwise been assessed for the purpose for which it is being used (i.e., accuracy, precision, specificity, detection limit, and quantification limit). Doing so would be well outside the realm of good regulatory science. To help assure the validity and reliability of information reported under the regulations, it is essential that the Agency incorporate the concept of validation into its regulatory explanation of what "commercially available analytical methods" will be acceptable.

Finally, it is critically important for the Agency to recognize that the vast majority of commercial PFAS compounds are proprietary chemicals for which there are no commercially

available analytical methods. Moreover, without analytical standards for these proprietary chemicals, commercial laboratories will not be able to develop analytical methods. As a result, it will be impossible for manufacturers of products containing these PFAS chemistries to comply with the requirements of subdivision 2 of the statute unless the Agency permits product manufacturers to report on the quantity and identity of PFAS in their products based on information provided by their suppliers of PFAS-containing components, rather than requiring testing which, in the vast majority of cases, product manufacturers will be unable to perform. For example, consider the following scenario. Company A manufactures a PFAS-containing component such as a gasket, which is sold to the manufacturer of an engine sub-assembly (Company B) located outside the State of Minnesota. The sub-assembly may be sold to another company located outside of Minnesota (Company C), which incorporates the sub-assembly into a finished complex article such as a tractor. As the manufacturer of the tractor and the company that offers the tractor for sale in Minnesota, Company C bears responsibility for reporting on the PFAS content of the tractor. Rather than requiring Company C to test all of the gaskets, hoses, and electrical wiring in the tractor to determine their PFAS content, Company C should be allowed to rely on PFAS content information provided by their supplier, Company B. For similar reasons it is essential for the Agency to establish approved reporting ranges. See also our comment immediately below concerning the phrase " information required."

Information required. Regarding the amount of each PFAS in a product sold, offered for sale, or distributed in the state, the Agency should allow reporting entities to report based on documentable information obtained from suppliers. Doing so would significantly reduce the reporting burden.

Range approved for reporting purposes. The ranges approved for reporting purposes, including any de minimis thresholds, should be codified in regulation well in advance of the first reporting deadline so that manufacturers with reporting obligations can prepare accordingly. We recommend that the Agency not develop ranges for different types of products. Doing so would create unnecessary confusion about the definition of products falling within each range and further complicate the ability of manufacturers with reporting obligations to report accurately and in a timely manner.

Significant change. The phrase "significant change" needs to be defined in regulation so that a manufacturer does not unknowingly violate the Agency's expectations when, in the manufacturer's legitimate view, only minor changes have been made to a product.

Standard for reporting. As discussed earlier, EPA has finalized a comprehensive reporting and record keeping rule for all PFAS compounds manufactured in the United States under Section 8(a)(7) of the Toxic Substances Control Act. Under this regulation, manufacturers subject to the rule must report required information to the extent that information is "known or reasonably ascertainable by" the manufacturer.[12] We strongly urge the Agency to adopt such a

[12] 40 CFR 710.23 "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

standard for this rule, especially since manufacturers, particularly manufacturers of complex articles, will be responsible for reporting information on components that may be incorporated into their product through a multi-tiered global supply chain. Notably, the federal standard does not create an obligation for novel testing, which would significantly reduce the burden for reporting and bring it into the realm of what is feasible. Aligning with existing federal regulations avoids a patchwork of conflicting regulation and reduces the burden for those entities already subject to the federal reporting rules.

3. How should the MPCA balance public availability of data and trade secrecy as part of the reporting requirements?

Minnesota's program would require manufacturers to disclose sensitive proprietary information about the specific chemical identities, functions, and amounts of PFAS in their products. Manufacturers derive independent economic value from this information and take the necessary steps to protect such information since, without such protection, manufacturers would be placed at a competitive disadvantage and their investments in innovation would be undermined. Given that fluoropolymers are essential to products in vital economic sectors such as electronics, energy, transportation, construction, and healthcare, including medical devices, inadequate protection could compromise national competitiveness, security, and infrastructure. In addition, manufacturers that are unable to assure the protection of their intellectual property in the State of Minnesota may choose to avoid the Minnesota market, which would inevitably result in Minnesota residents and businesses being deprived access to innovative products and technologies.

The concept of a "trade secret" is well established in Minnesota law and is defined in the Minnesota Uniform Trade Secrets Act as follows:

> *"Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process, that:*
>
> *(i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and*
>
> *(ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.*[13]

This definition of "trade secret" appears in the definition of "trade secret information" in the Minnesota Government Data Practices Act,[14] which requires that trade secrets be treated as general nonpublic data by Minnesota agencies. "Nonpublic data" is defined as "any government

to possess, control, or know." *See* 76 Fed. Reg. 50829 (August 16, 2011) for EPA's detailed explanation of the standard in the context of the TSCA Chemical Data Reporting Rule.

[13] Minnesota Statutes § 325C.01, subdivision 5

[14] Minnesota Statutes § 13.37 (General Nonpublic Data)

data classified by statute, federal law, or temporary classification as confidential, private, nonpublic, or protected nonpublic."[15] Furthermore, Minnesota Statutes § 115.A.06 states that:

> *(a) Any data held by the commissioner which consists of trade secret information as defined by section 13.37, subdivision 1, clause (b), or sales information, shall be classified as private or nonpublic data as defined in section 13.02, subdivisions 9 and 12. 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.*

Some types of proprietary information the Agency will request derive independent economic value and are the subject of efforts to maintain its secrecy. Such information may also be recognized as confidential by federal or other state agencies, and trade secrets that are inadvertently disclosed may compromise national security and infrastructure. Therefore, in the proposed rule, the Agency must provide clear instructions regarding the specific steps that must be taken to officially assert and/or substantiate a trade secrets claim for information submitted that qualifies as a trade secret under Minnesota law, including the timeline by which such claims must be made relative to the reporting deadlines.

The Agency also should define in regulation a process whereby a manufacturer is to be notified if its trade secret is subject to a public records request or is inadvertently disclosed by the Agency or any organization with which the Agency collaborates or contracts in the administration of the reporting program, including other states and any organization that designs, operates, or otherwise administers the reporting platform. The Agency should not enter into data sharing agreements with any organization, including but not limited to other states, if the Agency cannot assure that those organizations possess equivalently protective policies for trade secrets submitted to Minnesota. As we have previously noted in comments to the State of Maine, we are particularly concerned about how commercially valuable trade secret information will be managed by the Interstate Chemicals Clearinghouse (IC2) of which the Agency is a member.

[15] Minnesota Statutes § 13.02, subdivision 8a

4. Are there any terms used in subdivision 3 that should be further defined or where examples would be helpful?

There is a term used in subdivision 3 that should be further defined and for which examples should be provided.

Substantially equivalent information. The authorizing statute clearly gives the Agency authority to "waive all or part of the notification requirement under subdivision 2 if the commissioner determines that substantially equivalent information is already publicly available." The Agency should define in proposed regulations what it will consider "substantially equivalent information."

In addition, with respect to paragraph (c) of subdivision 3, the Agency should make clear in its regulations that, prior to entering into any agreement to share reported information, the Agency will assure that confidential business information will be protected by all parties to the agreement to the same extent, or greater, than such information is protected in Minnesota.

5. Are there specific portions of the reporting process that should not be defined through guidance or the development of an application form?

No part of the reporting process should be defined through guidance. Guidance may be a useful tool for providing illustrative examples, but its value is otherwise limited. The Agency must establish a clear and concise explanation of expectations and procedures in regulations so that subject manufacturers have regulatory certainty and an ability to comply with the Agency's rules. No regulatory obligation dictated by a "shall" statement in the statute or that concerns the protection of trade secrets should be left to guidance. Such requirements must be articulated in regulation.

We do not understand the part of the question about an application form. We do not know what an application form is or what the Agency anticipates a manufacturer to be potentially applying for. We would appreciate additional clarity from the Agency; however, as a general principle, an application form should not be used to establish new definitions not otherwise specified in regulation unless the application form itself is developed and vetted through a notice and comment process.

6. Other questions or comments relating to reporting or the process of reporting.

Reporting database. As the Agency is certainly aware, it will receive notifications for hundreds of thousands of products (if not more) from all sectors of the economy. We understand that the Agency may be considering utilizing a reporting tool and database being developed by the Interstate Chemicals Clearinghouse (IC2). However, we have serious concerns about the ability of the IC2 reporting tool to manage this task since, as far as we are aware, IC2 has not previously developed a reporting system of this scope and magnitude. Consequently, it will be essential that the Agency take whatever measures are necessary to build in a beta testing phase to help ensure that the IC2 system (or whatever system is utilized

by the Agency) is sufficiently robust to manage the number of users and volume of information anticipated, sufficiently flexible to allow for reporting of information that may not conform to a particular format contemplated by the Agency, and sufficiently protective of trade secrets claims (see our response to question #3 above). The Agency's rules should not become effective until the IC2 system has successfully completed beta testing.

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Thank you for the opportunity to provide these comments. Please contact me if you have any questions.

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November 28, 2023

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: SEMI's Comments on the MPCA's Planned Rulemakings for PFAS-Containing Products

Dear Commissioner Kessler:

On behalf of SEMI, the industry association serving the global semiconductor design and manufacturing supply chain, we write to offer comments on the regulations on per- and polyfluoroalkyl substances (PFAS) being developed by the Minnesota Pollution Control Agency (MPCA or the Agency), as authorized in Minn. St. § 116.943 (Section 116.943). These comments discuss the MPCA's planned rules concerning PFAS reporting and the fees associated with reporting.[1] We also discuss preliminary considerations for any future rulemakings to implement Section 116.943's PFAS restriction in products, on which we understand the MPCA plans to issue a specific request for comments in the future.

SEMI represents more than 530 member companies in the United States reflecting the full range of the country's semiconductor industry, including design automation and semiconductor intellectual property (IP) suppliers, device manufacturers, equipment makers, materials producers, and subcomponent suppliers. SEMI member companies are the foundation of the $2 trillion global electronics industry, and this vital supply chain supports 350,000 high-skill and high-wage jobs across the United States.

While SEMI fully supports the goal of limiting the release of PFAS into the environment, SEMI has serious concerns about the potential scope of these regulations as well as their incompatibility with the 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. As such, SEMI has provided specific recommendations in these comments to inform future rule drafting in a way that would avoid irreparable harm to the semiconductor manufacturing industry in Minnesota. In summary, SEMI requests that the MPCA:

- Grant a reporting waiver for any product, product components, materials, or semiconductor manufacturing and related equipment, its supporting ecosystem, and other microfabricated

[1] The MPCA released separate requests for comment on the planned new rules concerning PFAS reporting and PFAS reporting fees, each with their own submission links on the Minnesota Office of Administrative Hearings website. Given the interrelatedness of these two topics, SEMI has submitted these combined comments under both links.

products that utilize semiconductor-like manufacturing processes, since sufficient information on these PFAS uses is publicly available;

- Include reportable PFAS concentration ranges directly in the reporting rule, in order to facilitate regulation at a level that is manageable for both affected companies and the MPCA;
- Expressly incorporate in the reporting rule the U.S. Environmental Protection Agency's (EPA's) "known to or reasonably ascertainable by" standard that allows notifying entities to rely on supplier declarations, and to limit the scope of investigation that manufacturers would be expected to undertake with respect to upstream suppliers;
- Include with the reporting rule a robust system for the protection of confidential business information (CBI) and trade secrets;
- Assess reporting fees on a per-company level and decline to assess additional fees for updates to reported information; and
- In the future rulemaking concerning the PFAS restriction, make a currently unavoidable use designation for any product, product component, material, or semiconductor manufacturing and related equipment, its supporting ecosystem, and other microfabricated products that utilize semiconductor-like manufacturing processes. This is necessary given the lack of currently available PFAS alternatives in these products and the irreparable harm that will come if semiconductors must be removed from the Minnesota market when the material restriction takes effect.

1. WITHOUT CAREFUL DRAFTING, THE RULES WILL DAMAGE CRITICAL INDUSTRIES AND THE HIGH-TECH ECONOMY

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. 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 (pipes, pumps, valves, etc.);
- Various types of processing tools;
- Equipment (such as tubing, gaskets, containers, and filters);
- Lubrication (such as 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.

In short, the semiconductor manufacturing process is enormously dependent on PFAS, the majority of which currently have no viable alternatives.

b. The Semiconductor Industry is a Crucial Part of Minnesota's Economy That 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 and that manufacturer has received notification of MPCA-ordered testing under subdivision 4. 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.[2] Minnesota-based companies annually export over $1.2 billion in semiconductor-related components and import nearly $575 million in semiconductor-related components.[3] According to the Minnesota Department of Employment and Economic Development, the state's semiconductor and other electronic manufacturing sector includes 153 firms supporting 9,588 jobs with an average annual wage of $68,692.[4]

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 MPCA's planned rules 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 planning to invest 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, will be rendered unusable for one of its original purposes.

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 continue to impact global supply chains for several key industries and have highlighted the country's dependence on overseas suppliers of semiconductors and chips. Addressing these shortages has been one of the most

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[2] 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/#:~:text=Minnesota%27s%20companies%20annually%20export%20over,Engineering%20Research%20Associates%20in%20St.

[3] *Ibid*.

[4] Minnesota DEED, Industry Snapshots: Computer and Electronic Product Manufacturing (June 2019), https://mn.gov/deed/newscenter/publications/review/june-2019/industry-snapshots.jsp.

bipartisan issues at the federal level with the Biden Administration and Congress working together to incentivize the reshoring of semiconductor and chip manufacturing to the United States.

In August 2022 Congress passed and the President signed the bipartisan *CHIPS and Science Act*. The goals of this law, which is focused on supporting domestic semiconductor manufacturing, are multifaceted. 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.

As part of the implementation of this law, Representative Betty McCollum (D-MN) and U.S. Senate Majority Whip Dick Durbin (D-IL) made the following remarks in a letter[5] to Secretary of Commerce Gina Raimondo:

> *Over decades of use, PFAS have been widely integrated into our modern society and in many cases, there are not currently any viable replacements for their function. These 'essential uses' are vital to our economic and national security, particularly in regard to their use in semiconductor manufacturing . . .*
>
> *. . . The CHIPS and Science Act provides a unique opportunity for the Commerce Department to engage and invest in tackling the issue of PFAS essential uses. This monumental legislation has set the U.S. on a course to onshore semiconductor manufacturing and continue to lead the world in advanced technology development and production . . . it is vitally important that [the National Semiconductor Technology Center] priorities include research into PFAS alternatives, as well as recycling, removal, and destruction of these harmful materials.*

More recently, the U.S. Department of Defense weighed in on the issue of PFAS in its Report on Critical Per- and Polyfluoroalkyl Substance Uses.[6] 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.*

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[5] Letter from Rep. Betty McCollum and Senator Dick Durbin to Secretary Raimondo (May 22, 2023), https://mccollum.house.gov/sites/evo-subsites/mccollum.house.gov/files/evo-media-document/23.05.22-commerce-letter-support-pfas-alternatives-research-in-chips-act-implementation-mccollum-durbin.pdf.

[6] 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.

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.

This federal effort recognizes 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 of 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.

Unfortunately, unless carefully planned in light of these comments, the MPCA rules will run counter to the bipartisan effort to improve U.S. competitiveness in semiconductor and microchip development by adding costly and largely impracticable reporting requirements and material restrictions for PFAS in the semiconductor manufacturing process and in components of nearly all commercial and consumer electronic goods. The planned rule should be designed to avoid these consequences, as explained further below.

2. COMMENTS ON THE REPORTING RULE

a. Responses to General Request for Comment

i. The MPCA Should Grant a Reporting Waiver for Semiconductors, Since Reportable Information in these Products is Publicly Available

SEMI requests that the MPCA grant a waiver from all parts of reporting via subdivision 3(a) in Section 116.943 for any product, product components, materials, or semiconductor manufacturing and related equipment, its supporting ecosystem, and other microfabricated products that utilize semiconductor-like manufacturing processes.

Subdivision 3(a) provides that the MPCA may grant a reporting waiver if "substantially equivalent information is already publicly available." This is the case for the semiconductor industry. SEMI submits that the reportable information required under subdivision 2 as it relates to PFAS in semiconductors is found in technical papers that the Semiconductor PFAS Consortium (the Consortium) makes freely and publicly available on its website.[7] This reportable information, as described in detail in the Consortium technical papers, includes:

[7] Semiconductor PFAS Consortium Technical Papers, *available at* https://www.semiconductors.org/pfas/#:~:text=AND%20SEMICONDUCTOR%20PROCESSING%20%3E-,Technical%20Papers,-The%20Semiconductor%20PFAS.

- Descriptions of semiconductor industry chemicals and equipment (i.e., "the products");
- An outline of how PFAS is used in the semiconductor industry; and
- Detail on the amount of PFAS used in the semiconductor industry.

Requiring separate and distinct reporting by the semiconductor industry to the MPCA is unnecessarily duplicative of the Consortium's efforts. This industry work is also going beyond reporting basic information and has started publishing PFAS release mapping papers to identify the industry's impacts.[8]

b. **Responses to Specific Questions from the MPCA Regarding the Reporting Requirements**

i. Are there terms or processes in subdivision 2 for which clarifications will help reporting entities determine reporting status or data-gathering process?

Section 116.943 empowers the MPCA to determine a PFAS concentration range for the purposes of fulfilling reporting requirements. SEMI supports this approach because there is no commercially available methodology for identifying an exact quantity of PFAS. As part of this rulemaking, the MPCA should specify concentration ranges for all PFAS or groups of PFAS subject to notification. Failure to do so will add to the already excessive notification burden on the regulated community. The MPCA should determine and add the notification ranges to the draft before the rulemaking process is finalized. These concentration ranges should be harmonized with those enacted by EPA under its PFAS reporting rule for articles (but with an exclusion for products containing less than 0.1% PFAS):

- 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.

See 88 Fed. Reg. at 70556 (Oct. 11, 2023) (Table 3).

SEMI also recommends that the MPCA expressly incorporate EPA's "known to or reasonably ascertainable by" standard that allows notifying entities to rely on supplier declarations, and to limit the scope of investigation that manufacturers would be expected to undertake with respect to upstream suppliers. EPA has applied this standard for years in its *Toxic Substances Control Act* (TSCA) Chemical Data Reporting Rule and recently extended its use to its PFAS reporting rule. *See, e.g.*, 40 C.F.R. § 711.15; 88 Fed. Reg. 70516. The MPCA should mirror this standard to prevent a reporting scheme that is broader than EPA's PFAS reporting rule and is therefore more expensive to implement than EPA's $843 million estimate for the compliance costs associated with its rule. *See* 88 Fed. Reg. 70516. In addition, companies that manufacture semiconductors and semiconductor equipment and materials, including those operating in Minnesota, share numerous common chemical suppliers. There is a significant efficiency advantage to limiting the scope of due diligence to EPA's "known to or reasonably

[8] *Id*. (click "Download all 7 PFAS Release Mapping Papers").

ascertainable" standard in order to prevent burdensome and duplicative outreach by manufacturers to these suppliers.

ii. How should the MPCA balance public availability of data and trade secrecy as part of the reporting requirements?

It is currently unclear how, practically, a reporting entity could assert a CBI claim or trade secret under the planned reporting rule, or how that protection would be executed by the MPCA. A well-defined CBI framework for all notification and future rulemaking (e.g., for future exemptions) will be essential for the protection of valuable IP that might otherwise be jeopardized.

Semiconductor production, as well as the advanced manufacturing and technology sectors in general, treat the chemical composition of materials as proprietary information that is carefully protected and of significant commercial value. The planned reporting rule, therefore, needs to include detailed provisions about how such information can be reported (1) while respecting its status as CBI and trade secret; (2) in an aggregated manner to protect confidentiality while still providing for public release of nonconfidential portions; (3) through a system with clear standards on what information will be kept confidential; and (4) with assurances on how such confidential information in the MPCA's possession will be protected from disclosure. Information that requires careful protection would include, for example, the identity of any PFAS present in a product, the volume and concentration of such a substance, and any information relating to sales volumes or production volumes.

Further, the reporting rule should clarify to what degree the MPCA is allowed to share any data provided to it with other Minnesota government agencies, other states, and with the federal government. SEMI recommends that because the underlying goal of reporting is related to understanding and addressing the release of PFAS, the MPCA should be the only state agency with access to the information shared under these rules. If instead there is a desire for broader government access, the MPCA should require that whatever restrictions are placed on it regarding public dissemination of data equally applies to any other governmental entity receiving said data.

In addition, the MPCA should permit the use of generic chemical names or ranges instead of CAS numbers in any information that is made available to the public. SEMI recommends that the MPCA refer, for example, to EPA's recently finalized rule to centralize CBI claims under TSCA as a model for its own rules. See 88 Fed. Reg. 37155 (Aug. 7 ,2023). At a minimum, the MPCA's CBI procedures should include:

- A clear statement that reporting entities may assert a confidentiality claim for information at the time of its submittal, and that information claimed as confidential in accordance with the procedures will be treated as confidential and protected from release by the MPCA to the full extent allowed by Minnesota's *Government Data Practices Act*; and
- A provision setting out specifically what measures should be included to substantiate a claim of confidentiality (such as, for example, a certification by an appropriate company official, a requirement to mark and identify information claimed as confidential, confirmation that the submitter has taken steps to protect the confidentiality of information claimed as confidential and that its release will cause harm to the company's competitive position).

3. **RESPONSES TO SPECIFIC QUESTIONS ON THE REPORTING FEES RULE**

a. **Should the Agency consider a per-product or per-company fee?**

The MPCA should assess fees per company instead of by individual product. If the semiconductor industry is not provided a reporting waiver as discussed above, many companies in the industry will have to report various different products. Requiring a fee for each individual product would be tedious for reporting companies to pay and for the MPCA to process.

b. **Should the Agency consider a per-PFAS or PFAS amount fee?**

SEMI recommends that the MPCA assess fees on a per-company level as discussed above, rather than on a per-PFAS or PFAS amount basis. This will consolidate fees to a manageable level for both reporting companies and the MPCA, and it will avoid an overly complicated assessment of the individual fees that should be contributed to which PFAS amounts.

c. **Are there other state program fee structures on which the Agency should model the fees?**

The MPCA should harmonize its reporting rule and reporting fees with those being implemented by other states (e.g., Maine Department of Environmental Protection, unless the Maine statute is amended). This will prevent a jurisdictional patchwork of different reporting schemes from forming, and it will also ease the burden of the MPCA having to create its own reporting scheme from scratch.

d. **Should the Agency consider a fee to be paid when updates to information on previously reported products are submitted? (e.g., decreased amounts or elimination of one or more PFAS)**

SEMI recommends that an additional fee not be assessed when a company is required to update their reported information. This could disincentivize updates, and it would contribute to an overly complicated fee scheme.

4. **PRELIMINARY COMMENTS ON THE FUTURE PFAS RESTRICTION RULE: SEMICONDUCTORS SHOULD BE EXEMPT AS THEY REPRESENT A CURRENTLY UNAVOIDABLE USE OF PFAS**

SEMI understands that the MPCA plans to issue a separate request for comments regarding rules to implement Section 116.943's material restriction provisions. However, to facilitate proactive discussion for that future rulemaking, SEMI provides its preliminary comments on that future rulemaking here.

Section 116.943, subdivision 5(c) prohibits the sale, offer for sale, and distribution for sale in Minnesota of any product that contains intentionally added PFAS, starting January 1, 2032, unless the MPCA has determined that the use of PFAS in the product is a currently unavoidable use. SEMI requests that the MPCA make this currently unavoidable use designation for any product, product components, materials, or semiconductor manufacturing and related equipment, its supporting ecosystem, and other microfabricated products that utilize semiconductor-like manufacturing processes.

a. **Semiconductors and Related Products Meet the Statutory Definition of Currently Unavoidable Use**

The term "currently unavoidable use" is defined in statute 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." Semiconductors and related products constitute a currently unavoidable use of PFAS as these products, including the PFAS that they contain, are essential to a variety of economic sectors, including healthcare and safety, and are indispensable for the functioning of society. The critical need for and importance of semiconductors is readily apparent in the *CHIPS and Science Act*.[9] The industry has also sought to emphasize the challenges associated with developing suitable PFAS alternatives, including through the comments that SEMI submitted on the European Union's proposed restrictions on the manufacture, placing in market, and use of PFAS,[10] as well as through technical papers from the Semiconductor PFAS Consortium mentioned above.

b. **The Industry Will Not Be Able to Comply with the 2032 Ban without Incurring Irreparable Damage**

The semiconductor industry understands the concern regarding PFAS. Industry members are developing strategies to reduce dependence on PFAS, particularly PFAS that are persistent, bioaccumulative, and toxic. This can only be accomplished by ensuring the existence of a robust supply chain framework that can introduce alternative materials where possible and simultaneously adapt to regulatory changes and supply chain risks. Further, the 2032 prohibition is not feasible for the semiconductor industry due to its developmental timeframes. Even if fundamental challenges to the development of alternatives can be overcome by 2032 (which they will not), the timeline to implement these new chemistries at scale could be on the order of 15 or more years. Given these constraints, the semiconductor industry will have to exit Minnesota by 2032, causing permanent damage to the state's economy due to lost jobs and the lack of semiconductors to support a wide range of technologies in Minnesota.

5. COMMENTS ON FACILITATING PRODUCTIVE ENGAGEMENT WITH INDUSTRY

SEMI appreciates the MPCA's proactive outreach to the regulated community in advance of issuing draft rules and encourages the Agency to maintain this approach going forward. Engaging interested stakeholders from the outset through listening sessions, webinars, and other venues will afford them the opportunity to inform the MPCA's rulemaking activities in a way that empowers the Agency to meet its regulatory mandates while more effectively ensuring the long-term viability and competitiveness of the affected industries.

Building on these early-stage engagement activities, SEMI recommends that the MPCA institutionalize the communication stream between itself and its regulated industries. One way to accomplish this would be through the creation of a workgroup, comprised of stakeholder representatives, which would inform the drafting and implementation of the planned rules, further examine affected products, and identify ways to ease administrative burdens without sacrificing the public health and environmental imperatives that prompted passage of Section 116.943 in the first place.

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[9] *See, e.g.*, U.S. House of Representatives Committee on Science, Space, & Technology, CHIPS and Science Act information webpage, https://democrats-science.house.gov/chipsandscienceact.

[10] SEMI Europe, Comments on Proposed PFAS Restriction under REACH (May 26, 2023) (starting on page 51 of linked document), https://echa.europa.eu/documents/10162/17233/rest_pfas_rcom_part13_en.docx/5e750ee1-0541-fe43-8272-851fcbf75c4e?t=1686824437443&download=true.

6. **CONCLUSION**

SEMI is committed to balancing the need for environmental protection and the sustainability of semiconductor manufacturing operations, which is a complex challenge. SEMI welcomes the opportunity to engage with the MPCA to better explain the critical role that these substances have in the semiconductor manufacturing process.

SEMI is grateful for the opportunity to engage on the MPCA's planned rulemakings and is 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).

Sincerely,

Ben Kallen
Senior Manager, Public Policy & Advocacy
SEMI

Together, improving life

November 28, 2023

Minnesota Pollution Control Agency
Resource Management and Assistance Division
Office of Administrative Hearings Rulemaking eComments Website
https://minnesotaoah.granicusideas.com/

RE: 39507 Minnesota Pollution Control Agency Request for Comments on PFAS in Products Reporting Rule (R-4828)

W. L. Gore & Associates, Inc. (Gore) is submitting the following comments with regards to the request for "comments on planned new rules for fees to be paid upon submission of required information about products containing PFAS", Revisor's ID Number R-4827.

About Gore

Gore is a U.S.-based materials science company with more than 13,000 Associates globally, including 8,800 in the United States. Founded in Delaware in 1958, Gore solves complex technical challenges in the most demanding environments – from the inner workings of the human body - to the world's highest peaks - to outer space, the moon, and mars. With a team-oriented culture, our promise is "Together, improving life."

To make our products, Gore uses fluoropolymers which are a sub-category of PFAS with distinct characteristics. We have over six decades of experience leveraging the unique properties of PTFE (polytetrafluoroethylene) and other fluoromaterials to invent valuable products including:

- implantable medical devices such as vascular grafts and stents;
- components for use in aircrafts, automobiles, mobile phones and computers;
- protective apparel for first responders;
- filters, seals and vents that protect consumers from hazardous chemicals;
- environmental controls which reduce emissions from power generation and industrial processes; and,
- products used in the manufacture of pharmaceuticals.

Request for Comments

Gore submits the following comments in response to the below questions (in bold) which were included in the "Minnesota Pollution Control Agency Request for Comments on PFAS in Products Reporting Rule", Revisor's ID Number R-4828.

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1) Are there definitions in subdivision 1 for which clarification would be useful to understanding reporting responsibilities?

(j) "Currently unavoidable use" *" means 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.*

COMMENT: More clarity is needed regarding the criteria on which "currently unavoidable use" determinations will be made. In particular, the Agency should define **"essential for health, safety, or the functioning of society" and "reasonably available".** Defining these criteria will allow a process in which the Agency will evaluate whether the use of a certain PFAS constitutes a "currently unavoidable use." Critically, such a process must adequately allow manufacturers to confidently plan their product strategy, initiate research and development and invest in products used for the health, safety and functioning of society.

There are three main aspects that should be considered in the determination of a "currently unavoidable use": (1) the value of the finished product to society (e.g., critical infrastructure products have high value); (2) the function of the PFAS in the product (e.g., fluoropolymers provide necessary chemical or temperature resistance); and (3) the presence of reasonably available alternatives for those PFAS providing important functions to high value products.

The determination of whether a product is **"essential for health, safety or the functioning of society"** should address, at a minimum:

1. A Risk-based approach to determination of "essentiality".
    - Exempt PFAS, that meet the Organisation for Economic Co-operation and Development (OECD) criteria for Polymers of Low Concern (PLCs), from having to make a demonstration of essentiality or ensure that the threshold for what is determined to be essential is defined relative to the hazard. In other words, a low hazard PFAS/use should have a lower threshold to demonstrate that it is essential and currently unavoidable, in order to mitigate against an all-or-nothing approach, exclude low risk products from a potential ban and preserve the ability to continue to innovate where risk is appropriately identified and managed.
    - The low hazard profile and the unique combination of properties demonstrated by fluoropolymers support a presumption that there is no alternative material that will meet the technical requirements with a lower risk profile. Please see the attachment "W. L. Gore & Associates' Comments on Dossier Submitters' Draft EU REACH Restriction on PFAS"[i] for a more in-depth description of the properties of fluoropolymers.
2. Products serving sectors of the economy identified as "critical infrastructure" pursuant to the Cybersecurity & Infrastructure Security Agency (CISA) should

be deemed essential.[1] CISA, which is the national coordinator for critical infrastructure security and resilience, identified "sixteen critical infrastructure sectors whose assets, systems, and networks, whether physical or virtual, are considered so vital to the United States that their incapacitation or destruction would have a debilitating effect on security, national economic security, national public health or safety, or any combination thereof."[2] Products whose functions are intended to serve or maintain these critical infrastructure sectors should be determined to be essential for the health, safety or the functioning of society.

3. Publication of the process and criteria for determination of "essential" for all other products and sectors, including an opportunity to appeal such determination by the Commissioner. In addition, it would be extremely helpful if the Commissioner published a list of such products or product categories that it deems high value and provides an opportunity for public comment before finalization of such list.

4. The opportunity for innovation to enable new products which address critical societal needs.

The determination of whether an alternative is **"reasonably available"** (evaluation of current alternatives) should be risk-based and consider the following criteria, at a minimum:

1. Whether performance of the alternative product meets or exceeds the performance requirements of the end use application.

2. Whether alternatives increase human health and environmental impacts, including whether the alternative must be more frequently replaced and disposed of as waste. Specifically, the Agency should consider the hazard of the PFAS, the use of PFAS in the product as well as conditions or controls in place that determine the potential for exposure and risk. These factors should also be considered for the proposed alternative and the outcomes compared – if the alternative has a risk profile that does not represent an improvement (for example the chemistry has a higher hazard profile than the incumbent PFAS, or more is used which increases exposure potential, etc.) then the alternative is not a reasonable one, even if it is available.

[1] Presidential Policy Directive 21 (PPD-21): Critical Infrastructure Security and Resilience advances a national policy to strengthen and maintain secure, functioning, and resilient critical infrastructure. https://www.cisa.gov/topics/critical-infrastructure-security-and-resilience/critical-infrastructure-sectors

[2] Presidential Policy Directive 21 (PPD-21): Critical Infrastructure Security and Resilience advances a national policy to strengthen and maintain secure, functioning, and resilient critical infrastructure. https://www.cisa.gov/topics/critical-infrastructure-security-and-resilience/critical-infrastructure-sectors

3. Whether the technology on which the alternative relies is proven, currently available and scalable.

4. Whether existing supply chain and manufacturing capacity supports the commercial use of the alternative.

5. Whether use of the alternative imposes a comparable cost to manufacturers and users.

Additionally, the rulemaking process for making determinations could be overly lengthy, potentially leading to essential products for which no alternatives are available being banned before a determination can be made. Currently, the European Chemicals Agency (ECHA) is working through a similar, multi-year, broad and potentially far-reaching PFAS restriction pursuant to the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation, and is looking at exemptions prior to restricting products. The Agency should consider making determinations of unavoidable use prior to the required 2025 data reporting. This will reduce the necessity for manufacturers and the Agency to compile and review current usage data for products that are determined to be a currently unavoidable use.

(o) "Medical device" *has the meaning given "device" under US Code, title 21, section 321(h).*

COMMENT: The Agency should clarify, consistent with the broad exemption language used in Subdivision 8(b), that a broader category of medical products that may not fall within the definition of "device" are exempt under Subdivision 8(b), such as certain equipment, drugs, packaging, delivery devices that support medical treatment or the safety of those products, and any product "that is otherwise used in a medical setting or in medical applications" regulated by the U.S. Food and Drug Administration. Such clarification will provide more certainty that the public will still have access to a variety of medical products falling outside the definition of "device" that are otherwise undefined in the law.

(p) "PFAS" *means a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom.*

COMMENT: The legislation relies on an overly broad definition of PFAS to impose a product ban, which will cover countless products made by thousands of companies that pose minimal risks on human health and the environment. To protect public health and the environment more effectively without banning products of high societal value that pose minimal risks, the Agency should focus efforts on those fluorinated compounds that pose the greatest potential risk. To that end, Gore encourages the Agency to clarify that fluoropolymers that meet the OECD criteria for

PLCs[3,4] should have reduced regulatory requirements and be excluded from the PFAS that are subject to the product ban. OECD has defined PLCs as those polymers that can be deemed to have insignificant environmental and human health impacts based on 13 eligibility criteria.[5] The presence of fluorine in a polymer does not preclude it from being safe from an environmental and human health perspective. For example, polytetrafluoroethylene (PTFE) and other PLCs are highly valuable materials that have a unique combination of properties and enable high performing products while presenting minimal risk of impacts to human health and the environment. Gore urges Minnesota to continue allowing manufacturers to confidently use chemistries that can be deemed to have "insignificant environmental and human health impacts" based on the OECD PLC criteria.

In support of this position, Gore notes that the U.S. Department of Defense (DoD) recently published a "Report on Critical Per-and Polyfluoroalkyl Substance Uses, Aug 2023"[6], where, quoting the OECD, it cautions that the "The term 'PFASs' is a broad, general, non-specific term, which 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." The DoD repeats the OECD's assertion that "this definition should not be used in deciding how to group and manage PFAS in regulatory actions". In conclusion, the DoD warns that "If future PFAS legal and regulatory frameworks ignore the OECD caution on the use of its PFAS definition and seek to broadly restrict the use of PFAS based on chemical structure, ***there could be extensive economic, industrial competitiveness, and quality-of-life impacts to U.S. society.***" To this end, Gore recommends that PFAS meeting the OECD PLC criteria should be presumed by rule to have no reasonable available alternatives.

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[3] Henry et al., 2018. "A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers". *Integrated Environmental Assessment and Management* 2018 May; 14(3) 316-334 https://www.semanticscholar.org/paper/A-critical-review-of-the-application-of-polymer-of-Henry-Carlin/0cb1f59a7292fa5259f2ddcf07b4ba925e15be44

[4] Korzenowski, et al. 2023**. "**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. https://www.semanticscholar.org/paper/A-critical-review-of-the-application-of-polymer-of-Korzeniowski-Buck/0fb5143d86b7688d1628b5d20d3e230f69264c56

[5] OECD2009, "Data Analysis of the Identification of Correlations Between Polymer Characteristics and Potential for Health or Ecotoxicological Concern". IOMC, Environment Directorate, "Joint Meeting of the chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology", Paris (FR), 27 Jan 2009. https://www.oecd.org/env/ehs/risk-assessment/42081261.pdf

[6] "Report on Critical Per-and Polyfluoroalkyl Substance Uses", Aug 2023, U.S.A. Department of Defense (nam.org) https://documents.nam.org/ERP/DOD%20Report%20on%20Critical%20Per-%20and%20Polyfluoroalkyl%20Substance%20Uses%202023.pdf?utm_source=488996&utm_medium=email

(q) "Product" *means an item manufactured, assembled, packaged, or otherwise prepared for sale to consumers, including but not limited to its product components, sold or distributed for personal, residential, commercial, or industrial use, including for use in making other products.*

COMMENT: The current definition of product is not clear if the reference to "sale to consumers" includes commercial and industrial entities. To avoid confusion, rulemaking should clarify if "sale to consumers" applies to a commonly understood definition of consumers, such as private individuals, or to users generally which would more clearly incorporate commercial and industrial uses.

2) Are there terms or processes in subdivision 2 (info required) for which clarifications will help reporting entities determine reporting status or data-gathering process?

COMMENT: By way of a general comment on subdivision 2, Gore notes that the U.S. EPA recently finalized new rules pursuant to Section 8(a)(7) of the Toxic Substances Control Act (TSCA) which require manufacturers of PFAS to report a variety of information about the use of PFAS in commerce since 2011. Gore encourages the Agency to waive the law's submission requirements for manufacturers subject to the TSCA Section 8(a)(7) reporting requirements. This waiver would eliminate the unnecessary duplication of submitting substantially the same information and reduce confusion while ensuring that relevant information is still publicly available.

Additionally, Gore encourages the Agency to set a de minimis exemption for reporting. This will allow the Agency to focus its resources on products with higher PFAS volumes and alleviate potential lab capacity problems.

Below are additional comments about specific terms or processes in subdivision 2:

(2a)(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;*

- CAS Numbers: Not all PFAS are identified by a CAS number and chemical mixtures are often identified as trade secrets. The Agency should clarify that a manufacturer does not have to provide CAS numbers for PFAS that do not have a CAS number or where the CAS number is maintained by the manufacturer or its supplier as a trade secret.

- "Reported as an exact quantity determined using commercially available analytical methods or falling within a range". Approved reporting ranges should be provided well before reporting deadlines in order to provide sufficient clarity of ranges and sufficient time to collect information from suppliers to quantify product composition. Providing ranges early will also alleviate the burden on limited commercial analytical capability by minimizing the amount of lab analysis needed.

To further support the importance of providing appropriate reporting ranges for material content, Gore emphasizes that requiring analytical testing for thousands of products sold into the state likely would exceed analytical lab capacity in the State. These resources are limited today and regulatory requirements within a fixed time period would further challenge the capacity to perform such testing. In addition, new test methods may need to be developed for many PFAS that will increase the time and expense for testing, which can be approximately $20,000 per analyte and $200-$2,000 per sample.

While the option to report using ranges is helpful to improve the feasibility of the reporting requirement, Gore recommends caution in subsequently using reported ranges to extrapolate to total quantities sold or other impacts. Making assumptions that actual values can be conservatively estimated from the upper bound of each range will lead to a significant overestimation of the total amount of PFAS used. Such estimates should not be used as a basis for making further decision on prohibitions without seeking more precise information in those cases.

(2a)(4) *the name and address of the manufacturer and the name, address, and phone number of a contact person for the manufacturer; and*

COMMENT: The Agency should clarify whether the manufacturer of components of a product that are then used by another entity in the manufacture/assembly of a finished product are subject to the reporting requirements. If both manufacturers of product components and manufacturers of the final product are subject to the reporting requirement, then the reporting requirements would cause unnecessary duplication of information and create additional burdens for the Agency to review and act on submitted information.

(2a)(5) *any additional information requested by the commissioner as necessary to implement the requirements of this section.*

COMMENT: The Agency should clarify what "additional information" will be necessary as part of the reporting and how such information will be used.

(2b) *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.*

COMMENT: For timely and effective reporting, the Agency should include, as part of its rulemaking, permissible categories or types of products that all manufacturers may rely on for consistent reporting. Including these categories or types of products well in advance of the reporting deadline as part of the Agency's rulemaking will assist manufacturers in meeting their reporting obligations and reduce unnecessary burden of the reporting requirements.

(2c) *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.*

COMMENT: In Subd. (2a)(1), a manufacturer is required to provide a brief description of the product, including a UPC or SKU. The Agency should clarify the definition of "new product" in light of this requirement. For example, is any change to a SKU a new product? What is the definition of "new product" where reporting is done by product category or type? The Agency should also clarify that a manufacturer of a "new product" that contains intentionally added PFAS and is being sold, offered for sale, or distributed in the state has at least six months to submit the required information to the Agency. This will allow manufacturers to continue to innovate and offer new products to the public while ensuring that information about the products is submitted to the Agency in a reasonable amount of time.

Additionally, the Agency should clarify that the meaning of the term "significant change" is a change to the specific PFAS used in a product or the reported range, rather than any change to any previously submitted information.

Finally, the Agency should clarify that the manufacturer has six months from the date of the significant change to update and revise the information previously submitted.

3) How should the MPCA balance public availability of data and trade secrecy as part of the reporting requirements?

COMMENT: One of the most significant benefits of reporting is that it supports regulatory agencies in making well informed decisions. This benefit can be achieved through mechanisms that provide data to the agency while still protecting trade secret information from public disclosures. In some cases, manufacturers may be contractually prohibited from disclosing information to third parties. In other cases, disclosing this information would violate intellectual property protections and could even lead to national security implications (for example where confidential information is subject to ITAR or export control regulations). Robust protection of trade secrets from public disclosure by the Agency will allow businesses to protect their intellectual property, while enabling the Agency to make well-informed decisions on potential future product regulation.

Regarding balancing public availability of data and trade secrecy, the Agency should consider consolidation of all data by product type or chemical type rather than by submission (i.e., manufacturer). Additionally, the Agency should in its rulemaking, create a process for manufacturers to identify trade secrets and confidential business information in its submissions so that confidential and trade secret information can be withheld from public disclosure. At a minimum, these procedures should require manufacturers to designate Confidential Business Information (CBI) at the time of the submission, afford manufacturer notice and the right to litigate the claim of CBI prior to any public disclosure, prohibit Agency officials from using the CBI for personal gain and/or improperly disclosing it, and describe the process by which the Agency will protect CBI from improper or inadvertent disclosure.

The Agency should include the provision that "a manufacturer shall designate confidential business information claims in accordance with the laws of the State and the Uniform Trade Secrets Act[7]."

4) Are there any terms used in subdivision 3 (Information requirement waivers; extensions) that should be further defined or where examples would be helpful?

COMMENT: It is not clear when waivers will be granted. Gore encourages the Agency to consider a pre-notification list of waivers prior to manufacturers requesting waivers. Decisions on waivers are needed as soon as possible so that manufacturers do not unnecessarily incur expenses in trying to meet the law's notification report due date. Pre-notification waivers would both lessen the burden for manufacturers trying to collect a large amount of information in a short amount of time and help provide certainty as companies continue product planning and investing in research and development. In addition, it would allow the agency to focus resources on submissions that are most relevant to achieving the objectives of the law.

(3a) *The commissioner may waive all or part of the information requirement under subdivision 2* (INFO REQUIRED) *if the commissioner determines that substantially equivalent information is already publicly available. The commissioner may grant a waiver under this paragraph to a manufacturer or a group of manufacturers for multiple products or a product category.*

COMMENT: As noted previously, the U.S. EPA recently finalized new rules pursuant to Section 8(a)(7) of TSCA, which require manufacturers of PFAS to report a variety of information about the use of PFAS in commerce since 2011. Gore encourages the Agency to waive the law's submission requirements for manufacturers subject to the TSCA Section 8(a)(7) reporting requirements.

(3d) *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.*

COMMENT: The Agency should establish a process through rulemaking setting forth the criteria it will consider in determining whether more time is needed by a manufacturer to comply with the submission requirement. Establishing this process through rulemaking will provide manufacturers more certainty in understanding how to seek such a determination and whether it can meet the criteria. The current reporting deadline of January 1, 2025, will need to be extended. Gore recommends at least 12 months following promulgation of final rule, in order to give the regulated community adequate time to assemble data and submit the report in accordance with the implementing regulations.

[7] Minnesota Trade Secrets, Data Practices https://mn.gov/admin/data-practices/data/types/tradesecrets/#:~:text=Minnesota%20Statutes%2C%20section%2013.37%2C%20subdivision%202%2C%20allows%20government,establish%20that%20the%20trade%20secret%20classification%20is%20warranted

5) **Other questions or comments relating to reporting or the process of reporting.**

COMMENT: Subd8. Exemptions.
Given their minimal impact on human health and the environment, and their application in variety of products of high societal value, including in many markets identified as critical infrastructure, Gore recommends that the Agency exempt polymers that meet the Organisation of Economic Cooperation and Development (OECD) 13 criteria for "polymers of low concern" (PLCs). Because the definitions of "PFAS", "intentionally added PFAS", "product", and "product component" are all very broad, there is a risk that many products of high societal value containing materials that have insignificant environmental and human health impacts could be banned in the State, which will have a significant impact on the state's economy with limited environmental benefit.

Gore also recommends that the Agency explicitly exempt the following product categories from the reporting requirements and any product bans:

1. Products that are used to protect the environment such as discharge and emission control devices, landfill covers, and fuel cell applications. These products help combat climate change, keep the air and water that everyone breathes and drinks, clean and performs other critical environmental benefits for the planet. These products require a great deal of research and development and without certainty that these products can continue to be sold into the State, it would be difficult to product-plan for their future use and availability. Please see the attachment "W. L. Gore & Associates' Comments on Dossier Submitters' Draft EU REACH Restriction on PFAS"[ii] for a more in-depth description of Pollution Control and Dust Collection products.

2. Products purchased by the U.S. military. These products are vital for keeping the country safe, which is why states such as California and New York have exempted in recent apparel specific PFAS laws, personal protective equipment or clothing items purchased for exclusive use by the U.S. Military. Please see the attachment "W. L. Gore & Associates' Comments on Dossier Submitters' Draft EU REACH Restriction on PFAS"[iii] for a more in-depth description of Aerospace and Defence products.

3. Products that improve human health, such as pharmaceutical drugs, vaccines, products to develop and deliver them, as well as FDA-regulated medical devices and their packaging. Devices under FDA require years of extensive testing to show there is acceptable/no risk. "W. L. Gore & Associates' Comments on Dossier Submitters' Draft EU REACH Restriction on PFAS"[iv] for a more in-depth description of Medical Devices.

Thank you for allowing us to comment and taking the time to consider these views. Please feel free to contact me directly if there are any questions or you need further information.

Sincerely,

Michael Altman
Sustainability Leader
maltman@wlgore.com
410-506-8572

[i] Attachment 1: W. L. Gore & Associates' Comments on Dossier Submitters' Draft EU REACH Restriction on PFAS, Request for Derogation: Fluoropolymers, Public consultation, July 2023. (Attached pdf)

[ii] Attachment 2: W. L. Gore & Associates' Comments on Dossier Submitters' Draft EU REACH Restriction on PFAS, Request for Derogation: Pollution Control and Dust Collection, Public consultation, July 2023. (Attached pdf)

[iii] Attachment 3: W. L. Gore & Associates' Comments on Dossier Submitters' Draft EU REACH Restriction on PFAS, Request for Derogation: Aerospace and Defence, Public consultation, July 2023. (Attached pdf)

[iv] Attachment 4: W. L. Gore & Associates' Comments on Dossier Submitters' Draft EU REACH Restriction on PFAS, Request for Derogation: Medical Devices, Public consultation, June 2023. (Attached pdf)

W. L. Gore & Associates' Comments on Dossier Submitters' Draft EU REACH restriction on PFAS

Public consultation

Request for Derogation:
Pollution Control and Dust Collection

June 2023

Gore appreciates the opportunity offered by the public consultation process to provide comments on the Proposal for a Restriction of Per- and polyfluoroalkyl substances (PFAS) (hereinafter **'Restriction Proposal'**).

With this submission, we would like to explain why we believe that a derogation for **pollution control and dust collection equipment and in particular filters**, which are not covered by the derogations in the Restriction Proposal, is needed and justified. Further, we would like to explain why this derogation should be time-unlimited for applications requiring resistance to corrosive and chemically aggressive compounds and high temperatures, and why for other applications a derogation with a transitional period of 13,5 years is required.

The conclusions from our statement are summarized as follows:

- Pollution control and dust collection for industrial air emission streams are a critical function for human health and environmental protection. These applications are not sufficiently covered yet in the Restriction Proposal. It would be beneficial to create a sub-use for air pollution control and dust collection equipment to better capture this application.
- **For pollution control and dust collection applications requiring resistance to corrosive and chemically aggressive compounds or high temperature, neither alternative materials nor alternative techniques are available.** For applications in less demanding environments, substitution is likely to be possible, but development and qualifications activities will require a transition period of 13,5 years.
- Without sufficient derogations, significant adverse impacts from increased exposure to fine dust, dioxins, heavy metals and other toxic or carcinogenic pollutants as well as increased CO2 emissions are to be expected.

I. Derogation Request

Considering the arguments and evidence presented below, Gore respectfully requests to include the following application-specific derogations for pollution control and dust collection equipment in Column 2, paragraph 6 of the proposed restriction:

1. *Air filtration media for the purpose of pollution control and dust collection used in industrial or professional settings where flue gases contain corrosive or chemically aggressive compounds or where operation temperature is above 100°C;*
2. *Other [= no corrosive or chemically aggressive compounds and temperature ≤100°C] air filtration media for the purpose of pollution control and dust collection used in industrial or professional settings until 13,5 years after EiF.*

II. Description of the End Use

a) Overview of Industrial Filtration

A wide variety of filters are used to treat air emissions from industrial processes in areas such as chemical and cement manufacturing, metals processing, energy production and many others. The purpose of such filters is to prevent the release of harmful particulates and chemicals to the environment with significant benefits to human health. In some cases, the filters act as a physical barrier to particulates while allowing exhaust air to easily pass through. In other cases, the filters perform an additional function of promoting a chemical reaction on substances in the exhaust air stream to capture or convert those substances into something less harmful. Emissions are often regulated, so use of appropriate emissions controls is required for regulatory compliance.

Industrial processes vary significantly, therefore the operating conditions and substances found in air exhaust are also very different from process to process. Filters must be able to operate in these conditions which can include elevated temperatures and aggressive chemicals. They must also be able to withstand the physical demands of use. These properties along with air flow parameters and the degree to which particulate can be captured are all defined by the inherent properties of the materials used and the ability to create a porous physical form suitable for filtration.

As indicated in the derogation request, these industrial applications can be divided in two groups that are important when considering material options:

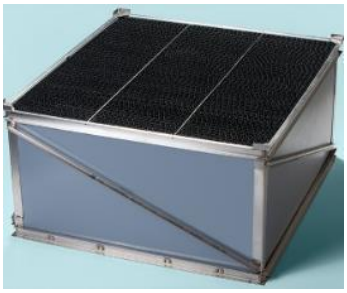
- Uses where flue gases contain corrosive or chemically aggressive compounds or where operation temperature is above 100°C
- Other air filtration uses for pollution control or dust collection

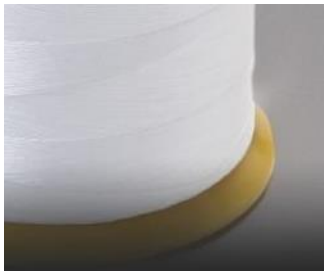
b) Product Examples

To clearly define the proposed new sub-use, detailed description of the type of products and their reliance on PFAS is provided below. The product examples are all Gore products, as details of comparable products manufactured by other companies are not publicly available. We believe that these products are representative of products manufactured and placed on the EU market by other companies.

Based on the current proposal the following pollution control products perform necessary functions, but would not be covered by the derogation proposed in Paragraph 5e:

Table 1. Pollution Control and Dust Collection Products

Product	Illustrations	Description
GORE® Catalytic Filter Bags		Filter bags that are used in baghouses to convert toxic or hazardous components such as gaseous dioxins and furans or nitrous oxides from aggressive and corrosive gas streams into harmless substances (i.e., to levels below regulatory limits). The filter's surface captures fine particles and releases these particles to be collected in the bottom of the baghouse hopper. Then, the filter lets the gaseous pollutants pass through into the catalytic felt where the catalyst reacts with the dioxin, furan or nitrous oxides (NOx) molecules to convert them into insignificant amounts of carbon dioxide (CO_2), water (H_2O), nitrogen (N_2) and hydrogen chloride (HCl). In most of the cases the catalytic conversion takes place at temperatures above 200 degrees Celsius; the minimum temperature is 180 degrees Celsius. These filters are typically applied in waste incineration, chemical processes, metallurgical processes, and cement manufacturing to help meet regulatory requirements for limiting air emissions.
GORE® Industrial Dry Filtration Products		These filter products are used to separate particulate from predominantly chemically aggressive and corrosive gas streams. The dust often consists of toxic, fine (sub-micron, sometimes nanoparticles), non-agglomerative, abrasive and/or sticky particulate such as heavy metals or dioxin containing fly ash. In operation, the filters are cleaned by a high-pressure pulse jet blast, or a reversed air flow, often combined with mechanical vibration. Typically used in waste incineration, chemical processes, metallurgical processes, and cement manufacturing at temperatures above 200 degrees Celsius to help meet regulatory requirements for limiting air emissions.
GORE® Mercury and SO_2 Control Modules		These modules are used to separate mercury from aggressive and corrosive gas streams and convert SO_2 into a dilute sulphuric acid. The modules consist of a metal frame which houses a PTFE based composite that contains adsorptive and catalytically active components. While PTFE is the functional material, PVDF is used as a mechanical stabilizer. Typically used in waste incineration, coal fired power generation, metallurgical processes and cement manufacturing to help meet regulatory requirements for limiting air emissions.

Product	Illustrations	Description
Rastex® / Gore industrial fibre		A sewing thread engineered specifically for the demands of filtration applications – it withstands exposure to chemicals, high temperatures, abrasives, and moist environments. The fibre can also be processed as a "staple fibre" used to create non-woven filter media.

All these products are made of fluoropolymers; other polymers are not used. The fluoropolymers meet the criteria for Polymers of Low Concern (PLCs), under the definition provided by the OECD Expert Group on Polymers. The fluoropolymers used for each product are listed below in Table 2.

Table 2. PFAS used in Pollution Control and Dust Collection Products

Example product	Type of PFAS	CAS number
GORE® Catalytic Filter Bags	PTFE	9002-84-0
GORE® Industrial Dry Filtration Products	PTFE	9002-84-0
GORE® Mercury and SO_2 Control Modules	PTFE	9002-84-0
	PVDF	24937-79-9
Rastex® / Gore industrial fibre	PTFE	9002-84-0

III. Reference in Restriction Proposal

a) Many industrial air filtration uses are not addressed in the Restriction Proposal

In the Restriction Proposal pollution control and dust collection products are discussed under the application TULAC and the sub-use technical fibers under the broad category of filtration and separation media. For certain products needed for high performance air and liquid filtration applications in industrial or professional settings that require a combination of water and oil repellence, a derogation is proposed in Paragraph 5e of the Restriction Proposal.

However, after carefully reviewing the Restriction Proposal, we have identified that filtration media for pollution control and dust collection are not covered by the proposed derogation yet. This omission translates into gaps in the justification, which seem to be closely related to the high number of products falling under the broad category of filtration and separation media.

In the Restriction Proposal it is acknowledged that there are various applications of filtration and separation media and that not all these applications are captured. It only refers to a few examples like gas turbines, hydraulic applications, nuclear industry, respiratory applications and air pollution control and dust collection as well as it refers to high performance membranes.

Even though air pollution control and dust collection were identified in the Restriction Proposal as a use within the sub-use category, the full range of necessary products covered by the use are not sufficiently captured. The use of PTFE in filtration applications is described in Section A.3.3.1.1./page 28f of Annex A, where it is pointed out that PTFE membranes are *"laminated to a wide variety of substrate materials such as polyester needlefelts and woven glass fibers to be made into filter bags [...]"*. **This only captures a very limited number of pollution control and dust collection products. For many of the products, PTFE or other fluoropolymers need to be used for membranes as well as substrates, since other materials would not withstand the harsh operating conditions (further explained below).** We would therefore like to take this opportunity to explain which other types of products fall under the category pollution control and dust collection.

b) Data Submitted to the PFHxA Restriction does not represent most Industrial Air Filtration Uses

In the Restriction Proposal it is recognized that there are filtration products requiring both water and oil repellence, and some that do not need oil repellence. The former being based on PFHxA and related substances, and the latter purely based on fluoropolymers (only PTFE is referenced). However, a derogation is only proposed for filtration products requiring a combination of water and oil repellence (Paragraph 5e), which is based on information provided in the PFHxA restriction process. **Because many filtration applications require the use of fluoropolymers, but not PFHxA-related substances, the information submitted for the PFHxA restriction proposal is not representative of all the PFAS use in this category.**

Even though the availability of suitable alternatives for filtration products made from PTFE are not apparent from the Restriction Proposal, a derogation is not proposed. The reasons for this remain unclear. It is stated on page 112 of Annex E that alternatives are available, however, the underlying evidence (Section E.2.2.4.2 and E.2.2.2.1) support the conclusion that alternatives are not available for the applications addressed herein. Polyester and polyurethane are mentioned as alternative substances in the Restriction Proposal, but it is not identified for which of the many products that fall under the category of filtration and separation media these alternatives would be technically feasible (see Section E.2.2.5.4., page 120 of Annex E). Also, Appendix E.2. does not provide information on alternatives for pollution control and dust collection products; no alternative for this sub-use is identified.

Overall, we believe that the assessment of alternatives in the Restriction Proposal has not been completed at a sufficient level of detail to allow for a conclusion on availability of suitable alternatives for all the products within the broad category of filtration and separation media.

IV. Need and Justification for Derogation Request

A derogation for pollution control and dust collection equipment and in particular filters is needed and justified. **Without a derogation significant increase of fine dust carrying dioxins, heavy metals and other toxic or carcinogenic pollutants as well as increase in CO_2 emissions is expected.** We propose that a derogation is justified based on the following points:

- The **performance requirements** for industrial air filtration applications
- The **lack of current alternatives** that would provide a sufficient level of performance
- The **time required** to develop, test, and commercialize new air filtration products, once a feasible material option is identified
- The **large socio-economic cost** of restricting the use

a) Performance Requirements

Detailed performance requirements for various industrial air filtration applications are listed in Annex I. Requirements vary based on the specific process and emissions being controlled and typically include combinations of the following:

- Filtration efficiency

  Filtration efficiency is a measure of the % of specified emissions captured by a filter. This is typically a primary indicator of the functional performance of a filter. To meet this requirement, a filter material needs a controlled pore size to allow air flow through while not allowing particulates to pass. It must also be able to maintain performance as particulate builds up inside the filter. Often efficiency is expressed as a percentage (like 99.99%) for a specific particle size. **While to readers unfamiliar with filtration technology, it may seem like the difference between 99% and 99.99% filtration efficiency is insignificant but in reality, such a difference indicated by the lower value can lead to enormous amounts of additional pollutants being released from a given process and failure to meet regulatory requirements.**

  As an example of regulatory requirements, the EU BAT Conclusions for Waste Incinerators sets dust emissions limits of ≤ 2-5 mg/Nm³, for certain Heavy Metals (Cd, Tl) ≤ 0.005 – 0.02 mg/Nm³ and for Dioxin ≤ 0.01 – 0.08 ng/Nm³. The dust content in the raw gas, together with the purposely injected additives, typically is on the order of 10-1000 g/Nm³. Hence the overall filtration efficiency needs to be at least (10,000 mg – 5 mg)/10,000 mg = 99.95 %. Dioxins need to be reduced from typically 2-3 ng/Nm³ in the unfiltered flue gas; hence the destruction removal efficiency needs to be at least (2 ng-0.08 ng)/2 ng = 96 %. Besides the minimum requirements of EU wide regulations, often there are stricter local or regional regulation.

- Temperature Resistance

  The temperature of flue gas streams varies by industrial process. Many require filtration of exhaust at temperatures up to 240°C. Filters need to withstand

continuous operation at these temperatures without degradation in strength or performance.

- Chemical Resistance

  Flue gas streams may contain acids, organic solvents, or other aggressive chemicals, including but not limited to HCl, HF, SO_2, NOx, and NH_3. Filters need to resist being damaged or degraded by constant exposure to these chemicals.

- Physical Strength

  Filters must be able to withstand the physical stresses experienced during use which can include high pulses as part of a periodic cleaning process. If filters tear or seams fail during use, particulates and other substances will be emitted to the atmosphere instead of being captured.

- Catalytic or Sorbent Function

  In addition to physical capture of particulates, some flue gas streams contain gaseous chemicals that need to be captured or destroyed. Filters need to contain embedded catalysts or sorbent that are retained in the filter yet come in direct contact with the flue gas to control emissions. End uses typically have % capture specifications which indicate the required effectiveness of the catalytic or sorbent activity.

b) Assessment of Alternatives

In September 2022 we provided a full Socio-Economic Assessment (SEA) prepared by eftec. The SEA has been submitted to all 5 Dossier Submitters. Since this information was provided after the end of the Call for Evidence in September 2021, the SEA is attached as **Annex II** to this derogation request. The SEA contains a comprehensive assessment of alternatives (see Section 3 (pages 36-42)).

To make the information more easily available and to take into account the information provided in the Restriction Proposal, we have summarized all information on alternatives in **Annex I** of this document, which also contains updated and supplementary information obtained after the SEA was submitted. The information on alternatives is provided at a 'product-type' level, referring to the products described in the Table 1 above.

The conclusions from Annex I are summarized as follows:

Catalytic Filter Bags: Destruction of certain toxins	**There are no alternative materials known which would work under the harsh operating conditions where the flue gases contain corrosive and chemically aggressive compounds or temperature is above 180°C.** Other materials cannot resist either the corrosive/chemically aggressive compounds (e.g., fiberglass) or the temperature (e.g., PET, PU, PI). Other techniques (solid catalysts or absorbent systems) are not considered a viable alternative since they are not able to remove dust without being combined with dust filters. There are no dust filters that do not require fluorinated materials with a sufficient filtration performance that can be used at the required temperature of above 180°C.

Industrial Dry Filtration: Dust filtration	For most (around 90%) of the applications of industrial dry filters there are no known alternative materials which would work due to the harsh operating conditions where the flue gases contain corrosive and chemically aggressive compounds or temperature exceeding 200°C. For applications without contact to harsh chemicals and at ambient/medium temperatures, other material could be used but would provide a much poorer filtration performance (75 – 99 % compared to ›99.9% for expanded PTFE). **An efficiency of 99% is not sufficient to comply with all requirements under the EU BAT Conclusions for Waste Incinerators,** therefore, they are not considered viable alternatives. Based on current knowledge, we believe that recently tested [redacted] could potentially be modified to provide sufficient performance in the future [redacted] for ambient/medium temperature applications (‹100°C).
Mercury and SO_2 Control	There are no known alternative materials which would work under the harsh operating conditions of applications where mercury and SO_2 control is needed. In addition, other materials lack a sufficient hydrophobicity to withstand flue gas which is typically saturated with water vapor. Other techniques (such as adsorption systems, limestone based wet scrubbing) are not considered viable alternatives since these techniques either cannot remove SO_2 from flue gas (adsorption system) or cannot remove mercury (limestone based wet scrubbing), both of which are needed to meet emission limitations in power plant and incinerators. Therefore, instead of a module combining both, an adsorption system as well as a limestone based wet scrubbing systems would need to be installed to fulfil the same function. In addition, there are severe disadvantages, in particular, a much higher carbon footprint (up to 100 times higher).
Industrial fibre for filtration: Thread and Staple	Except for asbestos, there is no known alternative material that would work under the harsh operating conditions of applications where industrial fibres are used (see section on Industrial Dry Filtration above).

c) Timeline

For highly technical, demanding and complex uses with strict performance requirements, such as pollution control and dust collection equipment, the in-depth identification and assessment of alternatives included in this document indicates that a general application of a 13,5 years derogation period is not sufficient to cover the needs of such uses.

The Restriction Proposal only advises transitional periods of 13,5 years or below, even in cases where no alternative exists or is likely to be found within the transition period. As pointed out on page 77 of the Restriction Dossier, this is based on the understanding of the Dossier Submitter that 13,5 years are *'normally sufficient for industry to take benefit from technical progress and to carry out scientific R&D activities to find and deploy technically and economically feasible alternatives'*. **This assumption does not accurately take into account the time needed to identify alternative materials, nor the time to develop, test, and commercialize products once an alternative material is identified.**

As explained above and in the SEA for Filters, so far, no alternative materials, techniques or products are available as potential substitutes for pollution control and dust collections products. Only for some (dry) dust filtration applications without contact to harsh chemicals and at ambient/medium temperatures (‹100°C), [redacted] has the potential to be modified to receive a sufficient performance in the future [redacted]. Timelines for each of these categories are described below.

(i) Need for time-unlimited Derogation for applications in harsh environments

Since an alternative material is not available for pollution control and dust collection applications in harsh environments, a new material would need to be found or invented. Thus, the development process needs to begin with creating a new material, potentially a non-fluorinated polymer that can still meet the temperature, chemical resistance, and porous structure requirements. The time needed for this is not known and very difficult to predict.

Examples from the past, show that the time span to develop new materials can vary significantly. For example, the development of acrylic polymer took several decades. The process from the first synthesis of acrylic acid to the introduction of the commercial polymer, was an 85-year journey.[1] While the development of PTFE from the "accidental" discovery to a commercial product took about 10 years, from 1938 to 1948[2], and then decades more to mature that technology into the materials used today. Development advances over this time have had to occur in polymerization, finishing, lubrication and blending, pelletization, extrusion, etc. In absence of such an initial unexpected discovery, we can only speculate that developing a new polymer until commercial availability will take more than 20 years.

After identifying a material, several steps would need to follow (see table 3).

Table 3: Substitution steps for developing an alternative to fluoromaterials in pollution control and dust collection products

Steps for substitution	What activities does this step entail?	Time required for step	Minimum one-off cost for this step
1. Identification and development of new material	Developing a new polymer	**Unknown** Estimate > 20 years	Approximately €> [redacted] million
2. Polymer process development – converting a polymer with sufficient inherent properties into a physical form suitable for filtration	Understanding how polymer can be processed into a strong porous membrane and embedded with catalyst or sorbent materials.	3 years	Approximately € [redacted] million

[1] See https://www.ptonline.com/articles/tracing-the-history-of-polymeric-materials-part-20.
[2] https://www.teflon.com/en/news-events/history#:~:text=An%20Accidental%20Discovery&text=Roy%20J.,to%20form%20polytetrafluoroethylene%20(PTFE).

3. Product development an iterative stage of R&D, (re)formulation and lab testing	Development of filters for specific end uses. Product Development from Technology Readiness Level 1 to 9, testing in lab, and pilot scale, including modification of polymer to ensure performance needs.	5 years	Approximately [redacted] million
4. Qualification and/or Validation - testing and validation with customers and/or external testers	Validation by end users, OEM and EPC to be applicable.	3 years	Approximately [redacted] million
5. Certification - review and testing by standard setters and/or regulators	Certification by test institutes to national and international standards. Other certifications and/or standards that need to be met by filters are EN 1822, ZH 1/487, VDI 3926.	1 year	Approximately [redacted] million
6. Production - implementing the manufacturing plan for the alternative, including a possible pilot phase, regulatory approval, and modifications to the production line.	Set up production, manufacturing capabilities, supply chains.	5 years	Over [redacted] million
Total	All steps	>37 years	> [redacted]

After an alternative material that has the performance attributes necessary to withstand the operating conditions described in Section 3 has been developed, the most important and time-consuming part would be to understand how the new polymer can be modified to ensure proper functioning as a filter. This requires that:

For catalytic filter bags

- Catalysts and adsorbents can be embedded into the porous structure. Alternatively, a coating technique would need to be developed to bind the catalyst to the polymer reliably for many years of operation
- A porous structure to filter dust particles of different sizes without getting clogged
- Physical strength to withstand cleaning in place while installed
- Conversion into a flat, gas permeable filtration media, that can be used as a filter bag

For dry filtration products

- A porous structure to filter dust particles of different sizes without getting clogged
- Physical strength to cleaning in place while installed
- Conversion into a flat, gas permeable filtration media, that can be used as a filter bag

For mercury and SO_2 control modules (GMCS)

- Catalysts and adsorbents can be embedded into the porous structure. Alternatively, a coating technique would need to be developed to bind the catalyst to the polymer reliably for many years of operation
- Conversion into a pleatable media, that can be used in GMCS modules

For Industrial fiber: thread and staple

- Seam integrity verification when used for filter bag sewing
- Ensure no bypass gaps, loosening at operating temperature, and integrity after back pulse
- In production sewing, confirmability to meet stitching specifications without knotting, kinking, abrading, or breaking.

When Gore developed catalyst filled ePTFE products for catalytic filtration, that process took [redacted] years from filing the patent to providing a commercial product (Steps 3 and 4 of Table 3). An equally long period of time was needed to develop catalyst filled ePTFE products to be used in Mercury and SO_2 Control Modules. This long period of time was necessary although Gore had already considerable know-how in working with and modifying PTFE. When working with a new material/polymer, a considerably longer period of time is expected to be needed.

Overall, **Gore estimates that substitution of all pollution control and dust collection products would take a minimum 17 years and cost at least [redacted] million after an alternative material has been identified**. The time and costs needed to identify a material could not be assessed, as there are no known candidate materials. Based on the examples presented above we can only speculate that this would take more than 20 years resulting in a total development time of more than 37 years.

If at any point during the substitution process a step ends with failure (e.g. a potential alternative substance does not pass a specific standard/certification), then the entire process will need to be restarted which can significantly increase the time and resources required. We believe that this uncertainty and the fact that the time needed to find an alternative material cannot be estimated, justifies the need for a time-unlimited derogation.

We believe that national and European regulatory standards further add to the justification for a time-unlimited derogation. This includes in particular the *EU BAT Conclusions for Waste Incinerators*. As demonstrated in Annex I, the performance requirements set by these regulatory standards cannot be met without the use of fluoropolymers. This situation is comparable to the application of PFAS in refrigerants in HVACR-equipment, which is one of the few uses where a time-unlimited derogation was proposed by the dossier submitters. According to page 150 of the Restriction Proposal, a time-unlimited derogation for refrigerants in HVACR-equipment was proposed since regulatory standards prohibit the use of alternatives substances due to safety concerns.

(ii) Need for transition period of 13,5 years for other applications

[redacted] is the only material identified by Gore as a potential substitute for (dry) dust filtration applications without contact to harsh chemicals and at temperatures below 100°C. As demonstrated in Annex I, filters made from [redacted] currently have a lower dust collection efficiency (99% vs. ›99.9% for PTFE). To increase collection efficiency and improve PE filter performance, which is, in particular, needed to comply with EU BAT Conclusions for Waste Incinerators (see explanation in Annex I below), modification of the [redacted] polymer is needed. As pointed out above, the time estimated to get from product planning to final product is a minimum of 17 years. Since initial R&D work has already been performed, a transition period of 13,5 years after EiF is expected to be sufficient.

V. Additional Information in SEA

Specific information requested in the stakeholder consultation is available in the full SEA which is attached as Annex II to this derogation request. The information provided in the SEA include the following

- Market and sales for filtration products (Section 2.3 and 2.5.2);
- Types and volumes of PFAS used (Section 2.4, 2.5.3 and 2.5.5);
- Material flow, including emission volumes Section (2.4.3 and 2.5.3);
- Further information on alternatives (Chapter 3);
- Economic impacts (Section 4.3);
- Impacts on health and the environment (Section 4.4);
- Social and wider economic impact (Section 4.5); and
- Comparison of impacts and proportionality (Chapter 5).

Please note that the SEA covers a broader variety of filtration products than just pollution control and dust collection, therefore, it also contains information on other filtration categories which fall under different applications/sub-uses.

In the following, we present a high-level summary of parts of the SEA. Gore kindly asks the dossier submitters and the committees to review the entire document:

a) Social and Economic Impacts

The SEA shows that not granting a derogation for filtration products similar to those set out in Table 1 will have large and wide-reaching impacts on the EU. These include significant economic costs throughout the value chain, impacts on employment (lost jobs) as well as adverse impacts on human health and the environment.

The SEA conservatively estimates that the minimum annuity costs, including lost profits and impacts on employment, of restricting the use of PFAS in pollution control and dust collection products amounts to €1.2 billion per year.

b) Impacts on Human Health and the Environmental

It is demonstrated in Section 4.4.3 of the SEA, that a restriction of PFAS in pollution control and dust collection products would have several adverse effects to human health and the environment. This includes that lower performing (non-PTFE membrane) filters would allow more fine dust, dioxins, heavy metals and other toxic or carcinogenic pollutants to be released into the environment, eventually ending up in ambient air and surface water.

c) Emissions

It is demonstrated in Section 2.4.3 of the SEA that emissions from product manufacturing, service life and end of life are negligible. Additional information on responsible manufacturing, processing and disposal of fluoropolymers and products made from fluoropolymers are provided in our derogation request for fluoropolymers.

In addition, an estimate of worst case emissions based on the "investigation report summaries" published by the DS in 2021 (National Institute for Public Health and the Environment (RIVM) et al., 2021) is provided (see section 2.5.3). This information has been compiled in order to create a basis for further consideration within the framework of the SEA. It does not correspond with our knowledge on emissions and in particular our knowledge on emissions from product manufacturing with emission control technologies in place. In our opinion, the emissions from product manufacture estimated in the investigation report summaries are significantly overestimated**. But even when applying highly conservative emission factors, the resulting costs of reducing PFAS through restricting pollution control and dust collection products is very high, with a minimum cost of €4.2 – €6 million per kg PFAS emissions reduced.**

A CE estimate does not in itself, indicate whether benefits of a restriction outweigh the costs. For cases where risks and impacts of reducing exposure to a substance are unknown, it is common to compare the cost-effectiveness estimates with some type of benchmark. A study by Oosterhuis et al. published in 2017 found that for PBTs, vPvBs and substances with similar properties (e.g., lead) emission reduction measures with a cost-effectiveness below €1,100[3] per kg emission reduced were generally not rejected due to costs i.e., the costs were found to be proportionate. Measures with costs above €56,400[4] per kg, on the other hand, were more likely to be rejected, i.e., costs at this level were found to be disproportionate. Cost in between could be either proportionate or disproportionate – a so called 'grey zone' (Oosterhuis et al., 2017). The Oosterhuis benchmarks (BMs) have been used for the assessment of a number of regulations of PBTs and vPvBs, which are substances of very high concern (SVHCs). These BMs are, however, not necessarily applicable to substances of low concern such as PTFE and other PLCs. The reasoning behind this is that the implied willingness to pay (acceptability of costs) would be higher, the higher the perceived risk of a specific substance. If the Oosterhuis BMs are to be used for substances of low concerns, it is reasonable to make some indicative, quantitative or qualitative, adjustments. For example, if the 'grey zone' for a PBT ranges from €1,100 –

[3] €1,000 in original study, uplifted to 2022 prices
[4] €50,000 in original study, uplifted to 2022 prices

€56,400 per kg PBT emission reduced, it is reasonable to assume that upper bound (and likely also the lower bound) would be significantly lower for substances of low concern.

There are uncertainties associated with all parts of the analysis and a multitude of impacts could not all be quantified and/or monetised. However, due to the consistent conservative approach taken it is believed that the most significant non-quantified impacts are costs of a possible REACH restriction and would therefore further strengthen the conclusions from the quantitative analysis. **It is therefore concluded that restricting the use of PFAS in industrial and professional air filtration end uses will result in highly disproportionate societal costs for the EU.**

Annex I – Comprehensive Alternative Assessment

Alternative Assessment for Catalytic Filter Bags

R&D activities conducted

Our R&D activities focused on an assessment of products made from polyimide which we compared to our fluoropolymer containing catalytic filtration product.

The R&D focus is based on the BREF Document for Waste incineration, as most of the catalytic filters are used in the Waste-to-Energy Industry.[5] In Section 2.5.3.5 of the BREF operational information on the following materials is provided:

Table 2.15: Operational information for different bag filter materials

Fabric	Maximum temperature (°C)	Resistance		
		Acid	Alkali	Physical flexibility
Cotton	80	Poor	Good	Very good
Polypropylene	95	Excellent	Excellent	Very good
Wool	100	Fair	Poor	Very good
Polyester	135	Good	Good	Very good
Nylon	205	Poor to fair	Excellent	Excellent
PTFE	235	Excellent	Excellent	Fair
Polyimide	260	Good	Good	Very good
Fibreglass	260	Fair to good	Fair to good	Fair

NB:
Not all of these materials are commonly used in incineration – see operational data below.
Source: [2, InfoMil 2002] [67, Inspec, 2004]

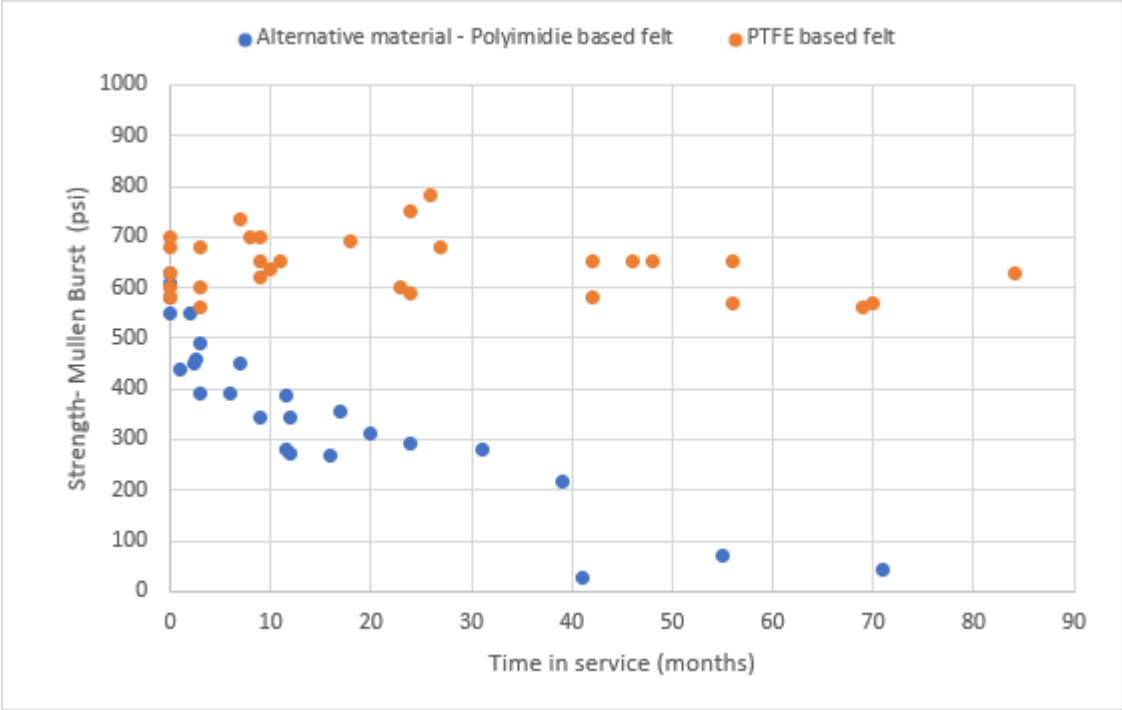
Further it is mentioned that the main media for municipal solid waste incineration (MSWI) plants are polyimide, polyphenylene sulphide (PPS) (rarely), PTFE, and fiberglass (with or without PTFE coating). Also, it is acknowledged that higher temperatures may lead to the melting of plastic

[5] https://eippcb.jrc.ec.europa.eu/sites/default/files/2020-01/JRC118637_WI_Bref_2019_published_0.pdf.

	components of the filter with a potential for fires and that high humidity in the flue-gas may cause the filter materials to stick together, leading to shutdowns. PTFE is mentioned as material to improve the removal of such sticky salts and solid particles from the bags. Due to low temperature resistance of most materials and insufficient resistance of fiberglass to acids and alkalis, polyimide is the only non-PFAS material available according to the BREF document. Please note that the temperature limits mentioned in the BREF document do not fully correspond with our understanding of the mentioned materials; however, the order of magnitude is more or less correct. See also further information on the performance requirements and materials below.
Performance requirements	The catalytic process always needs a relatively high temperature (minimum 180°C) to ensure sufficient destruction of the toxin. The temperature is needed to speed up the chemical reaction between catalyst and toxin, since the gas is in contact with the filter only for a short period of time (~0.1 seconds), thus the reaction needs to be fast. Catalytic Filter Bags are used in different applications, including waste incineration, chemical and metallurgical processes, and cement production. The requirements in these applications are slightly different: • Waste incineration: The baghouses equipped with catalytic filter bags are operated at 180-240°C. The flue gas contains acid and chemically aggressive gases (primarily HCl, HF, SO_2, NOx, NH_3) and corrosive constituents (e.g. $CaCl_2$). The filter cake can be hygroscopic, wet and sticky, especially at OTNOC Conditions (OTNOC = Other than normal conditions, e.g. start-up or process upsets). • Chemical processes: Among others, catalytic filters are applied for fumed silica production and optical fiber production. In these processes, the concentration of HCl in the gas can exceed 20%. Chlorine gas is also present. The operating temperature is 200-240°C. • Metallurgical processes: Relevant processes comprise steel manufacturing (e.g., sinterband, lime kiln, coke oven), aluminum recycling (via pyrolysis) and other similar applications. The flue gas contains corrosive and chemically aggressive compounds (primarily NOx, NH_3). The operating temperature of baghouses in these applications is 180 – 240°C. • Cement production: The gas contains corrosive and chemically aggressive compounds (primarily SO_2, NOx, NH_3), and high concentrations of abrasive dust ($CaCO_3$, CaO). The operating temperature of baghouses in these applications is 180 – 240°C. The filter material needs to be temperature and chemical resistant and cleanable under these conditions. Cleanability is needed, since, in addition to the pollutants mentioned above, the flue gas always contains dust/fine particulates. If a filter cannot be cleaned the product life will be tremendously shortened and the amount of catalyst material needed increases substantially. The cleaning process is performed by blasting compressed air from the clean side, knocking off the collected dust, which then drops down into the hopper and dust discharge device of the baghouse. If filters cannot be cleaned while installed, frequent process shutdowns would be needed to maintain/clean or change the filter.
Products on market without use of fluoropolymers/ fluoromaterials	There are no products without fluoropolymers on the market which can be used under the conditions outlined above (corrosive and chemically aggressive compounds in flue gas and temperatures between 180 – 240°C). Filters made from alternative non-fluoropolymer materials (e.g., polyimide, fiberglass, polyester) on the market are only used in less demanding applications (e.g., to collect coarse, non-hazardous dust from air streams at lower temperatures).

Alternative materials known or discussed in Restriction Proposal and performance of such materials	Polyester (PET)	Polyester (PET) filters are commonly used as filter media in industrial as well as HVAC applications, usually in the form of a felt. **PET filters can only be used at temperatures below 135°C, and only if the gas is sufficiently dry (normal humidity). In humid gases the temperature is limited to 100°C. Thus, PET filters are not a viable alternative to catalytic ePTFE filter bags where 180°C is the required minimum temperature.** In addition, PET filters are less efficient. In particular, the dust collection efficiency is in general lower than of ePTFE membrane filters (‹90 % vs. › 99.9 %). An efficiency of 90% is not sufficient to comply with the EU BAT Conclusions for Waste Incinerators. The EU BAT Conclusions for Waste Incinerators sets dust emissions limits of ≤ 2-5 mg/Nm³, for certain Heavy Metals (Cd, Tl) ≤ 0.005 – 0.02 mg/Nm³ and for Dioxin ≤ 0.01 – 0.08 ng/Nm³. As an example, the dust content in the raw gas, together with the purposely injected additives, typically is on the order of 10-1000 g/Nm³. Hence the overall filtration efficiency needs to be at least (10,000 mg – 5 mg)/10,000 mg = 99.95 %. Dioxins need to be reduced from typically 2-3 ng/Nm³ in the unfiltered flue gas; hence the destruction removal efficiency needs to be at least (2 ng-0.08 ng)/2 ng = 96 %. Besides the minimum requirements of EU wide regulations, often there are stricter local or regional regulation.
	Polyurethane (PU)	Polyurethane (PU) filters are commonly used as filter media in HVAC applications, usually in the form of a foam. **PU filters can only be used at temperatures below 100°C. Thus, PU filters are not a viable alternative to catalytic ePTFE filter bags where 180°C is the required minimum temperature.** In addition, PU filters are less efficient. In particular, the dust collection efficiency is in general lower than of ePTFE membrane filters (~75 % vs. › 99.9 %). An efficiency of 75% is not sufficient to comply with the EU BAT Conclusions for Waste Incinerators (see above). Also, PU filters cannot be cleaned during operation – they are so-called depth filters, while ePTFE membrane filters are surface filters. Additionally, since PU filters are much thicker than ePTFE membrane filters (› 10 mm vs. 1-2 mm), they cannot be produced in the form of a filter bag, which is required for the installment in a baghouse to control industrial emissions.
	Polyimide	Polyimide (PI) has been used by Gore as part of a catalytic filter system in the past in combination with an ePTFE membrane filter for use in certain less demanding applications. Even though the temperature resistance is considered to be 240°C , it showed 70 to 80% strength loss over 3 years at an operation temperature of 180 to 200°C. See Chart 1 below. Therefore, it was replaced by pure PTFE filters which last for 6-8 years. At higher temperatures, an even faster deterioration rate of the PI is expected. Due to the strength loss, the filter bags made from PI and PTFE broke in particular during the cleaning process (blasting of compressed air from the clean side).

Chart 1. Strength over time for PTFE and Polyimide Felts



Besides lower temperature resistance and lower resistance against aggressive and corrosive chemicals compared to PTFE, pure polyimide filters are not a viable alternative to catalytic ePTFE filter bags since PI cannot be expanded and therefore not be filled with the catalyst material. Since PI filter bags cannot be filled with catalyst but only coated, they have limited capability to load catalyst. Coating only gets to a maximum [redacted] catalyst area density, by filling it is possible to load greater than double that amount. The lower density results in faster decrease of efficiency and a shorter product life since the efficiency will fall under the minimum efficiency requirement much faster. Efficiency degrades because of undesired side reactions and deactivation of the catalyst. Once the efficiency reaches the minimum, the bags have to be replaced. If the initial efficiency is higher, it takes longer until the minimum is reached, hence bags with higher initial efficiency have a longer service life.

	Fiberglass	**Fiberglass has only "fair to good" resistance against corrosive and chemically aggressive gas components (see table in BREF document above). Although filter bags made from fiberglass can withstand the conditions for short periods of time (<1 year), a longer service life is not possible due to continuous degradation over time. Thus, pure fiberglass filters are not a viable alternative** to catalytic ePTFE filter bags since for all applications where catalytic filter bags are used, they need to be resistant under such conditions for a longer period of time (filter bags made from pure PTFE last for 6-8 years). The use of fiberglass filter bags would lead to the following unacceptable disadvantages: • Frequent shutdowns to change filter bag before it breaks • Increasing risk of breaks during operation which would lead to high dust emissions to the environment the need to immediately shut down the plant to install a new filter bag • Significant increase of consumption of catalyst materials which typically contain heavy metal oxides including some Critical Raw Materials (e.g., vanadium(V) oxide and tungsten trioxide) due to more frequent replacements • Significant increase of waste due to more frequent replacements Similar to the polyimide example above, fiberglass cannot be filled with a catalyst the way the expanded PTFE can, so coatings are used to provide catalytic functionality. Samples were tested and demonstrated severely reduced level of NOx capture efficiency (23.9%), as compared to a fluoropolymer-based catalytic filter (87.9%)
Alternative techniques known or discussed in Restriction Proposal and performance of such techniques	Solid catalysts	Other than fluoropolymer-based Catalytic Filter Bags, which combine dust removal and catalytic gas cleaning where toxins like dioxin and NOx are destroyed in one device (the catalytic baghouse), solid catalysts where toxins are destroyed but dusts are not removed need to be combined with a regular dust filter. The toxins removal efficiency (DRE) of solid catalysts is comparable to the performance of catalytic filter bags. Also, they are resistant with regard to temperature and corrosive and chemically aggressive compounds. Because they do not remove dust, they would need to be combined with dust filters. However, as described below in the section on industrial dry filtration uses, there is no viable alternative without the use of PFAS with a sufficient filtration performance that can be used at the required temperature of above 180°C. In addition, there are several disadvantages of solid catalysts compared to catalytic filter bags: <u>Increased capital costs</u> Solid catalysts can be applied in the form of pellets (filled in a fixed bed reactor) or are embedded in ceramic bodies, which have channels where the gas flows through (so-called honeycomb elements). Both forms require separate housing to hold the catalyst, including a steel support structure as well as various controls, and connections (pipes,

		ducts, electrical, etc.). The capital costs for installation are significantly higher than the cost for installation of filter bags, and a retrofit to existing plants sometimes is not possible, because of a lack of space. Higher operating costs and energy use Both forms (fixed bed reactors and honeycomb elements) cause additional pressure loss which leads to higher operating expenses since more energy is needed to move the gas through the flue gas cleaning system. Most of the commercially available solid catalysts operate at a higher temperature than the catalytic filter bags (›250°C instead of 180-240°C). Also, they need to be regenerated frequently (every 1000 hours) by heating them up to › 300°C. The higher temperature for solid catalysts is needed since the gas does not flow through the catalyst (like it flows through the filter bags) but passes by the catalyst (flows through the channels of the honeycomb). Therefore, the contact between gas and catalyst is much less intensive, which needs to be compensated by a higher temperature and more active catalyst material, that the chemical reaction takes place faster and more gas turbulence occurs. Without the frequent regenerating process the unwanted side reactions that are unavoidable would over time block the catalyst and significantly reduce the efficiency. This further increases the carbon footprint and the operating expenses due to the higher heat energy (steam, gas firing) consumption. Greater consumption of Critical Raw Materials and Increased Waste For solid catalysts more catalyst material is needed since the gas just “flows by” with less contact of flue gas and catalyst instead of “flowing through” like in case of filter bags. This is particularly important with regard to the catalyst materials which typically contain heavy metal oxides including several Critical Raw Materials (e.g., vanadium(V) oxide and tungsten trioxide). Finally, solid catalysts have on average a shorter lifespan than catalytic filter bags (3-5 years instead of ›7 years), and thus consume more resources, generate more waste and cause more frequent plant shutdowns to do the replacement. Due to the shorter lifetime of solid catalysts, approximately twice the amount of hazardous and rare catalyst materials is needed.
	Absorbent systems	As for solid catalysts, absorbent systems where toxins are not destroyed but bound need to be combined with a regular dust filter. When using absorbent systems, temperature, and corrosive and chemically aggressive compounds are not of issue. The toxins removal efficiency (DRE) of absorption systems depends on the quantity of sorbent which is applied. Fixed bed reactors filled with sorbent typically have a higher performance than catalytic filter bags. The DRE of sorbent injection systems depends on the amount of sorbent injected and the distribution of it in the flue gas. Typically, the DRE is

		comparable to the DRE that catalytic filter bags provide. However, because they do not remove dust, they need to be combined with dust filters. **Since there are no dust filters without the use of PTFE with a sufficient filtration performance that can be used at the required temperature of above 180°C (see information on Industrial Dry Filtration Products below) there is no viable alternative without the use of PFAS.** In addition, there are several disadvantages of absorbent systems compared to catalytic filter bags: Absorbents can be applied in the form of granules or pellets (filled in a fixed bed reactor) or by continuous injection into the flue gas. Both techniques require a continuous consumption of sorbent material (e.g., activated carbon produced from wood, coke or coal). The quantity of sorbent materials required is several orders of magnitude higher compared to filter bags. Further, it must be noted that the entire amount of used sorbent material ends up as hazardous waste since it contains the toxins that have been removed from the gas stream; in essence the pollution is only moved from gas to solid phase. This is in contrast to filter bags where toxins are destroyed. Furthermore, this technique leads to much higher operating expenses due to the high amount of sorbents needed and the additional costs of disposal of hazardous waste. Although the capital costs are lower compared to catalytic conversion, the total cost of ownership for catalytic systems typically are lower than for adsorption systems.

R&D activities conducted	See above	
Performance requirements	Dry filtration products are used in different applications, including waste incineration, chemical and metallurgical processes and applications and cement production. The requirements in these applications are slightly different. In most of the applications, the dry filtration products must be able to withstand flue gas containing corrosive and chemically aggressive compounds (comparable to conditions stated above) and the operating temperatures exceeding 200°C. Only in a small number of applications (10% within our portfolio), the dry filtration products do not need to be resistant to corrosive and chemically aggressive compounds and the needed temperature resistance may vary from ambient (e.g., post-processing area where products are packed) to medium temperatures (e.g., venting of product and raw material silos) below 100°C.	
Products on market without use of fluoropolymers/ fluoromaterials	Various fabrics made from polymer fibers are used as filtration media. At present, only PTFE can be used in environments which require resistance against corrosive and chemically aggressive compounds and high temperature. If harsh chemicals do not get in contact with the filtration media, alternative polymers (such as polyimide, polyphenylene sulphide or meta-Aramid) or fiberglass can be used up to certain temperature limits (see below). However, these materials alone provide a much lower filtration performance (particulate removal efficiency, pressure loss, lifetime) than filtration media that utilize the superior properties of expanded PTFE (ePTFE) membranes for filtration. Hence, it became industry standard to combine almost any filtration media with an ePTFE membrane (two-layer laminate).[6] Even when there is only a requirement with regard to temperature resistance fluoropolymers continue to need to be used. Recently, new membrane air filters based on [redacted] have been introduced into the market. Currently, the filtration performance of these is far below that of ePTFE. Also, the temperature and chemical resistance (e.g., against solvents) is much lower for the [redacted] filters. However, Gore believes that [redacted] could be modified to have a comparable/sufficient performance in ambient/medium conditions (temperature up to max. 100°C) in the future.	
Alternative materials known or discussed in Restriction Proposal and performance of such materials	Polyester (PET)	**As stated above, polyester (PET) filters can only be used at temperatures below 150°C, and only if the gas is dry (no humidity). In humid gases the temperature is limited to 100°C. Thus, PET filters could only be used in ambient to medium temperature environments.** However, also in such environments PET filters are not a viable alternative since they are less efficient. In particular, the dust collection efficiency is in general lower than that of ePTFE membrane filters (‹90 % vs. › 99.9 %), since PET cannot be modified in a way that the structure is fine enough to capture fine particles with high enough efficiency. An efficiency of 90% is not sufficient to comply with the EU BAT Conclusions for Waste Incinerators (see above)

[6] See https://www.baghouse.com/products/baghouse-filters/ptfe-filters/.

	Polyurethane (PU)	**As stated above, polyurethane (PU) filters can only be used at temperatures below 100°C. Thus, PU filters could only be used in ambient to medium temperature environments. However, also in such environments PU filters are not a viable alternative since they are less efficient. In particular, the dust collection efficiency is in much lower than of ePTFE membrane filters (~75 % vs. › 99.9 %).** An efficiency of 75% is not sufficient to comply with the EU BAT Conclusions for Waste Incinerators (see above). In addition, PU filters are not a viable alternative since they are so-called depth filters, while ePTFE membrane filters are surface filters. This means that they collect the dust in its internal structures. Therefore, PU filters cannot be cleaned during operation but have to be replaced when saturated. Since PU filters are much thicker than ePTFE membrane filters (› 10 mm vs. 1-2 mm), they cannot be produced in the form of a filter bag, which is needed for the installation in a baghouse to control industrial emissions.
	Polyimide	**As stated above, polyimide (PI) filters have a lower temperature resistance compared to PTFE. Even though temperature resistance is considered to be 240°C, it showed 70 to 80% strength loss over 3 years at an operation temperature of 180 to 200. Thus, PI filters could only be used in ambient to medium temperature environments. However, also in such environments PI filters are not a viable alternative since they are less efficient. In particular, the dust collection efficiency is in lower than of ePTFE membrane filters (~99 % vs. › 99.9 %)** and an efficiency of 99% is not sufficient to comply with all requirements under the EU BAT Conclusions for Waste Incinerators (see above).
	Polyethylene	Polyethylene (PE) is not sufficiently resistant against chemicals, since it is susceptible to certain acids and organic solvents as Table 4 demonstrates. As stated above, PE has just been introduced as a filter medium recently. Currently, the dust collection efficiency is still lower than of ePTFE membrane filters (~99 % vs. › 99.9 %) and an efficiency of 99% is not sufficient to comply with all requirements under the EU BAT Conclusions for Waste Incinerators (see above).

Table 4. Chemical Resistance of Polytetrafluoroethylene (PTFE) and Polyethylene (PE)

(Temperature 50C; 30 days exposure)

Chemical	PTFE	PE
Acids		
Acetic acid 99%	**	**
Nitric acid 20%	**	*
Sulfuric acid 50%	**	**
Bases		
Ammonia	**	**
Sodium Hydroxide	**	**
Caustic Soda 30%	**	**
Aqueous Solutions		
Detergents	**	**
Sodium Chloride	**	**
Organic Solvents		
Acetone	**	**
Ethanol	**	**
Heptane	**	**
Trichloroethylene	**	X
White Spirit	**	*
Xylene	**	*
Propylene Carbonate	**	**
Diethyl Carbonate	**	**

** Resistant, properties unaffected
* Moderately resistant, slight reduction of properties
X Not resistant, significant reduction of properties

Source: Figure 3 from Galka/Saxena/Crosby, Filtration+Separtion, 30 Jul 2009 (https://www.filtsep.com/content/features/high-efficiency-air-filtration-the-growing-impact-of-membranes/)

Polyphenylene sulphide	**Polyphenylene sulphide (PPS) filters can only be used at temperatures below 190°C. Thus, PPS filters cannot be used at very high temperatures like PTFE. In addition, PPS filters are not a viable alternative since they are less**

		efficient. In particular, the dust collection efficiency is much lower than of expanded PTFE membrane filters (99.7 vs. › 99.9 %). **While numerically this may seem close, it means that the PPS filter allows more than 50 times more particulate to pass through than the PTFE membrane filter based on lab testing.** An efficiency of 99.7% is not sufficient to comply with the EU BAT Conclusions for Waste Incinerators (see above).
	Meta-Aramid	**Meta-Aramid (mA) filters can only be used at temperatures below 200°C. Thus, mA filters cannot be used at very high temperatures like PTFE. In addition, mA filters are not a viable alternative since they are less efficient**. In particular, the dust collection efficiency is much lower than of ePTFE membrane filters (~95 % % vs. › 99.9 %). An efficiency of 95% is not sufficient to comply with the EU BAT Conclusions for Waste Incinerators (see above).

Alternative Assessment for Mercury and SO_2 Control Modules

R&D activities conducted	We have investigated [redacted] as a potential surrogate for ePTFE. It showed very low mechanical stability and integrity and does not provide sufficient level of hydrophobicity. Therefore, it is considered not technically feasible.
Performance requirements	Mercury and SO_2 Control Modules (GMCS) are primarily applied in flue gas cleaning of coal fired power plants, sludge incinerators and other processes where the flue gas needs to be cleaned from sulfur dioxide (SO_2) and/or mercury. The modules consist of a frame which houses a PTFE based composite that contains adsorptive and catalytically active components. By the absorptive components gas phase mercury emissions are captured and converted into stable mercury compounds which can be safely disposed of. For SO_2 control a catalyst is used to convert SO_2 to saleable sulfuric acid, a valuable and versatile chemical used for production of certain types of fertilizers. Both systems rely on the unique properties of PTFE to create highly porous, chemically inert scaffolds to hold the catalyst and sorbent particles, allowing for high activity in use. Furthermore, it is the hydrophobic nature of PTFE that allows the particles to maintain their activity in a wet environment. As sulfuric acid is formed by the reaction with SO_2, this must be removed from the individual catalyst particles, otherwise the reaction will effectively shut down due to mass transport limitations caused by liquid films. The PTFE structure supports the liquid to flow away from the catalyst surface, allowing the catalyst or sorbent to function for many years continuously without requiring any regeneration. In the processes where our modules are applied, there is always a high level of SO_2 present, often also other acid gases and corrosive constituents. The flue gas typically is saturated with water vapor. While the environment can be considered harsh because of this demanding combination of chemicals, the temperature level usually is around 50-70°C.
Products on market without use of fluoropolymers/ fluoromaterials	No comparable products on the market

Alternative materials known or discussed in Restriction Proposal and performance of such materials	There are no known alternative materials. As already described above, other polymers are not sufficiently resistant to corrosive and chemically aggressive flue gases and would not withstand the conditions where Mercury and SO_2 Control Modules are operated. In addition, other materials like polyethylene, polyester and polyurethane show a lack of hydrophobicity, since they have a higher surface energy than PTFE. Therefore, these non-PFAS materials cannot be used in a water saturated atmosphere where the modules are operated – the water would block the pores immediately and the flue gas could not pass through anymore. The hydrophobic nature – which based on current knowledge only PTFE provides – is essential to force liquids away from the catalysts and sorbents in order to preserve their activity.	
Alternative techniques known or discussed in Restriction Proposal and performance of such techniques	Adsorption systems	The next best technique for flue gas cleaning from mercury is the use of adsorption systems. Due to the water-saturated environment, traditional fixed bed reactors filled with sorbent material do not work, unless the flue gas is reheated ~20°C above the dew point. Therefore, the sorbent material (activated carbon) needs to be continuously injected to the flue gas stream. An adsorption system would also have to be combined with a limestone based wet scrubbing system, which comes with further challenges (described below). Even though the destruction removal efficiency (DRE) may be, depending on the amount of injected material, comparable. **this technique does not meet the performance need of removing both mercury and SO_2 from the flue gas.** In addition, there are further significant disadvantages of absorption systems: a very large amount of carbon is required to capture a relatively small quantity of mercury. The result is 3-4 orders of magnitude more solid waste generated compared the Mercury and SO_2 Control modules. As an example, 1 kg of media used in Mercury and SO_2 Control modules can replace 15,000 kg of activated carbon powder which would be needed if using absorption systems. Activated carbon can also contaminate other process residues that otherwise may have some beneficial use, such as fly ash use in concrete and cement, resulting in even larger waste volumes. Also, the process of producing activated carbon releases CO_2. In total the emissions of carbon dioxide are a hundred times higher than if using Mercury and SO_2 Control modules. While there are other filtration products available for reducing mercury and acid gas emissions, their overall performance is inferior to GCMS because: they require very large amounts of carbon to capture a relatively small quantity of mercury, resulting in 3-4 orders of magnitude more solid waste that must be managed; activated carbon can also prevent beneficial reuse of other by-products (such as fly ash use in concrete and cement), resulting in even larger waste volumes; use of activated carbon increases the total emissions of carbon dioxide by 100X compared to use of GCMS; higher energy and resource consumption is needed to produce and maintain absorption and limestone based wet scrubbing systems to achieve comparable overall emissions reduction performance of GCMS;

	Limestone based wet scrubbing	Flue gases can be cleaned from SO_2 via limestone based wet scrubbing. **This technique can only clean flue gasses from SO_2 and not from Mercury, as opposed to PTFE-based technology.** In addition, there are significant disadvantages with limestone-based wet scrubbing: In particular, the carbon footprint of this technique is much higher. Besides the need to install two different techniques to clean both SO_2 and Mercury, CO_2 is generated during the cleaning process. Furthermore, limestone-based wet scrubbing generates gypsum, which is regarded as waste in several countries. The wet scrubbing systems also consume a significant amount of parasitic power, resulting in lower overall plant efficiency.

Alternative Assessment for Industrial Fiber used as Thread or Staple in Filtration Applications

R&D activities conducted	See above for Industrial Dry Filtration Products	
Performance requirements	There are two different uses of expanded PTFE fiber: Threads are used in industrial filtration applications to sew filter bags together. Staple fiber is combined into a felt to reinforce expanded PTFE filter membranes; they are used as a second layer since an ePTFE membrane alone is not stable enough to be used as a filter alone. The performance requirements are the same as for the Industrial Dry Filtration Products (described above). The thread needs to be resistant to corrosive and chemically aggressive compounds and to operating temperatures above 200°C. Only in a small number of applications, resistance against corrosive and chemically aggressive compounds is not required and the resistance in ambient or medium temperatures might be sufficient.	
Products on market without fluoropolymers	There a few products using aramids and/or stainless-steel threads. However, both have limitations and are therefore non-viable alternatives (see section below)	
Alternative materials known or discussed in Restriction Proposal and performance of such materials	PET, PI, PU	As demonstrated above, materials like polyester, polyurethane, polyimide, and polyurethane are not sufficiently resistant to temperature and polyurethane as well as fiberglass are not sufficiently resistant against chemicals. Therefore, in most of the applications they are not a technically feasible alternative since they would lead to early failure of the equipment. Due to the low material thickness, the temperature and chemical resistance is of even greater importance. For example, temperature limitation for threads made from PE and PET would be 80°C and 60°C instead of 100°C. Even though the melting point is at 100°C, softening therefore weakening happens below that temperature. Seam failure and, therefore, uncontrolled emissions would be expected.

		In addition, the high temperature resistance and tenacity (strength to mass ratio) of PTFE thread allows for use of smaller diameter filaments in sewing application, this provides the best seal by minimizing the uneven seam that heavier thread would create.
	Aramids and Steel	Even though aramids have a high temperature resistance, they are not a viable alternative since they would break during cleaning process where compressed air from the clean side is blasted through the filter to knock-off the collected dust. As explained above, in all industrial filtration applications such cleaning is required. Seam failure and, therefore, uncontrolled emissions would be expected. Stainless steel has a high temperature resistance but no sufficient resistance against acids. For environments where only temperature resistance is required, stainless steel is not a viable alternative since it is very difficult to handle. Sewing with steel filaments has to be done with specialized equipment, guides need to be hardened or ceramic materials. A much slower sewing feed is required as well. Finally stainless thread will not conform to tight stitch requirements leaving gaps where bypass can occur at the seams. Similar to aramid thread, abrasiveness of the material would require special sewing considerations and the stiffness while not as severe as steel would not allow for tight stitch patterns needed for good containment. For both steel and aramid larger diameter bags could be used to minimize the thread gaps, however, in addition to redesign and rebuild of the bag house configuration larger bags would increase the space between bags reduces the effective filtration area and the overall efficiency of the system
	Polyamide	Polyamide thread has high strength and fair temperature resistance, however it exhibits brittle behavior when dry. This condition occurs occur with absorption and lime scrubbing noted above and sudden loading in the back pulse used to clean the filter. Seam failure and, therefore uncontrolled emissions would be expected.
	The only viable alternative being sufficiently resistant against high temperature and chemicals would contain asbestos which – for known reasons – has already been restricted.	

Annex II - SEA of restricting the use of PFAS in filters

See file submitted in the attachment

W. L. Gore & Associates' Comments on Dossier Submitters' Draft EU REACH Restriction on PFAS

Request for Derogation: Fluoropolymers

Public consultation

July 2023

CONTENTS

Executive Summary

Fluoropolymers are non-hazardous, non-toxic, non-bioavailable[1], non-bioaccumulative, non-water soluble, non-mobile and they do not degrade to such substances under relevant environmental conditions. They play a crucial role in a range of highly technical and often demanding applications with high socioeconomic value. In many of these applications alternatives that can provide the same combination of critical performance properties, are not currently available and are unknown or unlikely to be identified or developed.

To that end we would like to highlight the need for a derogation of fluoropolymers in technically demanding applications. We believe that all the concerns of the Dossier Submitters in terms of manufacturing/processing, in-use-phase and end-of-life can be addressed without prohibiting fluoropolymers:

- Manufacturing and Processing – Emissions of fluoropolymers and non-polymeric PFAS used or created during manufacturing and processing of fluoropolymers should be effectively managed by emission control technologies. Fluoropolymer manufacturers have committed to continuously improve best available techniques in the manufacturing processes and management of environmental emissions related to fluoropolymers. In addition, emissions can and should be regulated by emission control laws.
- In-Use-Phase – Products manufactured from fluoropolymers do not pose a risk to people or the environment during the in-use-phase, since fluoropolymers themselves are non-hazardous/non-toxic. The amount of low molecular weight residuals and oligomers is already low in the large majority of commercially available fluoropolymers and can be further reinforced by a revised derogation to limit residuals as suggested herein.
- End of Life –The relevant end-of-life management of fluoropolymers do not pose an environmental concern and we will provide data to demonstrate this. Finally, we would like to highlight on-going progress in the recycling of fluoropolymers.

Gore appreciates the opportunity offered by the public consultation process to provide comments on the Proposal for a Restriction of Per- and polyfluoroalkyl substances (PFASs) (hereinafter '**Restriction Proposal**').

[1] Bioavailability means a category of absorption; referring to a drug or chemical which will enter the circulation when introduced into the body and so able to have an active effect. Size is often cited as a limiting factor to bioavailability, but other considerations such as molecular weight, chemical and structural properties, and an ability to bind to cell surface receptors or signal events within the cell also play a role.

First, we would like to stress that, consistent with Gore's commitment to environmental stewardship, we support initiatives to reduce PFAS emissions.

For over 60 years, we've used science and advanced materials capabilities to create products that improve lives. We carefully consider the effects of our products and operations on the environment, as well as on the health and well-being of people all around the world. We are committed to the responsible and safe management of chemicals throughout our value chain over our products' entire life cycle.

The term PFAS generally refers to aliphatic substances with at least one fully fluorinated carbon atom. This is a very broad chemical definition that includes thousands of substances with different properties: polymers and non-polymers; solids, liquids, and gases; persistent and non-persistent substances; highly reactive and inert substances; mobile and insoluble substances; and toxic and non-toxic chemicals.

The significant differences of the substances falling into the broad PFAS group have not been sufficiently considered in the current Restriction Proposal. In many highly technical and demanding applications, fluoropolymers are indispensable and add critical value to society. In addition, fluoropolymers are non-hazardous, are not bioavailable, and are not classified as hazardous under EU CLP Regulation. They also do not degrade to or release such substances under relevant environmental conditions. As fluoropolymers emissions during manufacturing and processing can be controlled, and fluoropolymers can be used, and disposed of safely, they do not pose an unacceptable risk. Therefore, **from our point of view a prohibition of fluoropolymers under REACH cannot be justified**. While we acknowledge the concern regarding emissions from fluoropolymer manufacturing and processing, we believe that emissions control law is the right instrument to address this concern.

Since production of polymers may result in low molecular weight residuals and oligomers, we would like to propose the following derogation to restrict the amount of non-polymeric species.

We respectfully request a new lit. d. in Paragraph 4 of the draft restriction which would read as follows:

> ***d. Fluoropolymers which contain less than 5 ppm of low molecular weight residuals[2] and less than 5% of oligomers[3] smaller than 1.000 Da and less than 2% of oligomers smaller than 500 Da.***

We will explain the suggested derogation and the significance of these criteria in Section I and Annex II below. Proposed definitions of the terms used in the derogation request can be found in Annex I. In Section II we will also address the concerns raised in the Restriction Proposal. We believe we can address all concerns that have been expressed.

[2] See definition in Annex I.
[3] See definition in Annex I.

I. Explanation of Suggested Derogation

1. Need for Derogation for Fluoropolymers/Fluoropolymer applications

a) Properties of Fluoropolymers and Importance of Persistency/Stability

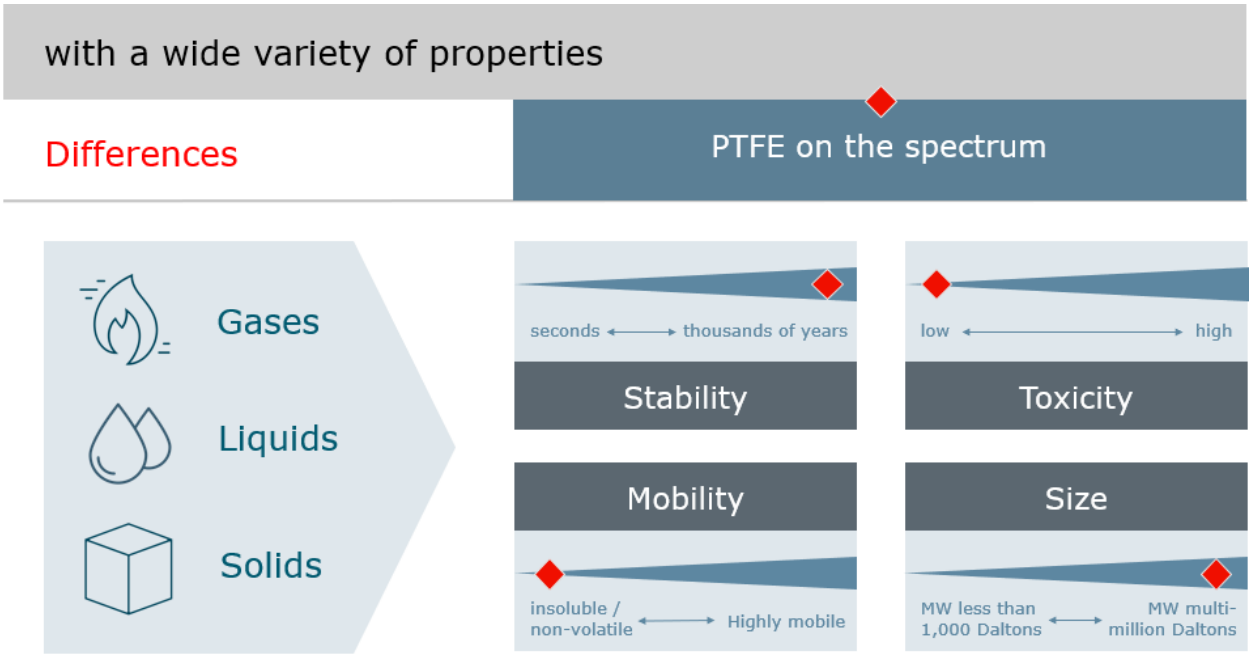
As already stated above there are significant differences of the substances falling into the broad PFAS group: polymers and non-polymers; solids, liquids, and gases; persistent and non-persistent substances; highly reactive and inert substances; mobile and insoluble substances; and toxic and non-toxic chemicals.

While fluoropolymers covered by this derogation request (e.g PTFE, ETFE, FEP and PFA) are persistent,

- they are not classified as hazardous under EU CLP Regulation and are non-toxic (see Annex II, Section III.5.);
- they have a high molecular weight meaning they are neither bioavailable[4] nor bioaccumulate in cells or organs since they cannot be absorbed into the blood stream through the lung, across the skin, or across the digestive tract (see Annex II, Section III.4.);
- they are non-water soluble and non-mobile molecules; this means they do not have the potential to become widespread in the environment (see Annex II, Section III.1.);
- and they do not degrade to such substances under relevant environmental conditions (see Annex II Section IV).

The wide variety of properties and where fluoropolymers such as PTFE are located in this broad spectrum is illustrated by the chart below:

[4] Bioavailability means a category of absorption; referring to a drug or chemical which will enter the circulation when introduced into the body and so able to have an active effect. Size is often cited as a limiting factor to bioavailability, but other considerations such as molecular weight, chemical and structural properties, and an ability to bind to cell surface receptors or signal events within the cell also play a role.



Further, we would like to stress that persistency, or stability, as it could also be called, is a critical property for technically demanding applications where fluoropolymers are used. Durable products, particularly those that must perform in harsh environments and/or where ongoing maintenance is a challenge or not possible, leverage the attribute of persistency to maintain needed performance over the lifetime of the product.

Persistence does not predict long-range transport potential, mobility, water solubility or ability to partition to air, water, sediment, or soil, toxicity, and bioaccumulation. Further, persistence does not equate to degradation. On the contrary, persistency is a degree of resistance to degradation or environmental transformation (see Annex II Section IV.).

While on the one side persistence is a characteristic of a substance indicating relative longevity in the environment, on the other side it ensures durable products even in harsh environments.

b) High Value to Society

Fluoropolymers play a crucial role in many applications with high socioeconomic value. In many cases, these substances are irreplaceable to meet all the needs of demanding applications. Among others, this applies to many applications in the field of green energy such as electrolysers for hydrogen production, hydrogen fuel cells and lithium-ion batteries. Fluoropolymers also play a key role in the medical technology sector, especially in endoscopy and minimally invasive surgery. Substitute materials are often unsuitable for the specific medical application such as cardiovascular implantable devices that save many patients' lives or/and increase their quality of life. These and many other applications clearly have high and indispensable value to society at large.

Gore will submit several proposals for end-use derogations that demonstrate the critical role that fluoropolymers play in a range of industries. The list is provided in Annex III.

c) Comparison to other Polymers

Like the broad PFAS group, properties of polymers vary greatly depending on factors such as molecular structure. As highlighted above, fluoropolymers are stable/persistent. Persistence is a property that they share with many other non-fluoro polymers such as high-density polyethylene (HDPE), polyether ether ketone (PEEK), polypropylene (PP) and polyethyleneterephthalate (PET).

Polymers for technical applications are selected for a broad range of performance criteria, for example,

- Chemical resistance – Table 1
- Thermal stability (Low and high temperatures), including continuous use and maximum operating temperatures – Table 2
- Surface energy which indicates hydrophobicity and oleophobicity: Lower surface energy indicates a more oleophobic and hydrophobic material – Table 3

Fluoropolymers are selected based on their ability to meet multiple challenging performance criteria of various end-uses. Please note that depending on the specific end use there are many other performance criteria.

Table 1 Chemical Resistance[5]; Please note that PTFE is referred to as TFE.

	ETFE	FEP/TFE/PFA	FLPE	FLPP	HDPE	LDPE	PC	PETG	PP	PVC	TPE***
Acids, Dilute or Weak	E	E	E	E	E	E	E	G	E	E	G
Acids, **Strong/Concentrated	E	E	G	G	G	G	G	N	G	G	F
Alcohols, Aliphatic	E	E	E	E	E	E	G	G	E	G	E
Aldehydes	E	E	G	G	G	G	G	G	G	G	G
Bases/Alkali	E	E	F	E	E	E	N	N	E	E	F
Esters	G	E	G	G	G	G	N	G	G	N	N
Hydrocarbons, Aliphatic	E	E	E	G	G	F	G	G	G	G	E
Hydrocarbons, Aromatic	G	E	E	N	N	N	N	N	N	N	N
Hydrocarbons, Halogenated	G	E	G	F	N	N	N	N	N	N	F
Ketones, Aromatic	G	E	G	G	N	N	N	N	N	F	N
Oxidizing Agents, Strong	E	E	F	F	F	F	F	F	F	G	N

*Not for tubing chemical resistance (except PVC) **Except for oxidizing acids (See oxidizing agents, strong) ***TPE gaskets

EXCELLENT	GOOD	FAIR	NOT RECOMMENDED
30 days of constant exposure causes no damage. Plastic may tolerate for 30 years.	Little or no damage after 30 days of constant exposure to the reagent.	Some effect after 7 days of constant exposure to the reagent. The effect may be crazing, cracking, loss of strength or discoloration.	Immediate damage may occur. Depending on the plastic, the effect may be severe crazing, cracking, loss of strength or discoloration, deformation, dissolution or permeation loss.

[5] Eason, M., & Vogel, R. (2022, May). Sealing Devices and the need for PFAS. Valve World, 20-22.

Table 2 Thermal Stability[6]

Polymer Name	Minimum operating temperature (°C)	Maximum operating temp (°C)
ABS - Acrylonitrile Butadiene Styrene	80.0	86
ETFE - Ethylene Tetrafluoroethylene	-100.0	140
EVA - Ethylene Vinyl Acetate	-60.0	45
FEP - Fluorinated Ethylene Propylene	-150.0	205
HDPE - High Density Polyethylene	-70.0	100
HIPS - High Impact Polystyrene	-20.0	60
LCP - Liquid Crystal Polymer	-50.0	200
LDPE - Low Density Polyethylene	-70.0	80
PA 6 - Polyamide 6	-20.0	80
PA 66 - Polyamide 6-6	-65.0	80
PAI - Polyamide-Imide	-196.0	220
PAR - Polyarylate	-95.0	130
PBT - Polybutylene Terephthalate	-40.0	80
PCTFE - Polymonochlorotrifluoroethylene	-250.0	150
PEEK - Polyetheretherketone	-70.0	154
PET - Polyethylene Terephthalate	-40.0	80
PP (Polypropylene) Homopolymer	-10.0	100
PSU - Polysulfone	-100.0	150
PTFE - Polytetrafluoroethylene	-200.0	260
PVC, Plasticized	-5.0	50
PVDF - Polyvinylidene Fluoride	-40.0	70
UHMWPE - Ultra High Molecular Weight Polyethylene	-30.0	110

Table 2 lists the minimum and maximum working temperatures (a.k.a. continuous use temperature), where the required properties are maintained.

[6] https://omnexus.specialchem.com/polymer-properties/properties/min-continuous-service-temperature.

Table 3 Surface Energy[7]

Polymer abbr.	Polymer Name	Surface Energy (dynes/cm)	Contact Angles (degrees)
PES	Polyethersulfone	46	90
	Styrene butadiene rubber	48	
PPO	Polyphenylene oxide	47	75
	Nylon 6/6 (polyhexamethylene adipamide)	46	
PC	Polycarbonate	46	75
	Nylon-6 (polycaprolactam)	38	
PET	Polyethylene terephthalate	42	76
PMMA	Polymethylmethacrylate	41	82
SAN	Styrene acrylonitrile	40	74
	Polyimide	40	83
PVC r	Polyvinyl chloride, rigid	39	90
	Polyester	41	70
	Acetal	36	85
ABS	Acrylonitrile butadiene styrene	35	82
PPS	Polyphenylene sulfide	38	87
PVA	Polyvinyl alcohol	37	10
	Polyacrylate (acrylic film)	35	
PVC p	Polyvinyl chloride, plasticized	35	89
PS	Polystyrene	34	72
	Nylon-12	36	
	Surlyn ionomer	33	80
PBT	Polybutylene teraphthalate	32	88
CTFE	Polychlorotrifluoroethylene	31	
PP	Polypropylene	30	88
PU	Polyurethane	38	85
PE	Polyethylene	30	88
PVF	Polyvinyl fluoride	28	
PVDF	Polyvinylidene fluoride	25	80
	Natural rubber	24	
PDMS	Polydimethyl siloxane (silicone elastomer)	23	98
FEP	Fluorinated ethylene propylene	20	98
PTFE	Polytetrafluoroethylene	19	120

Table 3 lists surface energy which is a measure of oleophobicity and hydrophobicity, with a lower number indicating that the polymer is more oleophobic and hydrophobic.

In summary, stability (or persistence) is a common attribute of many different types of polymers, not just fluoropolymers. One of the benefits of fluoropolymers is that it retains this stability over a broader array of use conditions. Regulation of fluoropolymers on the grounds of persistence alone is not appropriate nor is it consistent with treatment of other persistent polymers or other substances.

[7] https://www.tstar.com/blog/bid/33845/surface-energy-of-plastics

2. Criteria referred to in Suggested Derogation

In the following we would like to explain the criteria referred to in the suggested derogation.

a) Low Molecular Weight Residuals

As indicated above and in Annex II, Fluoropolymers themselves are non-hazardous and non-bioavailable.

Without bioavailability there can be no toxicity or bioaccumulation. It is well established that, in general, as the molecular weight of the substance increases, bioavailability and toxicity decrease, and that at a molecular weight › 1.000 Da, bioavailability is negligible.[8] Fluoropolymers typically have a molecular weight significantly above 1.000 Da ranging from 7.000 to millions of Da (see Annex II Section III.4.).

While fluoropolymers are non-bioavailable, low molecular weight residuals might be present in the polymer due to processing aids, monomers, other substances used in the polymerization process as well as any unintentional by-products created during the polymerization process.

Most of these residuals are removed in post polymerization processing/washing steps and destroyed or captured by emission control technologies (see Section II.1.a) below). To ensure purity of polymers, processors of fluoropolymers like Gore, oblige their suppliers to meet stringent specifications regarding fluorinated residuals.

However, it is mentioned in the Restriction Proposal that there are fluoropolymers on the market which do not meet these stringent specifications. This may be due to the fact that stringent specifications are not applied everywhere as such purity may not be requested for less technical applications. Our understanding seems to be confirmed by the examples mentioned in Annex B (p 208) of the Restriction Proposal, where it is referred to studies which reported 1-10 ppm of residuals in PTFE fine powder and much higher amounts in aqueous dispersion and up to 15-1000 ppm in personal care articles containing intentionally added PTFE fine particles.

To ensure that fluoropolymers manufactured in or imported to the EU contain limited levels of low molecular weight residuals, we suggest restricting the low molecular weight residuals content to less than 5 ppm. 5ppm is an appropriate limit for these residuals since Henry et al., 2018, and Korzenowski et al., 2022 demonstrated that polymers with less than 5ppm residuals have a low hazard profile and that 96% of all commercially available fluoropolymers have residuals below 5ppm.

b) Oligomers

In addition, we suggest restricting the oligomer content to less than 5% of oligomers smaller than 1.000 Da and less than 2% of oligomers smaller than ‹500 Da. Oligomers are short chains made up of a few monomers and are formed during all polymerization reactions. Our proposal

[8] BIO by Deloitte, 2015; De Mello, 1987; Beyer, 1993; Alberts et al., 2002; Schwarzmann et al., 1981; Birgit et al. 1977 Chemservice, RMOA prepared for Fluoropolymers Group (FPG) of Plastics Europe, 2021, p. 32 f; see also Annex II Section III.4.

results from current understanding of the various expert statements.[9] We also want to note that studies on a broad range of fluoropolymers demonstrated negligible oligomers in the range below 1.000 Da.[10] This limitation is recommended to apply to all polymers, not only fluoropolymers, where there are multiple studies which highlight the benefit of limiting oligomer content due to their small molecular size and potential bioavailability.

3. Possible Additional Criteria

Fluoropolymers are non-hazardous and not bioavailable, are not classified as hazardous under EU CLP Regulation and do not pose a risk to human health or the environment. They also do not degrade to or release such substances under relevant environmental conditions. Data which demonstrate this are provided in Section III.5 and Section IV of Annex II. Therefore, we believe a REACH Restriction prohibiting fluoropolymers cannot be justified.

We note that the Dossier Submitters raised concerns relating to consumer products. A potential response to this concern could be to align the fluoropolymer derogation with the latest draft of the PFHxA restriction published by the Commission on June 14, 2023, to exclude from the scope of the derogation wide dispersive product uses supplied to the general public, where it is difficult or not possible to implement risk management measures to minimize releases. Technically demanding products with high societal value and where alternatives are in general unlikely to be available or developed due to chemical limitations of alternatives, would remain unaffected by such addition. Dispersive non-professional/consumer uses where substitution might be more likely would be excluded from the scope of the proposed fluoropolymer derogation but remain subject to case-by-case assessment for consideration of use-specific derogations.

In any case, it needs to be ensured that components used in complex products used by the general public, such as components in automobiles or electronics, would remain in scope of the derogation because they are non-dispersive and technically demanding uses.

For clarity, even though the wide-dispersive use criterion is offered to address concerns stated by the Dossier Submitters, we believe that a ban of such products would not comply with REACH requirements for a restriction since fluoropolymers are non-hazardous/non-toxic.

[9] BIO by Deloitte, 2015; US EPA 1997; OECD 2009; EU Commission 2012; Wood 2020, CARACAL-48 (28 March 2023) AP 4.1.
[10] Korzeniowski et al., 2023.

II. Addressing Concerns Raised in the Restriction Proposal

In the Restriction Proposal, concerns regarding fluoropolymers were raised. This section provides information that we believe addresses all the concerns that have been expressed.

Hazards associated with fluoropolymers are addressed Section B.7.6 of Annex B of the restriction proposal where it is stated that fluoropolymers are indirectly of concern because monomers, oligomers, and by-products *"are emitted into the environment"* during their production and use and during waste incineration *"non polymeric PFAS may be formed and emitted"*. In particular, it refers to potential emissions of PFAS-based processing aids. Further, it is stated that fluoropolymers, as other polymers, pose an environmental hazard due to microplastics that can be formed during their use or end-of-life phase.

In the following section we would like to demonstrate that based on the life cycle of fluoropolymers, the potential emissions during manufacturing and processing of fluoropolymers can be controlled, and fluoropolymers can be used and disposed of safely and in accordance with environmental standards. Hence, there is no unacceptable risk.

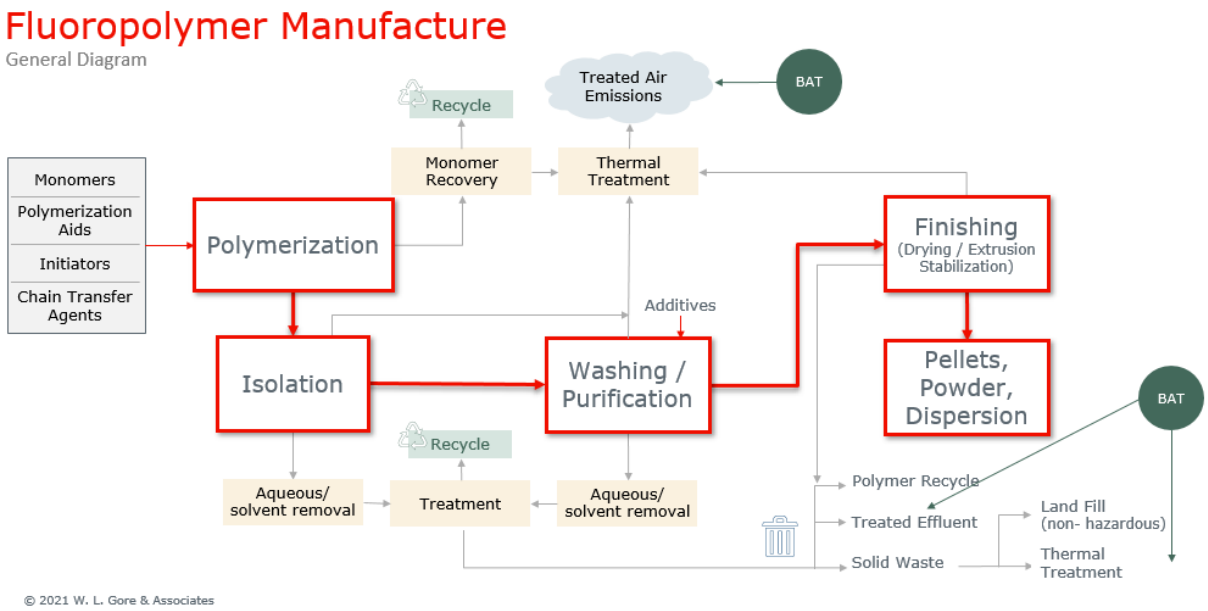
While it is true that non-polymeric PFAS have the potential to be released during manufacturing and processing of fluoropolymers, they can be effectively controlled by emissions control technologies. Therefore, a restriction is not the right instrument to regulate fluoropolymers, which are intrinsically non-hazardous. Emission control laws should be used to address potential emissions from manufacturing or processing.

1. Manufacture of Fluoropolymers

We believe that emissions from fluoropolymer manufacturing can be effectively controlled throughout all the manufacturing stages.

a) Emissions of non-polymeric PFAS

To manufacture fluoropolymers, substances like monomers, polymerisation aids, initiators, and chain transfer agents are needed which may fall under the broad PFAS group. The diagram below shows an overview of a generalised fluoropolymer manufacturing process and the potential sources for emissions:



As demonstrated, in the diagram above there is a potential for emissions to water and for emissions to air that can occur if effluent water and exhaust air are not sufficiently captured and treated.

To our knowledge, all EU fluoropolymer manufacturers have emission control measures as well as monitoring programs in place. This applies to both the exhaust air and the wastewater stream. Releases from post-polymerization steps (e.g. drying, sintering, compounding, washing) – which are referenced in Lohmann et al., 2020, and mentioned as a concern in Annex B, Section B.9.2.5 of the restriction proposal – are also captured by these emission control measures.

Gore only manufactures very small amounts [redacted] of PTFE, PFA, FEP, at its site in Burgkirchen, Germany, which are further processed into articles at other Gore sites. Even though Gore's small-scale polymerization facility might not be comparable to large manufacturing sites, additional information including information on emissions, emission control and monitoring can be found in Annex IV.

While the most common technology to control PFAS from exhaust air are thermal oxidizers where the PFAS destruction efficiency has been demonstrated to be 99,9%[11], there are different technologies to control PFAS from water effluent.

In September 2021, the members of the Fluoropolymer Group of the Plastics Europe, which represents all EU fluoropolymer manufacturers, committed themselves to responsible manufacturing principles to minimize emissions, which include the following[12]:

[11] See https://www.chemours.de/-/media/files/corporate/fayetteville-works/2020-0320-thermal-oxidizer-efficiency-results-announced.pdf?rev=87dbfd0ebb9c45aeaa475fddd2a899b4.
[12] ChemService, RMOA prepared for Fluoropolymers Group (FPG) of PlasticsEurope, 2021, page 169f.

1. To maintain, continuously improve and/or develop best available techniques in the manufacturing processes and management of environmental emissions related to fluoropolymers.

2. To maintain and continuously improve and develop containment, capture, and recycle technologies to minimize emissions into the environment from PFAS substances intentionally and non-intentionally present in fluoropolymers including fluorinated raw materials, polymerization aids, monomers, intermediates, and process chemicals as well as by-products.

This is now to be cemented by a commitment to establish a fluoropolymer platform to share good practice and support the deployment of state-of-the art technologies in emissions control across the industry. In addition, the platform participants committed to institute an exchange forum with key stakeholders and legislators. This exchange forum will guarantee transparency, accountability and supervises the implementation of the FPG Responsible manufacturing program. The exchange forum shall meet formally twice per year with a first meeting by the end of 2024.[13]

This commitment will further contribute to the continuous improvements in emission reduction. A restriction based solely on emissions that have occurred in the past is not justified.

Gore acknowledges that there are currently legally binding limits for emissions for only a small number of PFAS substances and that the EU BREF for polymer production of 2007[14] does not contain information specific to production of fluoropolymers. This regulatory gap should be closed, and emission control law is the right instrument to close this gap.

b) Emissions of Polymeric PFAS

During normal operation, releases of the manufactured polymer are not to be expected due to effective control measures such as filters to capture polymer particulates and separate drains and collection points for post-processing treatment.

In case of an unintended release (e.g., accident) of non-negligible quantities during manufacturing there is no risk of dispersal over long distances, as fluoropolymers are solid and practically insoluble in water (see Section III.1. of Annex II). Due to their poor solubility, polymers can be effectively removed physically from sewage water. There are many proven waste-water treatment technologies available to effectively remove particles of different sizes from wastewater streams.

c) Emission Estimates in Restriction Proposal

Regarding emissions in EU from manufacturing of PFAS in general (not only fluoropolymers), it is stated in the Restriction Proposal that relatively accurate information is available due to permits

[13] Commitment being finalized at time of writing

[14] Available at https://eippcb.jrc.ec.europa.eu/reference/production-polymers.

and enforcement information. Since emission estimates for manufacture of fluoropolymers are not provided in the Restriction Draft, the accuracy of the emission estimates could not be evaluated.

2. Processing of Fluoropolymers

Since processing takes place at closed sites, a release of fluoropolymers/polymeric PFAS is not to be expected due to particle filters and general EH&S practices. Releases of non-polymeric PFAS during any processing can also be effectively controlled.

Although fluoropolymers do not degrade under relevant environmental conditions, processing of fluoropolymers, in some cases, can lead to degradation and release of non-polymeric PFAS. Degradation and release depend on a variety of factors including heat, state change of the material, and time, and in particular on the type of the fluoropolymer.

Since processing often takes place at temperatures above typical continuous use temperatures, emission control technologies like ventilation systems leading to thermal oxidizers need to be used to destroy PFAS before the exhaust air is released into the environment. Thermal oxidation is a state-of-the-art process for cleaning exhaust air. The exhaust air is fed into a combustion chamber and oxidized (burned) at temperatures between 800 °C and 1.200 °C. This is a regenerative process that ensures elimination of pollutants and recovers up to 97% of the heat generated. These control technologies capture and destroy non-polymeric residuals that may be released during processing.

For all Gore's fluoropolymer processing activities in Europe, efficient emission control technologies and in particular oxidizers for its extrusion applications are in place.

However, the RMOA prepared by ChemService for the Fluoropolymers Group (FPG) of PlasticsEurope acknowledges that not all fluoropolymer processors have implemented these types of emissions control technologies. [15] This once again highlights a regulatory gap that should be closed through emissions control laws. Emission control laws should be amended to require appropriate control technologies be implemented in all fluoropolymer processing facilities to limit the potential for non-polymer emissions that may result from high-temperature (i.e., above typical continuous use temperature) processing to address facilities where such abatement technology may not already be in place. As a prior precaution, the FPG members have already committed themselves to help inform downstream users/processers by providing additional information on safe fluoropolymer processing by updating the Guide for the Safe Handling of Fluoropolymer Resins published in 2021 to include information on prevention of environmental releases.

Therefore, processing of fluoropolymers does not constitute a reason for a REACH restriction.

[15] ChemService, RMOA prepared for Fluoropolymers Group (FPG) of PlasticsEurope, 2021.

3. In-Use-Phase

Fluoropolymers used to manufacture products do not pose a risk to people or the environment during their use.

As stated above and demonstrated in Section III.5 of Annex II, fluoropolymers are non-hazardous/non-toxic. The inclusion of the suggested limitation of low molecular weight residuals and oligomers in the fluoropolymer resin, ensures in a legally enforceable manner that residuals cannot pose a risk either.

Risks due to degradation products are also not to be expected. As indicated above, fluoropolymers do not degrade or release substances under relevant environmental conditions.

Finally, we would like to address the concerns raised with regard to microplastics from fluoropolymers, as other synthetic polymers, which can according to the Dossier Submitter pose an environmental hazard if formed and released during their use or end-of -life phase. Such synthetic polymer microplastics that are intentionally added to products including uses where the release of microplastics is to be expected will, if appropriate, be regulated by the instruments the Commission is already working on. Considering this, from our point of view, it is neither appropriate nor required to discuss within the framework of the PFAS restriction.

4. End-of-Life

In this section we would like to demonstrate that the relevant end-of-life treatments of fluoropolymers do not pose an environmental concern. In particular, we would like focus on waste incineration to address the concern of the Dossier Submitters that non polymeric PFAS might be formed and emitted when incinerating PFAS.

a) Waste Streams

Based on the Study on Fluoropolymer waste in Europe 2020 prepared by Conversio for the industry association Pro-K which was published in January 2023,[16] there is a detailed understanding on how and where fluoropolymer containing products and corresponding wastes are generated as well as on the different treatment routes (recycling, energy recovery and landfill). The Study covers the following sectors Automotive, Aerospace, Electronics & Semiconductors, Chemicals, Medical, Pharma and Others (including cookware, lubricants, architectural and wearable textiles, military/defence, photovoltaic and wind power), which had been identified as main applications and products, where fluoropolymers are used.

According to the Study, in 2020 almost 84% of the assessed fluoropolymer applications were incinerated at the end of their life in energy recovery (MSWI ~72%) or thermal destruction (metal recycling ~12%) processes. 13% of the collected fluoropolymer waste was landfilled and around 3% was recycled.

[16] Final report, Fluoropolymer waste in Europe 2020– End-of-life (EOL) analysis of fluoropolymer applications, products and associated waste streams, January 2023.

b) Incineration

Regarding waste incineration of fluoropolymers, the Dossier Submitters are concerned that non-polymeric PFAS will be formed and emitted. While it is understood that decomposition end products, from fluoropolymer incineration, will be fractions like HF, CO_2 and H_2O it was considered uncertain if full breakdown would be achieved under typical operational conditions of waste incinerations plants.

This uncertainty seems to be based on certain statements, primarily that the effectiveness of incineration to destroy PFAS is not well understood[17] and the assumption that insufficient studies have been conducted. Available studies have been considered insufficient since

- only a limited number of PFAS were studied,
- most were laboratory-based studies which do not necessarily represent circumstances in reality
- full fluorine mass balances were not provided (see Annex B, Section 1.1.5.5).

In addition, Tetrafluoromethane (CF_4) and hexafluoroethane (C_2F_6) are explicitly referenced by the Dossier Submitters. The Dossier Submitters point out, that according to literature review,[18] these substances may be formed when incinerating fluoropolymers. With CF_4 considered most stable, it is only destroyed at temperatures above 1.400 °C.

We believe that the literature references the Dossier Submitters rely on do not correspond to the current state of knowledge and that the references to destruction temperature for CF4 is based on a misinterpretation of Tsang et al., 1998. We would like to take this opportunity to further elaborate on this in the following:

aa) Study conducted by KIT / Alexandrov et al., 2019

Effectiveness of incineration to destroy fluoropolymers like PTFE has been demonstrated by a study commissioned by Gore and conducted by the Institute of Technical Chemistry at the Karlsruhe Institute for Technology (KIT), Germany. PTFE pellets were incinerated in the pilot size municipal incineration plant of KIT at temperatures typical of a municipal waste incinerator. **The study was published in the July 2019 issue of Chemosphere, a peer reviewed scientific journal (hereinafter Alexandrov et al., 2019) and concluded that incineration of PTFE does not contribute to emissions of the 31 PFAS identified in the study.**

The incineration was performed at following conditions:

- 870 °C and residence time of 4.0 s in partial load scenario and
- 1020 °C for 2.7 s in full load scenario.

[17] Reference is made to Lohmann et al., 2020; Stoiber et al., 2020; Goldenman et al., The cost of inaction: A socioeconomic analysis of environmental and health impacts linked to exposure to PFAS Nordic Counsel. 2019 (http://norden.diva-portal.org/smash/get/diva2:1295959/FULLTEXT01.pdf); US EPA/Gullet et al., 2020.
[18] Reference is made to Huber et al., 2009, US EPA/Gullet et al., 2020.

These conditions were set by the combustion technology working group of the Karlsruhe Institute for Technology (KIT)[19] lead by Dr.-Ing. Hans-Joachim Gehrmann. The conditions were defined to correspond with typical incineration conditions. Art. 50 of Directive 2010/75/EU on industrial emissions specifies the minimum temperature and residence time for waste incineration plants in the EU as 850 °C for at least two seconds. The temperature and residence time relates to the gases generated after the combustion process. These minimum requirements also need to be met under unfavorable conditions, e.g., lower calorific value of waste. To meet these temperature and residence time and avoid shutdowns, operators need to balance multiple factors resulting in running at temperatures above 850°C.

In the study, the input materials were natural gas (mixture of gases including methane), commercial premium wood pellets, PTFE Polymer pellets and air. A control run using only natural gas, wood pellets and air was also assessed.

Flue gas samples were collected after the heat exchanger and before the pollution control equipment. This location was chosen since it represents the worst-case scenario, because the combustion gases have been thermally treated and reduced in temperature to 250-300 °C which allows for any potential condensation reactions to occur (i.e., new species formation). The samples were analyzed by independent commercial laboratories.

The flue gases were tested for 31 different PFAS substances. The substances were selected due to their occurrence in the environment, literature citation, and availability of validated methods from commercial laboratories.

To avoid false positive results due to contamination of samples from the environment, paired t-testing was utilized to determine if the addition of PTFE created a statistical difference from background levels. Paired t-testing is a standard statistical procedure used to determine whether there is a difference between two populations.

Of the 31 PFAS substances studied, 11 were detected. However, based on results of combustion process with wood pellets and PTFE compared to wood pellets only, 'the control run', no statistically significant evidence was found that low molecular weight PFAS were created. Since positive results were found in both pairs and even more in the control group without PTFE,[20] it was concluded that these signals are due to contamination of the samples from the environment.

The recovery rate of fluorine was 56 to 78%. Based on this it has been speculated that a wide variety of other PFAS could have been released.[21] This speculation has no scientific basis. Fluorine is the most reactive non-metal of all elements. This means it readily reacts with the masonry or steel of the incineration plant in the high heat region as well as forming HF. Therefore, a mass balance of 100% cannot be achieved. The high level of HF captured, 56–78%, was even higher than expected for the authors of the study. This study demonstrates that

[19] KIT resulted from the cooperation between the University of Karlsruhe and the Helmholtz Research Centre Karlsruhe and is the largest German research institution.
[20] See results in Annex V.
[21] Lohmann et al., 2020.

incineration is an effective method of fluoropolymers disposal when operated at permit conditions.

Alexandrov et al., 2019 is not mentioned in the Restriction Proposal and the papers that are referred to in the Restriction Proposal either (1) do not take the study into account[22] or (2) demonstrate that that the study was not fully understood. Regarding the first point, in particular US EPA/Gullet et al., 2020 needs to be mentioned. Although detailed information is now available, the statement that the effectiveness of incineration to destroy PFAS compounds is not well understood continues to be cited and distributed.[23] The second point is true for Stoiber et al., 2020 where the study by Alexandrov et al. was considered a laboratory study even though the study was conducted in a pilot size municipal incineration plant. Likewise, for Lohmann et al., 2020 where operation conditions were considered to be optimized, and the results based on paired-t-testing and fluorine mass balance were misinterpreted. Lohmann suggests that the Alexandrov et al. results were inconclusive with respect to stack emissions of PFAS, and with regard to the fluorine mass balance of 56-78% Lohmann concluded that the non-capture of fluorine could mean that a wide variety of other PFAS were released. As demonstrated above, the operation conditions correspond with typical incineration conditions and there is no experimental evidence or valid speculation that suggest that the Karlsruhe Institute of Technology's pilot size municipal incineration plant would operate differently or generate different flue gases from a full-size commercial operation. Stack emissions were not tested, but flue gas samples were collected after the heat exchanger and before the pollution control equipment to capture worst-case scenario. Paired-t-testing was used to avoid false positive results due to contamination of samples from the environment. The tests confirmed that incineration of PTFE does not contribute to emissions of the tested 31 PFAS since a statistically relevant difference between incineration of wood pellets and PTFE and wood pellets without PTFE could not be observed. Finally, the speculation drawn from the incomplete mass balance has no scientific basis. Due to the reactivity of fluorine, a mass balance of 100% or close to 100% cannot be achieved.

bb) Degradation Products and Formation of CF_4 and C_2F_6

The decomposition paths fluoropolymers will take in waste incinerations plants are difficult to predict due to the numerous materials they might react with.

In the Restriction Dossier, based on literature review, the following degradation products belonging to the large group of PFAS are referred for the incineration of fluoropolymers including PTFE (see Annex B, Table B.50): CF_4, C_2F_6, CHF_3, C_3F_6, $CClF_3$, C_4F_8, $C_2Cl_3F_3$, TFA and C_2F_4. Based on the Alexandrov et al., 2019 and stability of these substances, we believe that only CF_4 and C_2F_6 are relevant degradation products. CHF_3 and unsaturated PFAS such as C_2F_4/TFE, C_3F_6 and C_4F_8/HFP if formed during incineration, due to their molecular structure, will be destroyed shortly after formation.[24] TFA was tested by Alexandrov et al. and could not be detected. $CClF_3$, $C_2Cl_3F_3$ are not tested as they were not expected to be formed from the PTFE incinerated in this study.

[22] See US EPA/Gullet et al., 2020; NORDIC COUNCIL 2019. The cost of inaction: A socioeconomic analysis of environmental and health impacts linked to exposure to PFAS.
[23] E.g. Lohmann et al., 2020.
[24] Bakker et al., 2021(RIVM report 2021-0143), p. 62.

Geertinger et al., 2019 theorize the possibility of CCl_3F (CFC-11) or $C_2Cl_3F_3$ (CFC-113) as decomposition products, which was based on a more diverse waste source. However, they also reference 99.9% destruction efficiency for these materials in both pilot and full-scale incineration plants. We could not find a reference to $CClF_3$(CFC-13) in any of the papers; we assume this is based on a mis-citation in the Restriction Proposal.

Real world data demonstrate that formation of CF_4 and C_2F_6 in larger quantities is unlikely at temperatures above 850 °C with excess of oxygen, i.e., under typical conditions of municipal waste incineration plants.[25]

The importance of the operational conditions like presence or absence of oxygen, the presence or absence of other chemical substances and temperature is acknowledged by the Dossier Submitters (see Section 1.1.5.5 of the Restriction Draft). However, the understanding that CF_4 and C_2F_6 may be formed when incinerating fluoropolymers is solely based on reference to García et al., 2007 and Huber et al., 2009.

García et al., 2007 tested incineration of PTFE under pyrolysis and fuel-rich conditions. Pyrolysis means without oxygen and fuel-rich means that there is not enough oxygen to burn all the fuel (‹ 60% of oxygen). Both scenarios are not comparable to conditions in waste incineration plants where incineration is done in an excess of oxygen environment. We believe that this is also part of the reason why García found so many non-fluorinated hydrocarbons.

Huber et al., 2009, is a literature review focusing on decomposition products of fluoropolymers at temperatures below 600 °C. Just two references on decomposition products at temperatures above 850 °C are cited.[26] One reference is García et al., 2007, and the other one is the *Guide to the Safe Handling of Fluoropolymer Resins* from the Society of the Plastics Industry, which is not comparable either since it does not consider conditions in waste incineration plants but considers heating during manufacturing process and fire scenarios.[27]

In addition, based on the recommendation of Huber et al., 2009, to conduct on-site studies in Norwegian waste incineration plants to better understand contribution of incineration of fluoropolymers to global warming, the Norwegian Climate and Pollution Agency commissioned Norsk Energi to specifically measure CF_4 and C_2F_6 at the Klemetsrud Waste-to-Energy Plant on two different dates. The analysis laboratory (Eurofins MiljØanalyses AS) was not able to quantify CF_4 or C_2F_6 and used quantification limits for the worst-case predictions. By their estimates the maximum amount emitted from all of Norway's incinerators account for less than 0.01% of Norway's greenhouse gas budget.[28]

The only analysis of CF_4 and C_2F_6 in an actual municipal incineration facility showed that CF_4 and C_2F_6 were not detected at the detection limit available. We believe that this study demonstrates

[25] This is confirmed by Norsk Energi for Norwegian Climate and Pollution Agency, 2011 (see further information below).
[26] See Table 9 on page 22f.
[27] The Society of the Plastics Industry (2005), The Guide to Safe Handling of Fluoropolymer Resins – fourth edition. BP-101. Washington, SPI. P. 14, 76 (available at https://intechservices.com/content/SPI_Guide_for_Safe_Handling_of_Fluoropolymer_Resins.pdf).
[28] Otterlie ET, et al. Norsk Energi for Norwegian Climate and Pollution Agency, 2011.

the importance of operational conditions such as the presence or absence of oxygen, the presence or absence of other chemicals, and temperature, as also acknowledged by the Dossier Submitters

cc) Destruction of CF_4 / Tsang et al., 1998

The statement that CF4 will only be destroyed at temperatures above 1400°C seems to originate from Gullet et al. 2020 and is based on a reference to Tsang et al.,1998. We would like to highlight that the Tsang paper does not give a minimum incineration temperature for PTFE, but it does **demonstrate a model for** predicting destruction rates of these materials in a combustion environment. According to Tsang et al.,1998 this model is an extension of previous work on hydrocarbon combustion in Tsang and Hampson, 1986. It involves adding into the data, base reactions of the **fluorinated compounds and their decomposition products with each other, as well as reactions with the fuel and combustion generated radicals.**

Tsang et al. 1998 utilized the data in Table II and Table III below (labelled), to create the model. Please note, we have added Celsius table to the right of Table II for your convenience.

TABLE II Rate expressions for unimolecular decomposition at the high pressure limit. In the high temperature combustion environment they will be subject to fall-off effects. Thus actual rate constants may be somewhat smaller. Except for those marked with superscript (a) which are from Rodgers (1978), values are derived from Tsang (1986, 1990)

Reaction	*Rate Expression* s^{-1}	*Temp to achieve 4 nines destruction in 1 sec*	Kelvin	°C
a. Elimination (1,1 and 1,2)				
$C_2H_5Cl \longrightarrow C_2H_4 + HCl$	$1.6\times10^{13}\exp(-28400/T)$	1008	1008	735
$C_2HCl_5 \longrightarrow C_2Cl_4 + HCl$	$1.3\times10^{13}\exp(-30000/T)$	1072	1072	799
$C_2H_5F \longrightarrow C_2H_4 + HF$	$2.5\times10^{13}\exp(-30200/T)$	1068	1068	795
$C_2HF_5 \longrightarrow C_2F_4 + HF$	$4\times10^{13}\exp(-36000/T)$	1137	1137	864
$CF_3H \longrightarrow CF_2 + HF$	$1.3\times10^{14}\exp(-36340/T)$	1200	1200	927
b. C—C bond cleavage				
$CH_3—CH_3 \longrightarrow 2CH_3$	$5\times10^{16}\exp(-45000/T)$	1242	1242	969
$CCl_3—CCl_3 \longrightarrow 2CCl_3$	$6\times10^{17}\exp(-34400/T)$	888	888	615
$CF_3—CF_3 \longrightarrow 2CF_3$	$1.0\times10^{17}\exp(-45600/T)$	1234	1234	961
$CF_2=CF_2 \longrightarrow 2CF_2$	$2\times10^{15}\exp(-34700/T)$	1050	1050	777
c. C—X (H, Cl, X) bond cleavage				
$CH_4 \longrightarrow CH_3 + H$	$3.8\times10^{15}\exp(-52400/T)$	1557	1557	1284
$C_2Cl_6 \longrightarrow C_2Cl_5 + Cl$	$1\times10^{16}\exp(-34500/T)$	985	985	712
$CF_4 \longrightarrow CF_3 + F$	$1.5\times10^{17}\exp(-64000/T)$	1714	1714	1441
d. Radical Decomposition				
$CF_2CF_3 \longrightarrow CF_2 + CF_3$	$8\times10^{15}\exp(-28100/T)$	817	817	544
$CF_2CF_3 \longrightarrow CF_2CF_2 + F$	$1.7\times10^{14}\exp(-36400/T)$	1191	1191	918
$CF_3CF_2CF_2 \longrightarrow CF_3CF_2 + CF_2^a$	$1\times10^{16}\exp(-26300/T)$	759	759	486
$CF_2CF_2CF_3 \longrightarrow CF_2CF_2 + CF_3^a$	$8\times10^{13}\exp(-22700/T)$	761	761	488
$CH_2CH_3 \longrightarrow C_2H_4 + H$	$2\times10^{13}\exp(-19540/T)$	687	687	414
$CH_2CH_2CH_3 \longrightarrow CH_2CH_2 + CH_3$	$1.3\times10^{13}\exp(-15200/T)$	543	543	270
$CCl_2—CCl_2Cl \longrightarrow CCl_2CCl_2 + Cl$	$3\times10^{15}\exp(-8960/T)$	310	310	37
$CH_2—CH_2CL \longrightarrow CH_2CH_2 + Cl$	$4\times10^{13}\exp(-11180/T)$	384	384	111

TABLE III Rate expressions for some abstraction reactions of H and OH. Except for those marked with superscript (a) and (b) which are from Westenberg and deHaas (1975) and Stull and Prophet (1971), all other values are from Tsang (1986, 1990)

Reaction	*Rate Expression (cc/mol-s)*	*log (Rate Constant)* 900 K	1500 K
a. Abstraction by OH			
$OH + H_2 \rightarrow H_2O + H$	$6400 \times T^2 \exp(-1490/T)$	11.3	12.3
$OH + CH_4 \rightarrow H_2O + CH_3$	$4200 \times T^2 \exp(-1282/T)$	11.3	12.2
$OH + HCl \rightarrow H_2O + Cl$	$2.25 \times 10^{12} \exp(-514/T)$	11.9	12.1
$OH + CH_3Cl \rightarrow H_2O + CH_2Cl$	$2100 \times T^2 \exp(-585/T)$	11.7	12.4
$OH + HF \rightarrow H_2O + F$[16]	$1.9 \times 10^8 T^{1.6} \exp(-8360/T)$	8.9	10.9
$OH + CH_3F \rightarrow H_2O + CH_2F$	$2.6 \times 10^8 T^{1.5} \exp(-1480/T)$	11.4	12.3
$OH + CH_2F_2 \rightarrow H_2O + CHF_2$	$2.8 \times 10^7 T^{1.7} \exp(-1278/T)$	11.2	12.1
$OH + CHF_3 \rightarrow H_2O + CF_3$	$5.8 \times 10^6 T^{1.8} \exp(-2160/T)$	10.0	11.2
b. Abstraction by H			
$H + CH_4 \rightarrow H_2 + CH_3$	$22500 \times T^3 \exp(-4406/T)$	9.0	11.4
$H + HCl \rightarrow H_2 + Cl$	$8 \times 10^9 \exp(-1710/T)$	11.3	11.9
$H + CH_3CL \rightarrow CH_2Cl + H_2 \rightarrow HCl + CH_3$[a]	$3.7 \times 10^{10} \exp(-4680/T)$	11.3	12.2
$H + HF \rightarrow F + H_2$[b]	$5 \times 10^{11} T^{.75} \exp(-16310/T)$	6.0	9.4
$H + CF_4 \rightarrow CF_3 + HF$	$1.1 \times 10^{15} \exp(-22446/T)$	4.2	8.5
$H + CF_3H \rightarrow HF + CF_3$	$9000T^3 \exp(-4680/T)$	8.3	10.8
$H + CF_2H_2 \rightarrow HF + CF_2H$	$1650T^3 \exp(-2818/T)$	9.3	11.1
$H + CFH_3 \rightarrow HF + CFH_2$[a]	$2 \times 10^{13} \exp(-4953/T)$	10.9	11.9

The data in Table II are for unimolecular reactions (i.e., only CF_4 without oxygen or fuel) and while maybe accurate for pyrolysis, they are inadequate to predict incineration behavior on its own. In addition to these reactions in Table II the researchers included the data from the reactions from Table III to estimate decomposition rates in a combustion environment (i.e., with oxygen and fuel). Based on this Tsang et.al., 1998, estimate that CF_4 and C_2F_6 would be 99% destroyed at 927 °C (= 1.200 Kelvin) in tenths of seconds (0.225 and 0.1s respectively) in the presence of combusting fuel (methane 5%) and excess oxygen (O_2) as demonstrated in Figure 2 below.

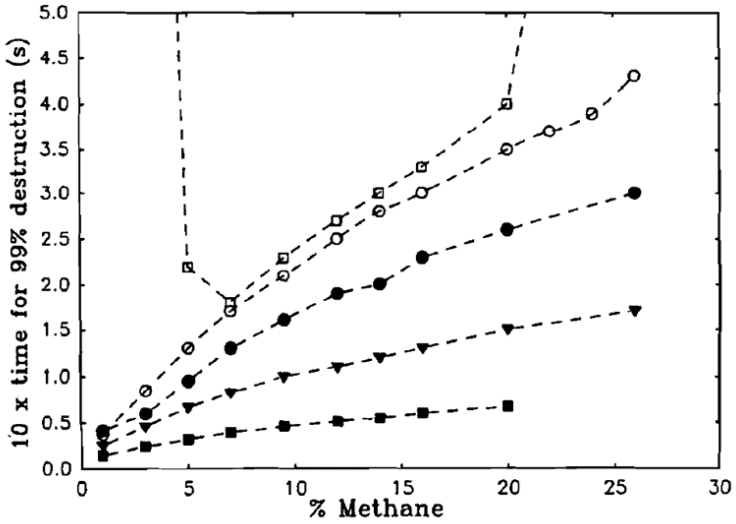


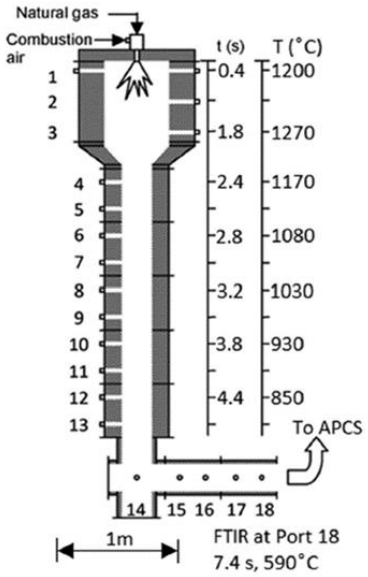
FIGURE 2 Time to achieve 99% conversion as a function of percentage of methane at 1 atm (open circle) and with 1% CF_4, (open square) CF_3H, (filled triangle) C_2F_6, (filled circle) C_2F_5H, (filled square) respectively. Initial temperature is 1200 K.

Tsang et.al 1998 theorized "*The strong beta C-F bond in the radical means that fluorine can readily displace hydrogen and practically all other groupings. In view of the strong H-F bond strengths, the only other alternative reaction channel, and undoubtedly very important, is the abstraction of a hydrogen atom by a fluorine atom."* This means that combustion products from the oxygen and fuel are needed to drive destruction, or in other words, that the addition of a fuel

such as methane in the calculations provides a source of Hydrogen radicals that drives a degradation of CF_4.

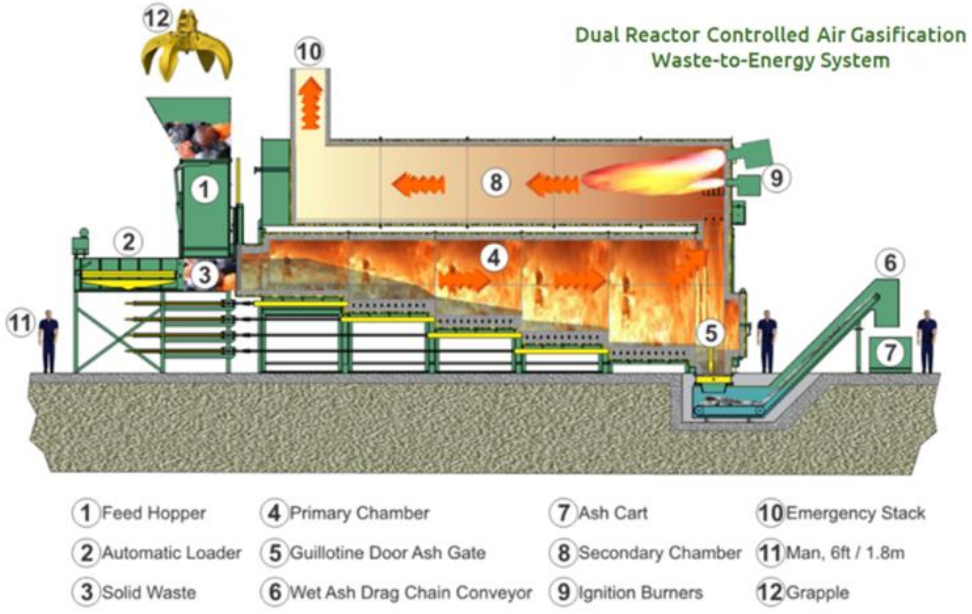
In short, using unimolecular reaction rates alone is inadequate to predict combustion behavior. Fuel, excess oxygen, and their combustion products (which are all present in waste incineration plants) are important components driving destruction of CF_4 and C_2F_6. **Tsang et al. 1998, demonstrates that while unimolecular thermal degradation of CF_4 takes place at temperatures around 1.400 °C, destruction of CF_4 under typical conditions in waste incineration plants will take place at much lower temperatures.**

The importance of combustion radicals was also demonstrated by Krug et al. (2022). Krug et al. "*utilized the EPA Rainbow furnace, which is a single burner combustor and did not incorporate an afterburner as part of this study."* The results of Krug et.al. showed approximately 90% destruction efficiency for CF_4 when introduced through the natural gas inlet, but the values dropped off significantly the farther the compound is injected from the combustion zone (see diagram below). In this case, use of the available afterburner could have helped provide the needed combustion radicals to break the CF_4 bonds.



These results correspond with the results of Tsang et al. 1998 and confirm that if CF_4 is formed it will be destroyed if combustion radicals (i.e., oxygen and fuel) are included in the process. It also demonstrates the importance of the post combustion flame as well as incinerator design considerations.

In the most common incineration designs, “Moving Grate” and “Rotary Kiln”, the waste materials will burn prior to leaving the primary combustion chamber. Once entering the post combustion chamber most designs have another set of burners to ensure the final post combustion chamber is greater than 850 ºC. The image below shows an IWI Waste-to-Energy incinerator design illustrating that flames from burners below the grates and in the post combustion or secondary chamber have ample combustion of fuel and oxygen to supply the radicals needed for destruction.



dd) Other Fluoropolymers

Thermal decomposition of PTFE is achieved at a temperature of about 800 °C. Since PTFE is the most thermally stable of all fluoropolymers, it can be assumed that other fluorine-containing polymers also thermally decompose completely at such temperature.[29] Since the most stable decomposition product (CF_4) is expected to decompose at typical conditions of municipal waste incineration plants, we can presume that all decomposition products of fluoropolymers will be destroyed. This is borne out by the analysis completed in Alexandrov et al (2019).

ee) Capacity of Waste Incineration Plants

Finally, it is pointed out in the Restriction Proposal that incineration plants can only tolerate limited amounts of fluoropolymers due to the corrosive nature of the hydrogen fluoride released during decomposition of fluoropolymers.

[29] See also Bakker et al., 2021(RIVM report 2021-0143), p. 62.

This is a question of the durability of the incineration plant. Due to the small proportion of fluoropolymers in the total post-user waste stream (less than 0.01% by weight[30]), we see little risk of premature corrosion of waste incineration plants.

c) Landfill

With regard to landfilling, the Dossier Submitters are concerned that non-polymeric PFAS that could be released from fluoropolymers or formed due to their degradation could contaminate soil and groundwater. Further, it is stated that this could contribute to release of microplastics.

According to the 2020 Pro-K Study on Fluoropolymer waste, only a small amount (13%) of fluoropolymers is disposed of via landfills at end-of-life.

Currently, there are no standardized tests to assess leaching of fluoropolymers from landfills. However, based on recent testing (see reference to Charles River Data below and in Annex II), data indicates that deposition of fluoropolymers covered by this derogation request will not cause an environmental concern. The most significant vectors of pollutants from landfills into the surrounding environment are water/solvent solubility, which then migrate into soil or groundwater. Our data and published literature[31] demonstrate that fluoropolymers like PTFE

- are insoluble in water (OECD105 and 120),
- do not partition between water/octanol (OECD107, 117, 122),
- and are neither adsorbed/desorbed into soil (OECD106) nor into sludge (OECD121).

In addition, due to the limited amount of residuals (‹ 5ppm), the leaching potential of low molecular weight residuals is very low.

Data supports the stability of fluoropolymers like PTFE and lack of biodegradation to other PFAS. Our data demonstrate no microbial biodegradation (OECD301B, 302C, 306), including no microbial biodegradation in sludge (unaudited preliminary report, 301F) as well as no growth inhibition to microbes in sludge (OECD301 Annex II).

Finally, preliminary tests suggest that PTFE is photolytically stable so degradation due to exposure to sunlight is also not expected (unaudited preliminary report, OECD316).

Detailed information on our data can be found in Section III.1., 2. and 3 and IV. of Annex II below.

With regards to microplastics we would like to refer Section II above. This is not a topic specifically related to fluoropolymers. On the contrary, compared to other types of plastic, fluoropolymers account for a negligible proportion of total plastic waste (0,01% of total post-user waste stream; see Section b(ee) above) which is also reflected in the very small percentage of fluoropolymers found in the environment. For example, based on samples taken at nine locations near the Norwegian HAUSGARTEN observatory, Bergmann et al., 2017, concluded that

[30] Conversion Study prepared for ProK, Fluoropolymer waste in Europe 2020 – End-of-life (EOL) analysis of fluoropolymer applications, products and associated waste streams, January 2023.

[31] McKeen LW. 2012. p255; Hanford WE and Joyce RM. 1946. Vol. 68 (10), p2082; Tuminello WH. 1999. pp 137-143.

polyethylene, polypropylene, and nylon are by far the largest contributors of microplastics in the environment (75%), while PTFE contributed 0.1 – 0.6%. If appropriate, microplastics should be regulated by the instrument the Commission is already working on.

d) Recycling

With regard to recycling there are mainly two concerns mentioned or indicated in the Restriction Proposal:

1. That fluoropolymers are not sufficiently recyclable and therefore do not meet the requirements of the circular economy.
2. The potential for PFAS emissions from recycling facilities.

We believe that the use of fluoropolymers does support the principles of the circular economy and in particular the waste hierarchy. As highlighted above, the use of fluoropolymers provides durability and reliability which extend product life, thus preventing waste across a range of products and industries as demanded by the waste hierarchy.[32]

ProK[33] categorize two physical recycling methods for fluoropolymers, namely grinding or thermo-mechanical recycling. Even though these two options are limited, due to the presence of fillers, colorants, and other materials in the composition of the products, they are well established processes for dealing with manufacturing waste. In addition to these physical methods, industry is making progress in chemical recycling processes:

- In 2015, Dyneon in Burgkirchen established a pilot plant with a capacity of 500 t/year, where PTFE, PFA and FEP processing waste and end-of-life components – for example tubes and pump linings, cable isolations – can be converted into their monomers (TFE and HFP) with a recovery rate of 90-95%. After distillation, TFE with purity of 99.99+ is obtained and can be used to manufacture new fluoropolymers with no loss in performance. Thus, this process has great potential to recycle waste to valuable raw materials for high performance products.[34]
- InVerTec is also able to provide turn-key chemical recycling plants for fluoropolymer end-of-life applications.
- The manufacturer BAUM is currently also working on a closed-loop solution for the recovery of PTFE and other EOL products.[35]

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[32] See information that will be provided in application-based derogation requests; overview of request in Annex III.
[33] Pro-K Fluoropolymergroup, Recycling of fluoropolymers, 2018, Technical Brochure 10. https://www.pro-kunststoff.de/assets/Merkbl%C3%A4tter%20und%20Co/FP%20TM-10-Recycling-of-fluoropolymers.pdf,
[34] Schlipf M, Schwalm T. 2014. Closing the recyling loop. Kunststoffe Intl 2014/06. [cited 2023 May]. https://www.kunststoffe.de/en/journal/archive/article/up-cycling-of-end-of-life-fluoroplastics-841786.html; InVerTec. 2017. Pilot project: Recycling of fluoropolymers (PTFE). [cited 2023 May]. https://www.invertec-ev.de/en/projects/environmental-care/ptfe-recycling/; Final report, Fluoropolymer waste in Europe 2020– End-of-life (EOL) analysis of fluoropolymer applications, products and associated waste streams, January 2023.
[35] Final report, Fluoropolymer waste in Europe 2020– End-of-life (EOL) analysis of fluoropolymer applications, products and associated waste streams, January 2023, P. 59.

[redacted]

It should be noted that recycling might not work for all end-of-life components regardless of their PFAS content, in particular when they are used in small components of larger finished articles. Dismantling for recycling might not be feasible nor economically viable for complex objects. However, it must also be noted that one of the largest shares of fluoropolymer waste is related to plant and production – industrial – equipment[36] where fluoropolymers are used as larger components with higher potential for recycling where such technology and capacity exists.

As far as emissions from recycling facilities are referred to as a concern, we would like to reiterate that these concerns can be addressed by using emission control technologies.

[36] Final report, Fluoropolymer waste in Europe 2020– End-of-life (EOL) analysis of fluoropolymer applications, products and associated waste streams, January 2023, p. 23.

Annex I – Definitions

Residuals: means substances, such as monomers, polymer processing aids, crosslinkers, some oligomers, and by-products that can leach out of the polymer. They can be identified by chemical analysis, by techniques such as thermal gravimetric analysis (TGA), gas chromatography mass spectrometry (GC-MS), or liquid chromatography mass spectrometry (LC-MS).

By-products: means substances that are created in the polymerization and finishing of fluoropolymers.

Oligomers: means a molecule of intermediate relative molecular mass, the structure of which essentially comprises a small plurality of constitutional units.[37]

[37] See Glossary of Basic Terms in Polymer Science, Commission on Macromolecular Nomenclature, Macromolecular Division, International Union of Pure and Applied Chemistry, draft: May 13, 1991.

Annex II – Properties of Fluoropolymers: Hazard Assessment and Degradation

In this Annex we will provide information on fluoropolymers, with supporting laboratory reports and publications (available at your convenience[38]), to demonstrate

- That persistency is not an appropriate basis for a REACH restriction since equating of increased environmental stock of a persistent substance with increased bioavailable exposure, and thus risk, lacks a scientific basis.
- The supporting concerns raised by the Dossier Submitters do not apply to fluoropolymers.
- Fluoropolymers such as PTFE will not degrade under environmental conditions to substances which could entail a risk.

Unless otherwise stated, the information refers to those fluoropolymers which are covered by our proposed derogation for fluoropolymers, and which are further described in Section I. below.

[38] Please note that most of the data have already been submitted in the public consultation on the restriction of PFAS in firefighting foams.

I. FLUOROPOLYMERS HAVE A LOW HAZARD PROFILE

We believe that the fluoropolymers meet the following requirements and therefore have a low hazard profile:

Criteria[39]		Comments relating to Derogation
High number-average molecular weight (Mn).	The number average molecular weight (Mn) and oligomer content are the most commonly used criteria for the hazard assessment of polymers. Most potential health concern polymers have a number average molecular weight, Mn, ‹ 1000 Da and oligomer content ›1%).[40]	Fluoropolymers have MW › 7000 to 45,000,000 Da
Low number of low molecular weight oligomeric species	Different jurisdictions differ widely on the level of oligomeric species that are permitted in the PLC category. Some nations specify limits for just ‹1000 Da content, whereas others regulate both ‹1000 Da and ‹500 Da.	Specifies Oligomer content ‹5% of ‹1000 Da and ‹2% of ‹500 Da species[41]
Reactive functional groups (RFGs) in the polymer	These are specific functional groups that are known to be associated with toxicity of polymers and include cationic species that are known to result in aquatic/environmental toxicity. Limits on RFG content can be defined in terms of the Functional Group Equivalent Weight (FGEW), a measure of the "dilution" of an RFG amongst the polymer's other components. RFGs or the FGEW are not universally considered for establishing a PLC. [42]	Fluoropolymers do not contain reactive functional groups of high concern[43]
Other criteria that are used by some jurisdictions to define a PLC include the polymer's stability, solubility (in water and other solvents), chemical/polymer class,	**Korzeniowski et al 2022 elaborates on these and highlights the following considerations**	
	Ionic character – Electrical charge or ionic character can be anionic, cationic, amphoteric, or nonionic. Specifically, cationic polymers have been associated with aquatic toxicity.	Not relevant for fluoropolymers. Fluoropolymers are neutral/non-ionic.[44]

[39] https://www.oecd.org/env/ehs/risk-assessment/42081261.pdf; https://www.oecd.org/env/ehs/oecddefinitionofpolymer.htm.
[40] BIO by Deloitte, 2015.
[41] OECD, 2009, p. 24; COM(2015)
[42] OECD, 2009.
[43] According to Henry et al.,2018, and Korzeniowski et al., 2023 there are no reactive functional groups of high concern in the assessed fluoropolymers. These papers cover approximately 96% of the fluoropolymers on the global market.
[44] See Henry et al.,2018, and Korzeniowski et al., 2023. These papers cover approximately 96% of the fluoropolymers on the global market.

Criteria[39]		Comments relating to Derogation
residual monomer content and human health hazard classification.	**Low MW Residuals** – High number of low MW residuals has been associated with risk of toxicity.	Covered by limitation of low MW residuals to ‹ 5ppm
	Particle size – Particle size of ‹ 5 µm were seen as a concern because they can reach the deep lung	Fluoropolymers have a particle size ›5 µm.[45]
	Water and lipid solubility and the octanol -water partition coefficient	Not relevant for fluoropolymers due to their insolubility.
	Stability (abiotic biotic and thermal)	Not relevant for fluoropolymers since fluoropolymers are stable and do not degrade under relevant environmental conditions

These criteria are closely aligned with those highlighted in the Wood report[46] specifically ionic character, molecular weight, oligomers, reactive functional groups and polymer degradability. While the Wood report is focused on Polymers Requiring Registration under REACH we wanted to highlight the alignment and overlap here.

These requirements are scientifically recognized criteria to identify polymers of low concern. Since most of the criteria are inherent to fluoropolymers, we believe only the criteria mentioned in the derogation request need to be specified. This is confirmed by Henry et al.,2018, and Korzeniowski et al., 2023. These papers cover approximately 96% of the fluoropolymers on the global market.

Additional criteria that could be considered for additional specification could be ionic and reactive functional groups. Based on our understanding of the fluoropolymers on the market today, we believe that these are not relevant, and we have not included them in the proposed derogation.

[45] See Henry et al.,2018, and Korzeniowski et al., 2023. These papers cover approximately 96% of the fluoropolymers on the global market.

[46] European Commission, Directorate-General for Environment, Bougas, K., Corden, C., Crookes, M.et al., Scientific and technical support for the development of criteria to identify and group polymers for registration/evaluation under REACH and their impact assessment – Final report, Publications Office, 2020, available at https://data.europa.eu/doi/10.2779/890644.

II. MAIN CONCERN OF DOSSIER SUBMITTERS: PERSISTENCE

According to the Restriction Proposal the main concern for all PFAS and/or their degradation products is their very high persistence. Due to the persistency, continued PFAS emissions will result in an increased environmental stock which is considered equivalent to increased exposure by the Dossier Submitters. This is the reason why the Dossier Submitters suggest treating PFAS as non-threshold substances: It is considered likely that known as well as unknown PFAS thresholds to cause adverse effects will be exceeded at some point in time. Therefore, release of PFAS is considered as proxy for risk by the Dossier Submitters.

We believe that persistency is not an appropriate basis for a REACH restriction. First, this is not supported by EU Chemicals Law. Persistence alone is not a hazard property under REACH and CLP Regulation.

Furthermore, the equating of increased environmental stock with increased exposure, and thus risk, lacks a scientific basis. It is well established that a risk is a function of both hazard *and* exposure. A hazardous substance with no exposure potential has a low risk, and similarly exposure to a substance that is non-hazardous has a low risk. As will be demonstrated in the Section on (Eco)Toxicological Effects below, fluoropolymers like PTFE are not hazardous. Also, it is well established that exposure to chemicals requires bioavailability of the respective substance. **Persistence does not contribute to potential exposure if the substance is not bioavailable**. As will be demonstrated in the Section on Bioavailability and Bioaccumulation below, fluoropolymers like PTFE are not bioavailable.

To demonstrate that the scientific community is not aligned on the concept that persistence alone is a hazard, we would like to offer the following discussion and would supply full text reprints upon request.

- Donald Mackay and colleagues (2014) believe that persistence is "[…] only one of several factors that influence exposure and risk." They stated that the blanket assertion that long persistence leads to high risk can be erroneous because risk is dependent on the quantity released, uptake in biota and toxicity (Mackay D et. Al., 2014). Uptake in biota can only occur if the chemical is bioavailable.
- Ehlers and Loibner (2006) agree: "Most risk assessment procedures consider the total pollutant concentration in soil as bioavailable resulting in an overestimation of risk." (Ehlers and Loibner, 2006).
- Jarkko Akkanen et al., 2012 assert "It has been established that the total concentration of a given contaminant in a given environment does not translate well into uptake or toxicity in organisms living in that environment. Ecotoxicological effects due to organic chemicals are *usually the result of uptake and bioaccumulation* of the chemical from the ambient environment or food, followed by toxicodynamic processes which actually result in eliciting the final effect. […] Uptake of contaminants is a complex interplay among biological, chemical, and physical factors and processes. Properties of chemicals,

environmental conditions, and characteristics of the organisms and the interaction among these ultimately dictate the exposure." (Akkanen et al., 2012).

- In explaining the importance of bioavailability, Semple et al., 2004 looked at contaminated land regulations. Where contaminated land is defined such that just the presence of substances of concern is not sufficient; there must be harm because toxic effects require that an organism takes up the contaminant (Semple et al., 2004). Semple et. Al. (2004) offers the definition (of bioavailability) (which is supported by Ehlers and Loibner) as "…the fraction of a contaminant that is free to be taken up by organisms (i.e., *free to pass through biological membranes*)."
- Factors such as polarity, aromatic content, aliphatic content, and molecular weight effect bioavailability of chemicals, per Akkanen (2012).
- Akkanen (2012) argues that "[…] bioavailability estimations would take us *closer to reality* and help with the management decisions." The National Research Council (Washington, DC, USA) agrees: "Explicitly *incorporating bioavailability routinely and rigorously into the risk assessment process* would offer the possibility of demonstrating in some cases that *only a fraction of a contaminant's total mass* contained in a soil or sediment actually *has the potential to enter potential receptors (biota)*." (National Research Council 2003).

III. SUPPORTING CONCERNS OF DOSSIER SUBMITTERS

Besides persistence, the following supporting concerns are mentioned in the Restriction Proposal: mobility, long range transport potential (LRTP), accumulation in plants, bioaccumulation, and (eco)toxicological effects. **In the following we would like to demonstrate that none of these supporting concerns referred to by the Dossier Submitters is relevant for fluoropolymers.**

Most of the data provided in this section are from studies commissioned by Gore and performed at Charles River Labs in Den Bosch, the Netherlands, to provide consistent evidence that any persistence of PTFE does not imply or indicate toxicity or bioaccumulation, nor does any persistence of PTFE imply future degradation, nor release or transformation into a continuous source of substances of concern. A fine powder PTFE test material that meets the specification ASTM D4895-18 and the OECD polymer of low concern criteria, was tested according to numerous OECD guidelines. An overview of the performed studies and summarized test results can be found below and will be addressed in more detail in the following sections. The challenges of analytical chemistry for certain OECD tests have delayed their full completion. Therefore, interim data will be provided for those studies, and separate submissions will be made when final results are received.

Due to size limitation on submission to the present public consultation (20MB) and that we already submitted the full test reports to the firefighting foam restriction proposal in 2022, we are not submitting them along with this derogation but have provided references in Annex VI.

Table A.1. Environmental Fate Testing of PTFE by Charles River Labs

Test Title (OECD Test Guideline Designation)	Status/Results	Relevance for PTFE
Melting Point/Melting Range (OECD 102)	The melting temperature of the test item was determined using differential scanning calorimetry (DSC). Melt transition observed at ~350 °C (662 °F), no further melting/decomposition below 400 °C	To support thermal stability at environmentally relevant temperatures.
Determination of the Number-Average Molecular Weight and the Molecular Weight Distribution of Polymers using Gel Permeation Chromatography (OECD 118)	Not sufficiently soluble to be evaluated by GPC even after sonication and stirring (19 hr) in representative lab solvents. By alternative methods MW is › 500.000 Da	To determine if low molecular weight fractions are available for migration out of the polymer.
Vapor Pressure (OECD 104)	‹1 x 10-10 mm Hg @ 20 °C; indicating very low potential of PTFE to partition to the air as a gas or vapor. The vapour pressure of the test item (PT) was determined by the isothermal thermogravimetric effusion method.	Volatility will help predict likelihood of partitioning to air and long-range transport potential.
Henry's Law Constant	Expert Statement; Due to the insolubility of PTFE, this test could not be performed.	Henry's law constant (HLC), a measure of the concentration of a chemical in air over its concentration in water, reflects volatility and likelihood to partition to air from water. High HLC means likely to volatize and have long range transport.
Water Solubility (OECD 105) and Water Solution/Extraction Behavior of Polymers in Water (OECD 120)	PTFE is not soluble in water.	Soluble substances may contaminate drinking, surface and ground water and move with the water.
Behavior in water system	Final report; PTFE was not soluble in water.	Supports lack of extraction/leaching of migrants from the polymer into water.
Determination of pH, Acidity, and Alkalinity (OECD 122)	Final report; PTFE was not soluble in water, thus modified methods were followed. Test results demonstrated PTFE is not corrosive, caustic, or ionizable.	Soluble and ionizable substances may contaminate drinking, surface and ground water and move with the water.

Test Title (OECD Test Guideline Designation)	Status/Results	Relevance for PTFE
Adsorption Coefficient on Soil and Sludge using HPLC (OECD 121)	Expert Statement: Due to the insolubility of PTFE in organic solvent, this test was not feasible.	Soluble substances may adsorb to soil or sludge, and then contaminate drinking, surface and ground water and move with the water.
Adsorption - Desorption Using a Batch Equilibrium Method (OECD 106)	Expert Statement: PTFE is not soluble in water or conventional organic solvents. Therefore adsorption/desorption behaviour determination was not possible.	To determine the likelihood of the substance partitioning to soil and/or sediment.
Partition Coefficient (n-octanol/water): Shake Flask Method (OECD 107)	Expert Statement: PTFE is not soluble in octanol or water. Therefore, no Partition Coefficient determination was possible.	Substances that are more soluble in n-octanol may be more likely to be fat soluble and bioaccumulative. Substances with Partition Coefficient tend to adsorb more readily to organic matter in soils or sediments because of their low affinity for water. Chemicals with very high Partition Coefficients (i.e., >4.5) have the potential to bio-concentrate in living organisms. N-octanol/water partition coefficient (Kow) is a screening test for bio-accumulation.
Partition Coefficient (n-Octanol/Water), High Performance Liquid Chromatography (HPLC) Method (OECD 117)	Expert Statement: PTFE is not soluble in octanol or water. Therefore, no Partition Coefficient determination was possible.	Substances that are more soluble in n-octanol may be more likely to be fat soluble and bioaccumulative. Substances with Partition Coefficient tend to adsorb more readily to organic matter in soils or sediments because of their low affinity for water. Chemicals with very high Partition Coefficients (i.e., >4.5) have the potential to bio-concentrate in living organisms. N-octanol/water partition coefficient (Kow) is a screening test for bio-accumulation.
Octanol-air partition coefficient (log K_{oa})	Expert Statement: PTFE is not soluble in octanol. Therefore, no Partition Coefficient determination was possible.	Useful for predicting partitioning behavior between various matrices (e.g., air and soil, vegetation)

Test Title (OECD Test Guideline Designation)	Status/Results	Relevance for PTFE
Hydrolysis as a Function of pH (OECD 111)	Analytical method development in progress	Abiotic stability – test for degradation in water.
Phototransformation of Chemicals in Water - Direct Photolysis (OECD 316)	Preliminary tests suggest that PTFE is photolytically stable so degradation due to exposure to sunlight is also not expected (unaudited preliminary report, OECD316).	Abiotic stability – test for degradation in sunlight
Phototransformation of Chemicals on Soil Surfaces (OECD draft document)	Preliminary tests suggest that PTFE is photolytically stable so degradation due to exposure to sunlight is also not expected (unaudited preliminary report, OECD316).	Abiotic stability – test for degradation in sunlight
Screening Test for Thermal Stability and Stability in Air (OECD 113)	Stable at continuous processing temperature 260 °C and only 5% loss in weight at 549 °C (1020 °F). PTFE is considered stable at room temperature when no decomposition or chemical reaction is observed ‹ 150 °C (302 °F).	Test for degradation from heat (relevant environmental temperatures)
Ready Biodegradability (OECD 301B)	Did not reach 60% degradation threshold at 28 days. Not readily biodegradable.	Biotic stability – test for biodegradability within 28 days
Inherent Biodegradability OECD 302 C (METI)	No inherent biodegradability. Did not reach biodegradation threshold in 28 days.	Biotic stability – test for biodegradability
Biodegradation of organic chemicals in Aerobic Sewage Treatment (OECD 303A)	Analytical method development in progress	Biotic stability – test for biodegradation in the presence of aerobic bacteria in sewage treatment
Biodegradability in Seawater (OECD 306)	PTFE was not sufficiently soluble for evaluation by guideline even after sonication (15mins) and stirring (83mins). PTFE does not degrade in seawater.	Biotic stability – test for biodegradation in seawater
Aerobic and Anaerobic Transformation in Soil (OECD 307)	Analytical method development in progress	Biotic stability – test for transformation in the presence of aerobic and anaerobic bacteria in soil

Test Title (OECD Test Guideline Designation)	Status/Results	Relevance for PTFE
Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (OECD 308)	Analytical method development in progress	Biotic stability – test for transformation in the presence of aerobic and anaerobic bacteria in sediment
Ready Biodegadability: Manometric Respirometry in Activated Sludge (unaudited preliminary report, OECD 301F)	No biologically relevant biodegradation of PTFE was observed. PTFE is completely inert and is non-growth inhibitory to activated sludge.	Biotic stability - test for biodegradation, inertness, or inhibition in sewage treatment.

Definitions and Descriptions of Terminology used in the Charles River Labs studies.

ASTM D4895-18 Standard Specification for PTFE Resin from Dispersion

- covers homopolymers of tetrafluoroethylene or modified homopolymers containing not more than 1% by weight of other fluoromonomers
- covers dry-powder resins of polytetrafluoroethylene (PTFE) resin produced from dispersion
- specifies resin shall be uniform and shall contain no additives or foreign material
- specifies color of the material as shipped by the supplier shall be natural white
- does not include:
    - mixtures of PTFE with additives such as colors, fillers, or plasticizers
    - reprocessed or reground resin or any fabricated articles because the properties of such materials have been irreversibly changed when they were fibrillated or sintered.
    - PTFE mixtures with additives

1. Mobility and Long-Range Transport Potential

Mobility and long-range transport potential of PFAS is stated as a supporting concern by the Dossier Submitters. They point out that the high persistence in the environment will lead, inevitably, after release to distribution of PFASs from one environmental compartment to another (e.g. from soil to freshwater to marine environment). PFASs may concentrate in the respective compartment into which PFASs partition according to their specific properties (e.g. water-soluble substances concentrate in water, while volatile substances partition to air) and that PFAS can be transported by air, water and matrices to which they are adsorbed or absorbed, such as dust, sediments, migratory animals, or through matrices in which it is included as additive, e.g. polymers. With regard to mobility, it is pointed out that PFAS that are volatile will be distributed via air and substances with a moderate to high solubility in water and a low adsorption potential are considered to have a high mobility in the aqueous environment. Further, it is pointed out that, mobility of PFAS in water contributes to their long-range transport and drinking water contamination potential.

In the following, we would like to demonstrate that none of these considerations apply to fluoropolymers such as PTFE. On the contrary, the data presented below prove the opposite. PTFE is non-volatile with low potential to partition to air, and non-water soluble and therefore not to be considered mobile in the aqueous environment. Therefore, the potential to contaminate drinking water is very low.

Upon deposition to soil and sediment its presence and persistence will depend on the physical movement through the system via mechanical transport processes rather than on chemical properties of the fluoropolymer because PTFE does not readily bind to organic matter.

In sum, long-range transport potential is very low based on air, water, and soil data.

a) Volatility

The likelihood that a liquid or solid will become a gas or vapor is described by volatility. Volatility helps predict the likelihood of a substance partitioning to air if it becomes a gas or vapor, and long-range transport potential of a substance once partitioned in air as a gas or vapor. With respect to the volatility and potential for long-range transport in air of fluoropolymers such as PTFE, as a gas or vapor, the following tests are relevant: OECD 104, OECD 113, Henry's Law and Log $K_{oa.}$

All tests confirm a lack of volatility under relevant environmental conditions of the tested PTFE. In detail:

aa) OECD 104: Vapor Pressure Testing

The vapor pressure, determined by the isothermal thermogravimetric effusion method, was ‹1 x 10^{-10} mm Hg @ 20 °C, indicating very low potential of PTFE to partition to the air as a gas or vapor.

bb) OECD 113: Thermal Gravimetric Analysis

In addition, thermal gravimetric analysis was performed to determine the mass of PTFE lost to air as a function of temperature and time, per OECD 113. This analysis resulted in

undetectable weight loss at temperatures less than 140 °C and 5% weight loss observed at 549 °C. A mass loss to the air as a gas or vapor under any global temperature environmental condition was therefore confirmed to be unlikely. OECD113 test results indicate PTFE's lack of volatility under ambient environmental conditions.

cc) Henry's Law Constant

Henry's Law Constant is a measure of a dissolved substance's ability to evaporate from water. It reflects volatility and the likelihood to partition to air from water. A high Henry's Law Constant means the substance is likely to volatilize and long-range transport potential increases the higher the volatility and Henry's Law Constant. Low Henry's Law Constant substances tend to stay in water and may be adsorbed onto soil or sediment. Henry's law constant is an important parameter that plays a fundamental role in predicting the transport, behavior, and fate of substances of concern in the environment and it is required to model the chemical transfer between air and water. OECD does not provide guidelines for Henry's Law testing, thus other guidance (REACH, 2017; Technical Guidance Document on Risk Assessment 2003) was followed.

PTFE is not soluble in octanol or water. Therefore, Henry's Law could not be determined. However, the vapor pressure results also demonstrated very low potential of PTFE to partition to the air as a gas or vapor. The lack of water solubility combined with the lack of volatility indicate that PTFE is not a continuous source of substances of concern, via the route of volatilization into a gas or vapor and partitioning to air from water.

dd) Log K_{oa}: Octanol–Air Partition Coefficient

Log K_{oa} or octanol–air partition coefficient is one of the key descriptors of chemical partitioning between various matrices, such as air, soil, and vegetation (Odabisi et al., 2006). The octanol–air partition coefficient is also a key descriptor of chemical partitioning between the atmosphere and other environmental organic phases such as soil and vegetation (Harner et al., 2000; Shoeib and Harner, 2002). The octanol-air partition coefficient is similar to the Henry's Law Constant, but instead measures the concentration of a test substance in air over its concentration in octanol. Also similar to the Henry's Law Constant, the octanol-air partition coefficient is an important parameter that plays a fundamental role in predicting the transport, behavior, and fate of substances of concern in the environment and it is required to model the chemical transfer between air and organic phases. OECD does not provide guidelines for octanol-air partition coefficient testing, thus other guidance was followed (Henry et al.,2018).

PTFE is not soluble in octanol or water. Therefore, the octanol–air partition coefficient could not be determined However, the vapor pressure results also demonstrated PTFE is not volatile in air as a gas or vapor. These two results combined indicate that PTFE is not a continuous source of substances of concern partitioning between air and other environmental media high in naturally occurring organic compounds, such as soil.

b) Water Solubility

Water solubility is very important to consider because water-soluble substances may migrate into drinking, surface, and ground water, and move with the water.

The water solubility of the tested PTFE was attempted to be measured as per OECD 105. The detection limits of the methods specified by OECD105 are 10^{-6} g/L, and it is well known to the chemical literature that **PTFE is insoluble in water** at concentrations much lower than 10^{-8} g/L. Thus, PTFE is practically insoluble in water according to the guidelines of OECD105, making PTFE **highly unlikely to be a water-soluble drinking, surface, or ground water contaminant, or to move with water as a water-soluble substance**.

Further efforts to characterize the ability of fluoropolymers to partition to water are shown in OECD 120, Solution/Extraction Behavior of Polymers in Water being conducted with a sample of the same fine powder PTFE. This study was performed to further investigate fluoropolymer behavior in water and confirmed insolubility.

c) pH Value

OECD 122 provides procedures to obtain data on pH, acidity and alkalinity of aqueous solutions or aqueous dispersion of chemicals (substances and mixtures). The data are used to assess the effects that the chemical may pose to human health and the safety and potential impact upon the environment. Substances which are highly acidic or highly alkaline can be corrosive or caustic and can pose a threat via physical contact. Furthermore, these substances tend to be ionizable, and can bind via ionic bonds with other compounds in the environment. Furthermore, these substances tend to be soluble or partly soluble in water and can have mobility in water or in organic matter such as soils or sediments.

OECD 122 requires that the test substance be soluble or dispersible in water. As mentioned above, PTFE is not soluble in water. Furthermore, data from Charles River Labs demonstrate that PTFE's dispersion in water is ‹ 0.5%. Thus, the guidance from OECD122 as written cannot be applied to PTFE, so modified methods were followed using mixtures of PTFE and water, rather than solutions or dispersions of PTFE.

The test results demonstrated that an aqueous mixture of PTFE and water had a mean **pH value of 6.9, which is neither acidic nor alkaline**, and is well within the normal pH range for surface water of 6.5 to 8.5, and for groundwater of 6.0 to 8.5. These results demonstrated that PTFE is neither corrosive nor caustic, is not ionizable, and is further evidence that PTFE is not soluble in water. **These results further demonstrate the lack of potential impact via water solubility of PTFE on drinking water, plants and crops, and long-range transport in water.**

2. K_{OW}: Octanol-Water Partition Coefficient

K_{OW} or octanol-water partition coefficient is a physical–chemical property used to represent the lipophilic or hydrophilic nature of a substance. Substances that are more soluble in n-octanol may be more likely to be fat soluble and stored in fat (e.g., bioaccumulate). The K_{OW} is useful in determining the tendency of substances to adsorb more readily to organic matter in soils or sediments because of their low affinity for water. Chemicals with very high K_{OW} (i.e., ›4.5) have the potential to bio-concentrate in living organisms. OECD does not provide guidelines for octanol-water partition coefficient testing, thus other guidance was followed (Henry et al, 2018).

OECD 107, Partition Coefficient (n-octanol/water): Shake Flask Method, and OECD 117 Partition Coefficient (n-Octanol/Water), High Performance Liquid Chromatography (HPLC) Method were performed for the fine powder PTFE sample.

PTFE is insoluble in water and is insoluble in octanol. Therefore, the octanol–water partition coefficient could not be determined. However, these two results combined indicate that PTFE is not fat soluble nor likely to bioaccumulate in fat via adsorption to organic matter in soils or sediments.

3. Uptake and Accumulation in Plants

Other than low molecular weight perfluoroalkyl acids (PFAAs), uptake and accumulation of fluoropolymers like PTFE in plants is not to be expected. While high water solubility, anionic ionizable form, and negligible vapor pressure combine to make low molecular weight perfluoroalkyl acids (PFAAs) candidates for uptake and accumulation in crops (Gredelj et al., 2020), PTFE has negligible water solubility and would not move through the plant via mechanisms such as transpiration of water-soluble compounds, as PFAAs would. Furthermore, fluoropolymers, like PTFE, are neutral and not anionic as per the results from the modified OECD122 tests (see also Henry et al., 2018).

There are studies that show that soil adsorption could enable a substance in the soil contacting the root to be transported and accumulate in plant tissues (Xu et al., 2022). Since PTFE is not sufficiently soluble the OEDC 106 and 121 could not be performed to prove that transport via the roots will not take place. However, due to insolubility, soil adsorption and transport via the roots is highly unlikely.

OECD 106: Adsorption/desorption using a batch equilibrium method, and OECD 121: Estimation of the Adsorption Coefficient on Soil and Sludge using High Performance Liquid Chromatography (HPLC) Method were conducted. Such studies are useful for generating essential information on the mobility of chemicals and their distribution in soil, water, and air. They are also useful for measuring the binding capacity of a substance to soil and sludge. For example, OECD 106 has been employed by Gredelj et. al. 2020 to study portioning of PFAAs between soil and water by adsorption/ desorption experiments. To determine the likelihood of PTFE to partition and adsorb to soil via OECD 106 and 121, a sample of the fine powder PTFE was provided to Charles River Labs in Den Bosch (Netherlands). However, it is not possible to obtain information regarding the mobility and distribution of PTFE in soil, water and air using OECD 106 and OECD 121, as OECD 106 requires the test substance to be completely soluble in water and OECD 121 requires the test substance to be completely soluble in conventional organic solvents or in solvent/water mixtures. As commented above, PTFE is insoluble in water, and is insoluble in octanol.

The challenges of conducting these two OECD tests, has motivated the initiation of other related soil/water/air studies that do not require water-soluble or organic solvent-soluble compounds, namely OECD 303A, 307, and 308. Nonetheless, there remain analytical challenges to adapt this guidance to fine powder PTFE. Separate submissions will be made when final results are received. As stated previously, because of the negligible water and octanol solubility of PTFE, the likelihood of soil adsorption is low so

bioavailability, uptake, and accumulation in plants would not occur, which these study results are expected to confirm.

4. Bioavailability and Bioaccumulation

In this section we provide information and references which demonstrate high molecular weight fluoropolymers have not been observed to be bioavailable or bioaccumulate.

Bioavailability means the extent to which a substance is taken up by living cells. In mammals the substance crosses the cell walls of the respiratory or intestinal tracts via inhalation or ingestion, respectively, or crosses cell walls in the skin via dermal contact. Bioaccumulation is the process of build-up of substances in an organism that takes place if the rate of intake exceeds the rate of elimination.

Substances not capable of being bioavailable or bioaccumulative do not penetrate cell membranes or do so only poorly (see Leeson 2012; ECETOC Special Report No.18. Brussels, July 2014.; Zhang and Wilkinson, 2007). There are two processes for passage into a cell membrane: passive and active transport.

Passive transport means the movement of a molecule across a cell membrane without expending energy, such as by diffusion from an area of high concentration to one of low concentration, or, facilitated diffusion, in which diffusion is aided by a transport protein in the cell membrane.

The conditions for passive transport of a molecule into a cell membrane, are defined by the so-called Lipinski's Rules or "rule of 5" (Leeson, 2012) which state that a molecular compound is more likely to be membrane permeable and easily absorbed by the body, if:

1. Its molecular weight is less than 500 Dalton (Da)
2. The molecule's lipophilicity, expressed as a quantity known as logP (the logarithm of the partition coefficient between water and 1-octanol), is less than 5
3. The number of groups in the molecule that can donate hydrogen atoms to hydrogen bonds (usually the sum of hydroxyl and amine groups in a drug molecule) is less than 5
4. The number of groups that can accept hydrogen atoms to form hydrogen bonds (estimated by the sum of oxygen and nitrogen atoms) is less than 10.

There are exceptions to Lipinski's rules most notably for "natural products", such as cyclosporine A, rapamycin, steroids, flavones, peptides, etc. (Zhang and Wilkinson, 2007). Those substances that meet these criteria are likely to be bioavailable, and there is evidence that "violating" more than 1 of these diminishes bioactivity (e.g., oral activity of a drug).

Applying Lipinski's Rules to fluoropolymers, when considering their molecular composition, they have *not* been observed in the literature to transport passively into cells because they do not meet any of the criteria:

1. of their size well above 500 Dalton ranging from 7.000 to millions of Da
2. of the lack of lipid solubility to penetrate the cell membrane
3. of the lack of oxygen and nitrogen atoms estimating groups accepting hydrogen atoms

4. they are highly hydrophobic and have little or no hydrogen bond donating potential because they have few or no hydrogen bonds
5. They are not structurally similar to steroids, peptides, natural compounds, etc., that are exceptions to Lipinski's Rules.

Active transport means moving molecules across a cell membrane using energy.

Active transport and cell surface binding/signaling require interaction with the cell surface and are dependent on physical characteristics of the molecule such as shape, volume/size, etc. However, the types of high molecular weight compounds that can be bioavailable through active transport or cell surface binding/signaling are "natural compounds" like cyclosporine A, rapamycin, steroids, flavones, peptides, etc. (Zhang and Wilkinson, 2007). When considering their molecular composition, fluoropolymers are not subject to active transport because they do not bind to cell surface receptors to trigger events within the cell and are very different from steroids, peptides, cyclosporine, and other "natural compounds".

The accuracy of the understanding of active and passive cell membrane transport has been questioned with regard to polystyrene micro- and nanoparticles that have been used to deliver chemotherapeutic drugs to cancer cells (Lohmann et al., 2020, p. D).

Active or passive transport of polymer micro- and nanoparticles into cell membranes, are dependent upon many variables that extend beyond the molecular composition of the polymer. These variables include size, shape, charge, crystallinity, surface reactivity, particle concentration, and dissolution into intracellular compartments. No single particle property can be identified as the most important for bioavailability and bioaccumulation. However, it is hypothesized that surface reactivity may be the best predictor for transport, and particle surface reactivity has been proposed for classifying into hazard groupings (Braakhuis et al., 2014; Maocai et al., 2019).

Using the surface reactivity of a micro- or nanoparticle to predict its potential for bioavailability and bioaccumulation is not inconsistent with Lipinski's Rule. Micro- and nanoparticles do not behave universally, and the behavior of one particle type can not necessarily extrapolate to other particle types.

As an example, it is informative to compare transport across the gut wall of a high surface reactive polymer particle (polystyrene, "PS") to a low surface reactive polymer particle (high molecular weight PTFE). Studies (Lu L. et al., 2016; Kashiwada, 2006; Jin et al., 2022; Deng et al., 2017; Lu Y. et al., 2018; Hayati et al., 2022; Gaspar et al., 2018) have demonstrated, across a variety of species, that PS micro- and nanoparticles are bioavailable via ingestion across the gut wall, and bioaccumulate in various cells and organs, including stem cells, Leydig cells, spermatogenic cells, hepatopancreas cells, hepatocytes, liver, gills, testes, and the blood-brain barrier. PS microparticles have been identified in human blood, also speculated from ingestion (Leslie et al., 2022). Intracellular bioaccumulation of PS micro- and nanoparticles can disrupt numerous cellular processes and enzymatic pathways. Numerous mechanisms have been proposed for PS particle-induced intracellular disruptions, which involve the chemical reactivity of PS's molecular composition and/or PS particles' surface reactivity.

In comparison, studies examining the transport of PTFE particles across the gut wall demonstrate absent bioaccumulation, which implies low or absent bioavailability.

Rodents fed large quantities of PTFE nanoparticles did not show bioaccumulation in the blood, brain, heart, kidney, lung, spleen, testes, or ovaries (Lee et al., 2022).

Other studies permit direct comparison of the biological response to particles comprising PS and PTFE, at the scale of the organ wall and at the scale of the whole body. At the organ wall scale, inhaled particles of PS and PTFE were both found (Geiser et al., 2003) submersed in the hamster respiratory wall's aqueous lining layer and adjacent to epithelial cells; however, only PS particles were found phagocytosed within resident macrophages. At the whole-body scale, inflammatory bowel disease (IBD) status was correlated to the total concentration of polymer particles found in human feces (Yan et al., 2021). For healthy vs. IBD patients, the approximate median concentration of PS particles was 1.1 vs. 1.4 particles/g (dry weight) respectively, whereas for PTFE the approximate median concentration was 1.1 vs. 0.4 particles/g (dry weight) respectively. These data suggest that there is a positive correlation between PS particle concentration and IBD, but a poor correlation between PTFE particle concentration and IBD.

As IBD is an inflammatory disease significantly mediated by activated T cells, these data further suggest that the bioavailability and bioaccumulation of PS particles is greater than that of PTFE particles. This suggestion is consistent with the importance of particle surface reactivity and is not inconsistent with Lipinski's rule.

In conclusion, the data from all these studies demonstrate, in terms of bioavailability and bioaccumulation, that particle properties do not necessarily extrapolate from one polymer composition to another. High molecular weight fluoropolymer particles comprise low surface reactivity, contributing to their observed absent bioavailability and bioaccumulation.

5. (Eco)Toxicological Effects

The discussion about environmental and health effects in the Restriction Proposal demonstrates that the group of PFAS substances is too broad to be assessed together. Even though the Dossier Submitters acknowledged that experimental data is limited for many PFAS, they conclude that there is sufficient evidence that demonstrates the risks of PFAS exposure and regard the importance of the uncertainty as low (See Annex F, page 5).

In this section we would like to demonstrate that – at least for fluoropolymers like PTFE – this risk assessment is not correct since fluoropolymers are not hazardous/toxic. They have demonstrated neither environmental effects nor effects on human health.

a) Environmental Effects

Due to insolubility in water and low bioavailability (see above) aquatic toxicity of fluoropolymers is very unlikely. Because they are insoluble in water, there is no route of exposure to aquatic organisms. Even if there were an exposure pathway, the demonstrated low bioavailability and low surface activity are further indication of low risk. This is recognized by exemptions for testing in REACH Regulation: According to Annex VII entry 9.1.1, 9.1.2 and Annex VIII entry 9.1.3 and 9.1.4 REACH Regulation, short-term toxicity testing on invertebrates, algae, fish and activated sludge is not required *if mitigating factors indicate that aquatic toxicity is unlikely to occur, as for instance, if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes*.

Due to stability (see Section IV.1. below), degradation to substances with potential of aquatic toxicity is also not to be expected.

In the Restriction Proposal no information to the contrary can be found. With regard to the ecotoxicity of fluoropolymers, it is primarily referred to possible hazards from microplastics. However, this is not a substance-inherent hazard and should be handled separately (see already Section II in main document).

b) Human Health Effects

Based on a large body of data, human health effects are not to be expected from fluoropolymers like PTFE.

aa) Information Provided in Restriction Proposal

With regard to fluoropolymers, very little information is provided in the Restriction Proposal. Section B.5. of Annex B, references a few studies and the Dossier Submitters acknowledge the gaps in some of these studies.

As an additional point of reference, we would ask the DS to note that pre-clinical studies with various animal models over extended implantation durations have not demonstrated systemic toxicity of PTFE. PTFE-containing implantable medical devices have been on the market since 1975. It is estimated that there are now over 45 million PTFE-based Gore medical implants in patients worldwide and that number grows annually as new configurations are developed to serve new applications or supplant or improve upon existing technologies. Examinations of devices over protracted clinical implantation durations continue to affirm the biological safety of ePTFE as a biomaterial. The clinical history of the safe implantation of PTFE medical devices over 45 years, toxicity data, preclinical data, and chemical extractable testing confirm that fluoropolymers are not bioavailable and safe to use in their intended uses in implantable medical devices.

bb) Low Risk Potential

In general, fluoropolymers have a low hazard and low bioavailable exposure, and therefore, low-risk potential. This is mainly based on their molecular size and the resulting non-bioavailability (see Section 4 above). To be capable of producing systemic toxicity including carcinogenicity a substance needs to be bioavailable.

There are several publications speaking to the low human hazard as well. For example, Ebnesajjad (2013) stated that, “This family of plastics (fluoropolymers) has low toxicity and almost no toxicological activity. Fluoropolymers have not been known to cause skin sensitivity or irritation in humans.”

With respect to chronic toxicity in humans with PTFE implants, Brand and Brand (1980) investigated the incidence of foreign-body cancers associated with implantations and concluded that “*low number actually observed permits the prediction that the incidence of cancer at implantation sites will remain low*.” Similarly, Radulovic and Wojcinski (2014) conclude that “The lack of toxicity (of PTFE) is most likely due to the following: gastrointestinal absorption of PTFE is negligible given its extremely high molecular weight (1,000,000 – 10,000,000 for PTFE fine powder)” and that “PTFE is chemically inert under physiologic conditions, and PTFE is not metabolized.”

Also, the World Health Organization's International Agency for Research on Cancer concluded that "Organic polymeric materials (like fluoropolymers) as a group are not classifiable as to their carcinogenicity to humans (Group 3)," (WHO IARC, 1999).

cc) Data on PTFE, FEP and PFA

The understanding outlined above is confirmed by evidence in experimental animals proving proof of biocompatibility and lack of toxicity.

The biocompatibility is largely due to its relative inertness in physiologic environments (Ebnesajjad, 2013). A key component of the chemical structure of the polytetrafluoroethylene molecule is the presence of many carbon-fluorine bonds, one of the strongest chemical bonds known among organic compounds. Because the carbon backbone is protected by a fully fluorinated envelope, fluoropolymers resist attack by even the most highly corrosive chemicals and solvents precluding the possibility of chemical cleavage of the polymer chains *in vivo.* This effectively eliminates the possibility of chemical degradation *in vivo* to produce potentially toxic leachables. The resistance of PTFE to microbial degradation was documented in Guidoin et al., 1993 who noted that "PTFE was proven to have sufficient resistance to *in vivo* degradation…" (Guidoin et al., 2013).

For certain applications such as food, pharmaceutical, and medical devices, there are country-specific data requirements for fluoropolymers. For example, formal biocompatibility evaluations are required by the USFDA and other global regulatory authorities to support submissions for approval of medical devices and pharmaceuticals (e.g., combination products, such as drug-eluting stents or prefilled single-dose syringes). The *International Organization for Standardization (ISO) 10993 Biocompatibility of Medical Devices standards* describe a broad array of biocompatibility tests that require consideration for each new device or significant changes to existing devices (ISO 2009). Over the years, medical devices containing PTFE have been evaluated using ISO 10993 and US Pharmacopeia (USP) Class VI standards (USP 2016), and have been determined to be biocompatible in their intended uses.

The ISO 10993 standards are globally accepted standards which provide guidance for evaluation of the biological response to a medical device. The USFDA and most international regulatory agencies, recognize and use ISO 10993 standards to guide safety evaluations of medical devices submitted for their approval. Biocompatibility and regulatory authority-specific requirements of medical devices are set forth in ISO 10993-1, (e.g., PMDA 2003; USFDA 2016). See Henry *et al.*, 2018 for more details.

In the Supplement to Henry *et al.*, 2018 we first published the following tables of PTFE data from ISO 10993 and OECD guideline toxicity studies.

Table 2 Summary of GLP toxicological studies that confirm the non-toxic nature of PTFE, FEP and PFA		
Study	**Standard/Guideline**	**Result**
In vitro Cytotoxicity	ISO 10993-5	Non-cytotoxic
In vivo skin sensitization	ISO 10993-10; OECD 406	Non-sensitizing
In vivo irritation	ISO 10993-23	Non-irritating
In vivo acute toxicity	ISO 10993-11	Not acutely toxic
In vivo subchronic toxicity	ISO 10993-6, ISO 10993-11	No adverse effects observed
In vivo and *in vitro* genotoxicity assays	ISO 10993-3	Non-genotoxic
In vivo implantation	ISO 10993-4, ISO 10993-6	No adverse effects observed
In vitro hemocompatibility assays	ISO 10993-4	Hemocompatible

Note: 90-Day Subchronic Toxicity Studies included hematology, urinalysis, clinical chemistry, gross pathology, microscopic histopathology, organ weights, clinical observations. Histopathology performed on: ovaries, testes, brain, heart, liver, kidneys, spleen, thymus, adrenal glands, lymph nodes.

PTFE

Fine powder PTFE, meeting the ASTM D4895 and OECD polymer of low concern criteria, in three physical forms (sheet (form A), fiber (form B), tube (form C)) was subjected to the ISO 10993-1 (Biological evaluation of medical devices – Part 1: Evaluation and testing) testing in compliance with Good Laboratory Practices (GLPs, 21 CFR, Part 58) at an accredited contract laboratory, NAMSA (Northwood, OH), in accordance with current ISO 10993 guidelines. All three physical forms of PTFE were manufactured, sterilized, and packaged using methods intended for commercial product. **The test results demonstrate the low toxicity and *in vivo* biocompatibility of PTFE.**

Final reports for these GLP studies from accredited contract laboratories have been provided in full to the fire-fighting foam restriction process in 2022 (see Annex VI)

Table A.3. PTFE Form A

Test Performed (Lab Report No.) (Date Completed) Testing Guideline(s)	Extraction Vehicle(s) Conditions	Test Article and Control(s)	Conclusions
In Vitro Cytotoxicity *MEM Elution Test* (12T_29147_03) (May/2012) ISO 10993-5 ISO 10993-12	Extraction: Minimum Essential Medium with 5% fetal bovine serum, 2% antibiotics, 1% L-glutamine. Conditions: 37 ºC, 24 hours. Extraction Ratio: 6 cm^2/mL Test system: Mouse fibroblast L-929 cells.	PTFE fiber, Code: SMR108316 Neg. Control = High density polyethylene (HDPE) Pos. Control = Powder-Free Latex Gloves	**PASS** – non cytotoxic Test article was not cytotoxic.
Delayed-Type Hypersensitivity *Kligman Maximization Test in Guinea Pigs* (12T_29147_06, 12T_29147_07) (June/2012) ISO 10993-10	Extraction: 0.9% NaCl; sesame oil. Conditions: 50 ºC, 72 hours. Extraction Ratio: 6 cm^2/mL	PTFE fiber, Code: SMR108316 Neg. Control = 0.9% NaCl, sesame oil Periodic Pos. Control = 1-chloro-2,4-dinitrobenzene (DNCB)	**PASS** - non-sensitizing All animals increased in weight, no signs of systemic toxicity, no reaction to challenge.
Irritation *Intracutaneous Irritation Study in Rabbits* (12T_29147_04, 12T_29147_05) (May/2012) ISO 10993-10	Extraction: 0.9% NaCl; sesame oil. Conditions: 50 ºC, 72 hours. Extraction Ratio: 6 cm^2/mL	PTFE fiber, Code: SMR108316 Neg. Control = 0.9% NaCl, sesame oil Pos. Control: N/A.	**PASS** – non-irritating No treatment-related signs of toxicity. The difference in the mean score for both test and control was ≤ 1 for both the NaCl and sesame oil test.
Systemic Toxicity *Acute Systemic Toxicity Study in Mice* (12T_29147_08, 12T_29147_09) (May/2012) ISO 10993-11	Extraction: 0.9% NaCl; sesame oil. Conditions: 50 ºC, 72 hours. Extraction Ratio: 6 cm^2/mL	PTFE fiber, Code: SMR108316 Neg. Control = 0.9% NaCl, sesame oil Pos. Control: N/A	**PASS** – not systemically toxic No treatment-related signs of toxicity or loss of body weight in any group.

Rabbit Pyrogen Study (Material Mediated) (12T_29147_10) (May/2012) ISO 10993-11 USP 151	Extraction: 0.9% NaCl. Conditions: 50 °C, 72 hours. Extraction Ratio: 6 cm^2/mL	PTFE fiber, Code: SMR108316 Neg. Control = 0.9% NaCl. Pos. Control: N/A	**PASS** – non-pyrogenic Body temperature increases were ‹ 0.5 °C for individual test animals and ‹ 3.3 °C for all treated animals.
<u>Genotoxicity</u> *Bacterial Reverse Mutation Assay* (12T_31264_03, 12T_31264_04) (May/2012) OECD Test No. 471 ISO 10993-3 ISO 10993-12	Extraction: 0.9% NaCl, dimethyl sulfoxide Conditions: 50 °C, 72 hours. Extraction Ratio: 6 cm^2/mL Test system: *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537; *Escherichia coli* strain WP2uvrA.	PTFE fiber, Code: SMR108316 Neg. Control = vehicle only Pos. Control = Sodium azide, Methyl Methanesulfonate, Benzo[a]pyrene, 2-aminoanthracene, 2-Nitrofluorene, ICR-191	**PASS** – non mutagenic The test article extracts were not considered to be mutagenic.
Mouse Lymphoma Assay (12T_31264_05, 12T_31264_06) (July/2012) OECD Test No. 476 ISO 10993-3 ISO 10993-12	Extraction: RPMI culture medium, dimethyl sulfoxide Conditions: RPMI: 37 °C, 72 hours dimethyl sulfoxide: 50 °C, 72 hours Extraction Ratio: 6 cm^2/mL Test system: Mouse Lymphoma L5178Y/$TK^{+/-}$ cells	PTFE fiber, Code: SMR108316 Neg. Control = vehicle only Pos. Control = 3-Methylchol-anthrene, Methyl Methanesulfonate	**PASS** – non mutagenic The test article extracts did not induce gene mutations or chromosomal damage.
Mouse Peripheral Blood Micronucleus Study (12T_31264_07, 12T_31264_08) (June/2012) OECD Test No. 474 ISO 10993-3 ISO 10993-12	Extraction: 0.9% NaCl, Sesame Oil Conditions: 50 °C, 72 hours. Extraction Ratio: 6 cm^2/mL	PTFE fiber, Code: SMR108316 Neg. Control = 0.9% NaCl, Sesame Oil Pos. Control = Methyl methanesulfonate, 50 mg/kg	**PASS** – non mutagenic The test article extracts did not induce micronuclei formation.
<u>Local Effects after Implantation</u> *Muscle Implantation Study in Rabbits (4 weeks)* (12T_29147_11) (June/2012) ISO 10993-6	N/A	PTFE fiber, Code: SMR108316 Four 1×1×10 mm sections were implanted/rabbit. Neg. Control = HDPE. Four 1×1×10 mm sections were implanted/rabbit.	**PASS** - Non adverse No adverse effects were observed micro- or macroscopically. The test article was a non-irritant.

Hemocompatibility **Hemolysis Study** **Direct Contact and Indirect Contact** (12T_29147_13) (May/2012) ISO 10993-4 ISO 10993-12 ASTM F756	Direct contact: The test article was introduced directly to test system at 6 cm^2/mL Indirect contact: Extraction: PBS Conditions: 50 °C for 72 hours. Test Article: extracted at 6 cm^2/mL	PTFE fiber, Code: SMR108316 Negative Control = HDPE Positive control = sterile water for injection	**PASS** – Non-hemolytic. Direct contact: ≤ 2% hemolysis. Indirect contact: ≤ 2% hemolysis.
Partial Thromboplastin Time, Direct Contact (12T_29147_14) (May/2012) ASTM F2382 ISO 10993-12	No extraction. The test article was introduced directly to human plasma at 4 cm^2/mL	PTFE fiber, Code: SMR108316 Negative Control = Polypropylene tube Positive Control = soda lime glass beads	**PASS** – No effect on coagulation. The average Partial Thromboplastin Time was 94% of the negative control.
Complement Activation **C3a Complement Activation Assay (Direct Contact)** (12T_29147_15) (May/2012) ISO 10993-4	No extraction. Test article was directly exposed to test system at a ratio of 6 cm^2/mL at 37 °C for 60 minutes.	PTFE fiber, Code: SMR108316 Negative Control = HDPE Negative Control = LDPE; Positive Controls = latex gloves, Cobra Venom Factor (CVF)	**PASS** – No activation of complement. The test article sample was not statistically higher ($p<0.05$) than both the activated human serum and negative controls.
SC5b-9 Complement Activation Assay (Direct Contact) (12T_29147_16) (May/2012) ISO 10993-4	No extraction. Test article was directly exposed to test system at a ratio of 6 cm^2/mL at 37 °C for 60 minutes.	PTFE fiber, Code: SMR108316 Negative Control = HDPE Negative Control = LDPE; Positive Controls = latex gloves, CVF	**PASS** – No activation of complement. The test article sample was not statistically higher ($p<0.05$) than both the activated human serum and negative controls.
Subchronic toxicity ***13-Week Systemic Toxicity Study in Rats*** (12T_29147_12) (September /2012) OECD Test No. 408 ISO 10993-11	N/A	PTFE fiber, Code: SMR108316 Test Article Dose: 90 linear cm/rat. Based upon an average male 250 g rat (i.e., 360 cm/kg), which is equivalent to a 70 kg patient receiving 25,200 linear cm. Neg. Control = HDPE	**PASS** – There were no clinical or systemic signs of toxicity (including gross-, microscopic-, and clinical-pathology evaluations). The test article was considered a non-irritant.

Table A.4. PTFE Form B

Test Performed (Lab Report #) Testing Guideline(s)	Extraction Vehicle(s) Conditions	Test Article and Control(s)	Conclusions
***In Vitro* Cytotoxicity** **L929 MEM Elution Test** Completed April4/2012 12T_28380_03 ISO 10993-5 ISO 10993-12	Test article was extracted at a ratio of 6cm^2/ml in 1X MEM media + 5% FBS + 2% antibiotics at 37 °C for 24 hours. Test system: Mouse fibroblast L-929 cells	Test article name: VT6 Lot: SMR108669 Negative Controls = HDPE, 1X MEM Positive Control = Powder-free latex gloves	**PASS** – non cytotoxic Test article was not cytotoxic.
Delayed-Type Hypersensitivity **Kligman Maximization Test in Guinea Pigs** Completed June/2012 12T_28380_06 12T_28380_07 ISO 10993-10	Test article was extracted at a ratio of 6cm^2/ml in 0.9% USP NaCl and sesame oil at 50 °C for 72 hours.	Test article name: VT6 Lot: SMR108669 Negative Controls = 0.9% USP NaCl, sesame oil; Positive Control = Dinitrochlorobenzene.	**PASS –** non-sensitizing All animals increased in weight, no signs of systemic toxicity, no reaction to challenge.
Irritation **ISO Intracutaneous Study in Rabbits** Completed May/2012 12T_28380_04 12T_28380_05 ISO 10993-10	Test article was extracted at a ratio of 6cm^2/ml in 0.9% USP NaCl and sesame oil at 50 °C for 72 hours.	Test article name: VT6 Lot: SMR108669 Negative Controls = 0.9% USP NaCl, sesame oil; Positive Control: N/A.	**PASS** – non-irritating No treatment-related signs of toxicity. The difference in the mean score for both test and control was ≤ 1 for both the NaCl and sesame oil test.

Test Performed (Lab Report #) Testing Guideline(s)	Extraction Vehicle(s) Conditions	Test Article and Control(s)	Conclusions
Systemic Toxicity **Acute Systemic Toxicity Study in Mice** Completed May/2012 12T_28380_08 12T_28380_09 ISO 10993-11	Test article was extracted at a ratio of 6cm^2/ml in 0.9% USP NaCl and sesame oil at 50 °C for 72 hours.	Test article name: VT6 Lot: SMR108669 Negative Control = 0.9% USP NaCl, sesame oil; Positive Control: N/A	**PASS** – not systemically toxic No treatment-related signs of toxicity or loss of body weight in any group.
Rabbit Pyrogen Study (Material-Mediated) Completed April/2012 12T_28380_10 ISO 10993-11 USP 151	Test article was extracted at a ratio of 6cm^2/ml in 0.9% USP NaCl at 50 °C for 72 hours.	Test article name: VT6 Lot: SMR108669 Negative Control = 0.9% USP NaCl; Positive Control: N/A.	**PASS** – non-pyrogenic Body temperature increases were ‹ 0.5 °C for individual test animals and ‹ 3.3 °C for all treated animals.

Test Performed (Lab Report #) Testing Guideline(s)	Extraction Vehicle(s) Conditions	Test Article and Control(s)	Conclusions
Subchronic Toxicity **13-Week Systemic Toxicity Study in Rats via subcutaneous implantation** Completed September/2012 12T_28380_12 ISO 10993-11 OECD 408	No extraction: Test article was directly implanted in each animal as 1cm x 2cm sections (0.07g each) at 6 sites (corresponding to 1.68g material/kg body weight). This corresponds to approximately 87% of what occurs in a worst-case clinical scenario; implantation of more material was not surgically practical.	Test article name: VT6 Lot: SMR108669 Neg. Control = HDPE Pos. Control = N/A	**PASS** – There were no clinical or systemic signs of toxicity (including gross-, microscopic-, and clinical-pathology evaluations). The test article was considered a non-irritant.
Genotoxicity **Bacterial Reverse Mutation Assay** Completed May/2012 12T_30064_02 12T_30064_03 OECD 471 ISO 10993-3 ISO 10993-12	Test article was extracted at a ratio of $6cm^2$/ml in 0.9% USP NaCl and dimethyl sulfoxide (DMSO) at 50 ºC for 72 hours. A dose range finding study was also performed that used test article extracted at a ratio of $6cm^2$/ml in DMSO at 50 ºC for 72 hours. Test systems: *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537; *Escherichia coli* strain WP2uvrA.	Test article name: VT6 Lot: SMR108669 Negative Controls = 0.9% USP NaCl, DMSO; Positive Controls = Sodium azide, methyl methanesulfonate (MMS), 2-aminoanthracene, benzo[a]pyrene, 2-nitrofluorene, ICR-191.	**PASS** – non mutagenic The test article extracts were not considered to be mutagenic.
Mouse Lymphoma Assay Completed June/2012 12T_30064_04 12T_30064_05 OECD 476 ISO 10993-3 ISO 10993-12	Test article was extracted at a ratio of $6cm^2$/ml in serum free cell culture media ($RPMI_0$) at 37 ºC for 72 hours; test article was extracted at a ratio of $6cm^2$/ml in DMSO at 50 ºC for 72 hours. Test system: Mouse Lymphoma L5178Y/$TK^{+/-}$ cells	Test article name: VT6 Lot: SMR108669 Negative Controls = DMSO, $RPMI_0$. Positive Controls = MMS, 3-methylcholanthrene.	**PASS** – non mutagenic The test article extracts did not induce gene mutations or chromosomal damage.

Test Performed (Lab Report #) Testing Guideline(s)	Extraction Vehicle(s) Conditions	Test Article and Control(s)	Conclusions
Mouse Peripheral Blood Micronucleus Study Completed May/2012 12T_30064_06 12T_30064_07 OECD 474 ISO 10993-3 ISO 10993-12	Test article was extracted at a ratio of 6cm^2/ml in 0.9% USP NaCl and sesame oil at 50 °C for 72 hours.	Test article name: VT6 Lot: SMR108669 Negative Control = 0.9% USP NaCl, sesame oil; Positive Control =MMS, 50mg/kg	**PASS** – non mutagenic The test article extracts did not induce micronuclei formation.
Local Effects after Implantation **Muscle Implantation Study in Rabbits, 4 weeks** Completed June/2012 12T_28380_11 ISO 10993-6	No extraction. 10mm x 1mm x 1mm sections of the test article representative of all materials in the device were implanted directly into the test system.	Test article name: VT6 Lot: SMR108669 Negative Control = HDPE; Positive Control = N/A	**PASS –** Non adverse No adverse effects were observed micro- or macroscopically. The test article was a non-irritant.
Hemocompatibility **Hemolysis-Rabbit Blood (Direct and Indirect Contact)** Completed April/2012 12T_28380_13 ISO 10993-4 ISO 10993-12 ASTM F756	Test article was directly exposed to test system at a ratio of 6cm^2/ml for the direct contact test; for the indirect contact test, test article was extracted at a ratio of 6cm^2/ml in Ca- and Mg-free phosphate buffered saline at 50 °C for 72 hours.	Test article name: VT6 Lot: SMR108669 Negative Control = High density polyethylene. Positive control = Sterile H_2O for injection	**PASS** – Non-hemolytic. Direct contact: ≤ 2% hemolysis. Indirect contact: ≤ 2% hemolysis.

Test Performed (Lab Report #) Testing Guideline(s)	Extraction Vehicle(s) Conditions	Test Article and Control(s)	Conclusions
Partial Thromboplastin Time Assay **(Direct Contact)** Completed April/2012 12T_28380_14 ISO 10993-4 ISO 10993-12 ASTM F2382	No extraction. Test article was directly exposed to human plasma at a ratio of 4.0cm^2/ml at 37 °C for 15 minutes.	Test article name: VT6 Lot: SMR108669 Negative Control = Polypropylene tube Positive Controls = Soda lime glass beads	**PASS** – No effect on coagulation. The average Partial Thromboplastin Time was 84% of the negative control.
C3a Complement Activation Assay **(Direct Contact)** Completed April/2012 12T_28380_15 ISO 10993-4	No extraction. Test article was directly exposed to test system at a ratio of 6cm^2/ml at 37 °C for 60 minutes.	Test article name: VT6 Lot: SMR108669 Negative Control = LDPE; Positive Controls = latex gloves, Cobra Venom Factor (CVF)	**PASS** – No activation of complement. The test article sample was not statistically higher ($p<0.05$) than both the activated human serum and negative controls.
SC5b-9 Complement Activation Assay **(Direct Contact)** Completed April/2012 12T_28380_16 ISO 10993-4	No extraction. Test article was directly exposed to test system at a ratio of 6cm^2/ml at 37 °C for 60 minutes.	Test article name: VT6 Lot: SMR108669 Negative Control = LDPE; Positive Controls = latex gloves, CVF	**PASS** – No activation of complement. The test article sample was not statistically higher ($p<0.05$) than both the activated human serum and negative controls.

Note: VT6 = PTFE tube

Table A.5. PTFE Form C

Test Performed (Lab Report No.) (Date Completed) Testing Guideline(s)	Extraction Vehicle(s) Conditions	Test Article[a] and Control(s)	Conclusions
In Vitro Cytotoxicity *MEM Elution Test* (12T_2724_03) (April/2012) ISO 10993-5 ISO 10993-12	Extraction: Minimum Essential Medium with 5% fetal bovine serum, 2% antibiotics, 1% L-glutamine. Conditions: 37 °C, 24 hours. Extraction Ratio: 6 cm^2/mL Test system: Mouse fibroblast L-929 cells.	PTFE patch, Code: SMR108314 Neg. Control = High density polyethylene (HDPE) Pos. Control = Powder-Free Latex Gloves	**PASS** – non cytotoxic Test article was not cytotoxic.
Delayed-Type Hypersensitivity *Kligman Maximization Test in Guinea Pigs* (12T_2724_13, 12T_2724_14) (June/2012) ISO 10993-10	Extraction: 0.9% NaCl; sesame oil. Conditions: 50 °C, 72 hours. Extraction Ratio: 6 cm^2/mL	PTFE patch, Code: SMR108314 Neg. Control = 0.9% NaCl, sesame oil Pos. Control = 1-chloro-2,4-dinitrobenzene (DNCB)	**PASS –** non-sensitizing All animals increased in weight, no signs of systemic toxicity, no reaction to challenge. One (sesame oil, Test group) animal (#6256) was euthanized on day 26. Necropsy revealed a broken left rear leg. No evidence of sensitization was observed in the sesame oil group; therefore, the loss of this animal did not impact the conclusion.

Irritation *Intracutaneous Irritation Study in Rabbits* (12T_2724_06, 12T_2724_07) (May/2012) ISO 10993-2 ISO 10993-10 ISO 10993-12	Extraction: 0.9% NaCl; sesame oil. Conditions: 50 °C, 72 hours. Extraction Ratio: 6 cm^2/mL	PTFE patch, Code: SMR108314 Neg. Control = 0.9% NaCl, sesame oil Pos. Control: N/A.	**PASS** – non-irritating No treatment-related signs of toxicity. The difference in the mean score for both test and control was ≤ 1 for both the NaCl and sesame oil test.
Systemic Toxicity *Acute Systemic Toxicity Study in Mice* (12T_2724_04, 12T_2724_05) (May/2012) ISO 10993-2 ISO 10993-11 ISO 10993-12	Extraction: 0.9% NaCl; sesame oil. Conditions: 50 °C, 72 hours. Extraction Ratio: 6 cm^2/mL	PTFE patch, Code: SMR108314 Neg. Control = 0.9% NaCl, sesame oil Pos. Control: N/A	**PASS** – not systemically toxic No treatment-related signs of toxicity or loss of body weight in any group.
Rabbit Pyrogen Study (Material Mediated) (12T_2724_12) (May/2012) ISO 10993-11 USP 151	Extraction: 0.9% NaCl. Conditions: 50 °C, 72 hours. Extraction Ratio: 6 cm^2/mL	PTFE patch, Code: SMR108314 Neg. Control = 0.9% NaCl. Pos. Control: N/A	**PASS** – non-pyrogenic Body temperature increases were < 0.5 °C for individual test animals and < 3.3 °C for all treated animals.
Genotoxicity *Bacterial Reverse Mutation Assay* (12T_30255_03, 12T_30255_04) (May/2012) OECD Test No. 471 ISO 10993-3 ISO 10993-12	Extraction: 0.9% NaCl, dimethyl sulfoxide Conditions: 50 °C, 72 hours. Extraction Ratio: 6 cm^2/mL Test system: *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537; *Escherichia coli* strain WP2uvrA.	PTFE patch, Code: SMR108314 Neg. Control = vehicle only Pos. Control = Sodium azide, Methyl Methanesulfonate, Benzo[a]pyrene, 2-aminoanthracene, 2-Nitrofluorene, ICR-191	**PASS** – non mutagenic The test article extracts were not considered to be mutagenic.

Mouse Lymphoma Assay (12T_30255_05, 12T_30255_06) (June/2012) OECD Test No. 476 ASTM E1280 ISO 10993-3 ISO 10993-12	Extraction: RPMI culture medium, dimethyl sulfoxide Conditions: RPMI: 37 °C, 72 hours dimethyl sulfoxide: 50 °C, 72 hours Extraction Ratio: 6 cm^2/mL Test system: Mouse Lymphoma L5178Y/$TK^{+/-}$ cells	PTFE patch, Code: SMR108314 Neg. Control = vehicle only Pos. Control = 3-Methylchol-anthrene, Methyl Methanesulfonate	**PASS** – non mutagenic The test article extracts did not induce gene mutations or chromosomal damage.
Mouse Peripheral Blood Micronucleus Study (12T_30255_07, 12T_30255_08) (June/2012) OECD Test No. 474 ISO 10993-3 ISO 10993-12	Extraction: 0.9% NaCl, Sesame Oil Conditions: 50 °C, 72 hours. Extraction Ratio: 6 cm^2/mL	PTFE patch, Code: SMR108314 Neg. Control = 0.9% NaCl, Sesame Oil Pos. Control = Methyl methanesulfonate, 50 mg/kg	**PASS** – non mutagenic The test article extracts did not induce micronuclei formation.
<u>Local Effects after Implantation</u> *Muscle Implantation Study in Rabbits (4 weeks)* (12T_2724_15) (June/2012) ISO 10993-6	N/A	PTFE patch, Code: SMR108314 Four 1×1×10 mm sections were implanted/rabbit. Neg. Control = HDPE. Four 1×1×10 mm sections were implanted/rabbit. Pos. Control: N/A	**PASS** – Non adverse No adverse effects were observed micro- or macroscopically. The test article was a non-irritant.
<u>Hemocompatibility</u> **Hemolysis Study Direct Contact and Indirect Contact** (12T_2724_11) (April/2012) ISO 10993-4 ISO 10993-12 ASTM F756	Direct contact: The test article was introduced directly to test system at 6 cm^2/mL Indirect contact: Extraction: PBS Conditions: 50 °C for 72 hours.	PTFE patch, Code: SMR108314 Negative Control = HDPE Positive control = sterile water for injection	**PASS** – Non-hemolytic. Direct contact: ≤ 2% hemolysis. Indirect contact: ≤ 2% hemolysis.

	Test Article: extracted at 6 cm^2/mL		
Partial Thromboplastin Time, Direct Contact (12T_2724_08) (May/2012) ASTM F2382 ISO 10993-12	No extraction. The test article was introduced directly to human plasma at 4 cm^2/mL	PTFE patch, Code: SMR108314 Negative Control = Polypropylene tube Positive Control = soda lime glass beads	**PASS** – No effect on coagulation. The average Partial Thromboplastin Time (PTT) was 75% of the negative control.
Complement Activation **C3a Complement Activation Assay (Direct Contact)** (12T_2724_09) (May/2012) ISO 10993-4	No extraction. Test article was directly exposed to test system at a ratio of 6 cm^2/mL at 37 °C for 60 minutes.	PTFE patch, Code: SMR108314 Negative Control = HDPE, LDPE Positive Controls = latex gloves, Cobra Venom Factor (CVF)	**PASS** – No activation of complement. The test article sample was not statistically higher ($p<0.05$) than both the activated human serum and negative controls.
SC5b-9 Complement Activation Assay (Direct Contact) (12T_2724_10) (May/2012) ISO 10993-4	No extraction. Test article was directly exposed to test system at a ratio of 6 cm^2/mL at 37 °C for 60 minutes.	PTFE patch, Code: SMR108314 Negative Control = HDPE, LDPE Positive Controls = latex gloves, CVF	**PASS** – No activation of complement. The test article sample was not statistically higher ($p<0.05$) than both the activated human serum and negative controls.
Subchronic toxicity ***13-Week Systemic Toxicity Study in Rats*** (12T_2724_16) (October/2012) ISO 10993-6 ISO 10993-11	N/A	PTFE patch, Code: SMR108314 Test Article Dose: 6, 1 mm x 1 cm x 2cm pieces per animal was the maximum implant in this subcutaneous rat model. Neg. Control = HDPE Pos. Control = N/A	**PASS** – There were no clinical or systemic signs of toxicity (including gross-, microscopic-, and clinical-pathology evaluations). The test article was considered a non-irritant.

FEP

The tests were also conducted for fluorinated ethylene propylene (FEP). The results which also demonstrate the low toxicity and biocompatibility, are presented in the table below and have also been provided to the fire-fighting foam restriction process in 2022 (see Annex VI).

Table A.6. Biocompatibility Tests, Conditions, and Conclusions for FEP

Test Performed (Lab Report No.) (Date Completed) Testing Guideline(s)	Extraction Vehicle(s) Conditions	Test Article* And Control(s)	Conclusions
In Vitro* Cytotoxicity** ***Cytotoxicity Study Using ISO Elution Method (12T-49383-03) (November/2012) ISO 10993-5	Extraction: Minimum Essential Medium with 5% fetal bovine serum, 2% antibiotics (penicillin, streptomycin, amphotericin B) and 1% (2mM) L-glutamine Conditions: 37 °C, 48 hrs. Extraction Ratio: 6 cm^2/mL Test System: Mouse Fibroblast L-929 Cells	PTFE, FEP, silicone Neg Control = High density polyethylene (HDPE) Pos. Control = Powder-free Latex Gloves	**PASS** – non cytotoxic Test article was not cytotoxic
Delayed-Type Hypersensitivity ***Kligman Maximization Test in Guinea Pigs*** (12T-49383-14, 12T-49383-15 (January/2013) ISO 10993-10	Extraction: 0.9% NaCl, Sesame oil Conditions: 50 °C, 72 hours Extraction Ratio: 6 cm^2/mL	PTFE, FEP, silicone Neg. Control = 0.9% NaCl, Cottonseed Oil Pos. Control = Dinitrochlorobenzene (DNCB)	**PASS** – non-sensitizing All animals increased weight, with no signs of systemic toxicity, nor reaction on challenge were observed.

Irritation ***Intracutaneous Rabbit Study*** (12T-49383-06, 12T-49383-07) (November/2012) ISO 10993-10	Extraction: 0.9% NaCl, Sesame Oil Conditions: 50 °C, 72 hours Extraction Ratio: 6 cm^2/mL	PTFE, FEP, silicone Neg. Control = 0.9% NaCl, Sesame Oil Pos. Control =N/A	**PASS** – No difference between the test extract overall mean score and the corresponding control overall mean score was observed for both NaCl and Sesame Oil extracts
Systemic Toxicity ***Acute Systemic toxicity in Mice*** (12T-49383-04, 12T-49383-05) (October/2012) ISO 10993-11	Extraction: 0.9% NaCl, Sesame oil Conditions: 50 °C, 72 hours Extraction Ratio: 6 cm^2/mL	PTFE, FEP, silicone Neg. Control = 0.9% NaCl, Sesame Oil Pos. Control = N/A	**PASS –** None of the animals treated with the test extract exhibited a significantly greater reaction than the control animals.
Rabbit Pyrogen Test (Material Mediated) (97G-2330) (December/1997) ISO 19003-11	Extraction: 0.9% NaCl Conditions: 50 °C, 72 hours Extraction Ratio: 6 cm^2/mL	PTFE, FEP, silicone Neg. Control = 0.9% NaCl Pos. Control = N/A	**PASS –** non-pyrogenic Body temperature increases were <0.5 °C and summed <3.3 °C for all treated animals
Subchronic Toxicity ***13-Week Systemic Toxicity Study in Rats Following Subcutaneous Implantation*** (12T-49383-16) (March/2013) ISO 10993-11 ISO 10993-6	N/A	PTFE, FEP, silicone 15x3x1mm Neg. Control = High density polyethylene 20x10x1mm 15x3x1mm 10x1mm discs Pos. Control = N/A	**PASS** – No evidence of systemic toxicity, including gross, microscopic, and clinical pathology evaluations. The test article was considered a non-irritant.

Genotoxicity ***Mouse Lymphoma Assay*** (12T-52351-03, 12T-52351-04) (January/2013) ISO 10993-3	Extraction: Serum-free culture medium ($RPMI_0$), Dimethylsulfoxide (DMSO) Conditions: 37 °C, 72 hours ($RPMI_0$) 50 °C, 72 hours (DMSO) Extraction Ratio: 6 cm^2/mL Test system: Mouse Lymphoma L5178Y ($TK^{+/-}$) cells	PTFE, FEP, Silicone Neg. Control = $RPMI_0$ medium, Dimethylsulfoxide (DMSO) Pos. Control = Methylmethane sulfonate (MMS), 3-methylcholanthrene (3-MCA)	**PASS** – non-mutagenic The test article extract was not considered mutagenic
Bacterial Reverse Mutation Study (12T-52351-01, 12T-52351-02) (December/2012) ISO 10993-3	Extraction: DMSO, 0.9% NaCl Conditions: 50 °C, 72 hours Extraction Ratio: 6cm^2/mL	PTFE, FEP, silicone Neg. Control = Dimethylsulfoxide (DMSO) Pos. Control = sodium azide, methyl methanesulfonate, 2-aminoeanthracene, benzo[a]pyrene, 2-nitrofluorene, ICR-191	**PASS** – non-mutagenic The test article extract was not considered mutagenic.
Local Effects after Implantation ***Muscle Implantation Study in Rabbits (4 Weeks)*** (12T-49383-13) (January/2013) ISO 10993-4 ISO 10993-6	N/A	PTFE, FEP, Silicone Neg Control = USP High density polyethylene 1x1x10mm sections were implanted in rabbit Pos Control = N/A	**PASS** – No adverse effects were observed micro or macroscopically. The test article was a non-irritant. The difference between the average scores for all categories of biological reaction for the test article and control article implants sites were <1, and the difference between mean scores for test article and control article sites was <1.

Hemocompatibility ***Partial Thromboplastin Time*** (12T-49383-11) (November/2012) ISO 10993-4	Extraction: Human plasma Conditions: 37 °C, 15 minutes Extraction Ratio: 4 cm^2/mL	PTFE, FEP, silicone Neg Control = Human plasma Pos Control = Glass beads	**PASS –** Test article was considered a minimal activator
Hemolysis Study ***Direct Contact and Indirect Contact*** (12T-49383-12) (November/2012) ISO 10993-4	Extraction: Calcium and magnesium-free phosphate buffered saline (CMF-PBS) Conditions: 50 °C, 72 hours Extraction Ratio: 6 cm^2/mL	PTFE, FEP, silicone Neg. Control = High density polyethylene (HDPE) Pos Control = Sterile Water for Injection (SWFI)	**PASS –** Both the test article in direct contact with blood and the test article extract were non-hemolytic (0.0%)
Complement Activation ***C3a Complement Activation Assay*** (12T-20497-05) (February/2012) ISO 10993-4	Extraction: Normal Human Serum (NHS) Conditions: 37 °C, 1 hour Extraction Ratio: 6 cm^2/mL	PTFE, FEP, silicone Neg Control: LDPE, Inactivated Normal Human Serum Control Pos Control: Cobra Venom Factor (CVF)	**PASS** – Overall, the C3a concentrations obtained for the test article were within the historic range of the activated NHS control and negative control, although the C3a concentrations obtained for the test article were statistically higher than both the activated NHS and negative controls in this experiment.

SC5b-9 Complement Activation Assay (12T-49383-09) (November/2012) ISO 10993-4	Extraction: Normal Human Serum Conditions: 37 °C, 1 hour Extraction Ratio: 6 cm^2/mL	PTFE, FEP, Silicone Neg Control: Normal Human Serum, Low Density Polyethylene Pos Control: Cobra Venom Factor	**PASS –** Overall, although the SC5b-9 in the test sample was statistically higher than both the activated NHS and negative controls in this study, the concentration of SC5b-9 in the test article sample was less than the historical range of activated NHS and negative controls. Therefore, the test article was considered a low potential activator of the complement system.

PFA

The tests were also conducted for a tetrafluoroethylene copolymer with perfluoroalkyl vinyl ethers known as a perfluoroalkoxy polymer, or PFA. The results which also demonstrate the low toxicity and biocompatibility of PFA, are presented in the table below with final reports also provided as comments to the fire-fighting foam restriction process in 2022 (see Annex VI). Note that PFA is labeled as PATT in this table and in the final reports also provided in the Non-confidential Attachment.

Table A.7. Biocompatibility Tests, Conditions, and Conclusions for PFA

Test Performed (Lab Report No.) (Date Completed) Testing Guideline(s)	**Extraction Vehicle(s)** **Conditions**	**Test Article* And Control(s)**	**Conclusions**
***In Vitro* Cytotoxicity** **MEM Elution Test**	Extraction: Minimum Essential Medium with 10% serum, 292 mg/l L-glutamine, 2.3 g/l	PATT	**PASS –** non cytotoxic Test article was not cytotoxic

(MEM97-342-21, A097-342-20, MEM99-193-2) (December/1997) (A099-193-3) (September/1999) ISO 10993-5 (MEM99-193-2) (July/1999) ISO 10993-5	sodium bicarbonate, 3.6 g/l HEPES and gentamycin 100 ug/m Conditions: 37 °C, 24-30hrs Extraction Ratio: 6 cm^2/mL Test System: Mouse Fibroblast L-929 Cells Extraction: Minimum Essential Medium with 10% serum, 292 mg/l L-glutamine, 2.3 g/l sodium bicarbonate, 3.6 g/l HEPES and gentamycin 100 ug/m Conditions: 37 °C, 72-75 hours Extraction Ratio: 6 cm^2/mL Test System: Mouse Fibroblast L-929 Cells	Neg Control = Minimum Essential Medium Test Media Pos. Control = Thermolite in PTFE	
Delayed-Type Hypersensitivity ***Kligman Maximization Test in Guinea Pigs*** (00-4477-G1, 00-4477-G2 00-4478-G1, 00-4478-G2) (November/2000) ISO 10993-10 (97G-2331) (January/1998) ISO 10993-10	Extraction: 0.9% NaCl, Cottonseed oil Conditions: 70 °C, 24 hours Extraction Ratio: 6 cm^2/mL	Name: PATT Neg. Control = 0.9% NaCl, Cottonseed Oil Pos. Control = 0.1% Dinitrochlorobenzene (DNCB)	**PASS** – non-sensitizing All animals increased weight, with no signs of systemic toxicity, nor reaction on challenge were observed**.**

Irritation ***Intracutaneous Irritation Study in Rabbits*** (99-2325-G1, 99-2327-G1) (December/1999) ISO 10993-23 (97G-2384) (January 1998) ISO 10993-23 (96-0692) March/1996 ISO 10993-23	Extraction: 0.9% NaCl, Cottonseed Oil, 1:20 Ethanol in NaCl and Polyethylene Glycol Conditions: 70 °C, 24 hours Extraction Ratio: 6 cm^2/mL	PATT Neg. Control = 0.9% NaCl, Cottonseed Oil, 1 in 20 Ethanol 0.9% NaCl; Polyethylene Glycol 400 (PEG) Pos. Control = N/A	**PASS –** No significant signs of erythema or edema were observed at any of the test or control article sites. All animals increased weight. The difference in mean reaction scores (erythema/edema) was <1 for all extracts.
Systemic Toxicity ***Acute Systemic Toxicity Study in Mice*** (99-2325-G1, 99-2327-G1) (December/1999) ISO 10993-11 (96-0692) March/1996 ISO 10993-11 (97G-2383) January/1998 ISO 10993-11	Extraction: 0.9% NaCl, Cottonseed Oil, 1:20 Ethanol in NaCl and Polyethylene Glycol Conditions: 70 °C, 24 hours Extraction Ratio: 6 cm^2/mL	PATT Neg. Control = 0.9% NaCl, Cottonseed Oil, 1 in 20 Ethanol 0.9% NaCl; Polyethylene Glycol 400 (PEG) Pos. Control = N/A	**PASS –** No animals showed overt signs of toxicity at any observation point. No significantly greater biological reaction in the animals treated with control articles was observed. All animals increased in weight.

Rabbit Pyrogen Test (Material Mediated) (97G-2330) December 1997 ISO 10993-11	Extraction: 0.9% NaCl Conditions: 37 °C, 72 hours Extraction Ratio: 1 g/5 mL	PATT Neg. Control = 0.9% NaCl Pos. Control = N/A	**PASS –** non-pyrogenic Body temperature increases were <0.5 °C and summed <3.3 °C for all treated animals
Subchronic Toxicity **13-Week Systemic Toxicity Study in Rats; Subcutaneous Implantation** (12T-20497-03) (June/2012) ISO 10993-6 ISO 10993-11	N/A	PATT Test article = 1.2 cm sections, implanted Neg. Control = High Density Polyethylene (HDPE) 1 x 1 x 12 mm sections	**PASS** – No evidence of systemic toxicity, including gross, microscopic, and clinical pathology evaluations). The test article was considered a non-irritant.
Chronic Toxicity **2 Year Systemic Toxicity Study in Rabbits; Subcutaneous Implantation** (June/1997)	N/A	PATT (0.25 mm thick), silicone rubber (0.25 mm thick)	**PASS** – No evidence of systemic toxicity, minimal foreign-body tissue response, no evidence of inflammation or calcification
Genotoxicity ***Mouse Bone Marrow Micronucleus Assay*** (97G-2367, 97G-2368) (May/1998) ISO 10993-3	Extraction: Cottonseed Oil, 0.9% NaCl Conditions: 37 °C, 72 hours Extraction Ratio: 6cm^2/mL	PATT Neg. Control = Cottonseed Oil Pos. Control = Mitomycin C	**PASS –** Non-mutagenic The test article extract did not induce gene mutations

(00-2092-G2, 00-2093-G2) (July/2000) ISO 10993-3			
Bacteria Reverse Mutation Assay (97G-2365) (December/1997) ISO 10993-3 (99G-0681) (April/1999) ISO 10993-3 (00-2091-G1, 00-2093-G1) (July/2000) ISO 10993-3	Extraction: DMSO, 0.9% NaCl Conditions: 37 °C, 72 hours Extraction Ratio: 6cm^2/mL	PATT Neg. Control = Dimethylsulfoxide (DMSO) Pos. Control = 2-Aminoanthracene, Sodium Azide, 2-Nitrofluorene, 9-Aminoacridine, 1-Ethyl-3-Nitro-1-Nitrosoguanidine (ENNG)	**PASS** – non-mutagenic The test article extract was not considered mutagenic.
Mouse Lymphoma Mutagenesis Assay (00-2093-G3, 00-2092-G3) (July/2000) ISO 10993-3 (97G-2369, 97G-2370) (March/1998) ISO 10993-3	Extraction: Fischer's Cell Culture Medium, Dimethylsulfoxide (DMSO) Conditions: 37 °C, 72 hours Extraction Ratio: 6cm^2/mL Test system: Mouse Lymphoma L5178Y ($TK^{+/-}$) cells	PATT Neg. Control = Fischer's Cell culture medium, or Dimethylsulfoxide (DMSO) Pos. Control = Dimethyl benzanthracene (DMBA), Ethylmethane sulfonate (EMS)	**PASS** – non-mutagenic The test article extract was not considered mutagenic

Local Effects after Implantation ***Intramuscular implantation in rabbits (2 weeks)*** (99-2325-G1, 99-2327-G1) (December/1999) ISO 10993-4 ISO 10993-6 96-0693 (Apr/1996) USP 23, NF 18, 1995 ISO 10993-4 ISO 10993-6 (07-5345-G1) (February/2008) ISO 10993-4 ISO 10993-6 ***(1 week)*** (96-0692) (March/1996) ISO 10993-4 ISO 10993-6	N/A	Four 1 x 1 x 10 mm PATT sections were implanted/rabbit Neg. control = Negative Control Plastic, or Negative Control High Density Polyethylene (1 x 1 x 10 mm sections) were implanted/rabbit Pos. Control: N/A	**PASS** – No adverse effects were observed micro or macroscopically. The test article was a non-irritant. The difference between the average scores for all categories of biological reaction for the test article and control article implants sites were <1, and the difference between mean scores for test article and control article sites was <1.

Subchronic Subcutaneous implantation in rabbits (2 weeks, 1 month, 3 months, 6 months, 12 months) ISO 10993-6	N/A	PATT (92-122 µm thick), PTFE (80-211 µm thick) silicone rubber (85-166 µm thick)	**PASS** – no adverse effects were observed. No evidence of foreign-body tissue response. Inflammation associated with healing was observed at 2 weeks but subsided with minimal fibrosis. Calcification observed at 12-months.
Chronic Subcutaneous Implantation in rabbits (3, 6, 12 months) ISO 10993-6	N/A	PATT (205-282 µm thick), silicone rubber (208-362 µm thick)	**PASS –** no adverse effects were observed. Minimal foreign-body tissue response, with no evidence of inflammation. No evidence of calcification was observed.
Prothrombin Time Assay (99-2326-G1, 99-2327-G4, 99-2325-G4) (October/1999) ISO 10993-4	Extraction: 0.9% NaCl Conditions: 70 °C, 24 hours Extraction Ratio: 6 cm^2/mL	PATT Neg Control = 0.9% NaCl, Negative Control Plastic Pos Control = Oxalic Acid	**PASS** – There was no significant difference in Prothrombin Time relative to the untreated and negative control
Hemolysis – Rabbit Blood (97G-2329) (December/1997) ISO 10993-4 (12T-20497-04) (February/2012) ASTM F756 ISO 10993-4	N/A	PATT Neg. Control = 0.9% NaCl Pos Control = Water for Injection, USP PTAU (PATT+Gold) Neg Control = High density polyethylene (HDPE) Pos Control = Sterile Water for Injection, USP	**PASS –** The test article demonstrated ≤5% hemolysis.

Complement Activation ***SC5b-9 Complement Activation Assay*** (99-2327-G2, 99-2325-G2) (October/1999) ISO 10993-4 (97-G-2371) (January/1998) ISO 10993-4 (12T-20497-06) (February/2012) ISO 10993-4	Extraction: 0.9% NaCl, Normal Human Serum Conditions: 70 °C, 24 hours, 37 °C, 1 hour Extraction Ratio: 6 cm^2/mL	PATT Neg Control = Negative Control Plasma, Untreated Plasma, Low Density Polyethylene Pos. Control = Cellulose Acetate, Cobra Venom Factor	**PASS –** No increased in C3a or SC5b-9was observed when compared to the untreated plasma and the negative control.

Note the chronic duration of the implantation studies with PFA resulted in no evidence of systemic toxicity, minimal foreign-body tissue response, and no evidence of inflammation or calcification.

IV. RESISTANCE TO DEGRADATION

In this section, we would like provide data to demonstrate that fluoropolymers like PTFE do not degrade under relevant environmental conditions.

1. Environmental Fate Testing of PTFE by Charles River Laboratories

The standard environmental fate studies performed on PTFE by Charles River Laboratories demonstrate lack of degradation/transformation to low molecular weight substances, e.g., perfluoroalkyl substances. PTFE does not degrade in oxygen[47], UV light (unaudited preliminary report, OECD 316), water and seawater (OECD 105, 306), or under relevant environmental temperatures (OECD 102, 113). The resistance of PTFE to microbial degradation was already documented in Guidoin et al., 1993 who noted that "PTFE was proven to have sufficient resistance to *in vivo* degradation [...]," (Guidoin et al., 2013). Biotic stability was confirmed by Charles River Laboratories (OECD 301B,302C). Non-biodegradability, inertness, and non-inhibition in activated sludge was also confirmed by Charles River Laboratories (unaudited preliminary report, OECD301F).

2. Data on GORE® TENARA® Sewing Thread

To further support the stability of PTFE, we would like to share simulation of environmental conditions and real-world ageing of our product GORE® TENARA® Sewing Thread.

TENARA® Sewing Thread is made of expanded polytetrafluorethylene (ePTFE) which is used in outdoor, marine, and other applications. The use applications of the product are such that the thread needs to resist UV sunlight, chemicals, saltwater, extreme weather, and acid rain, while allowing it to maintain its strength, flexibility, and appearance for an extended period of time. The information presented below compares these key application properties of PTFE to other materials after long term exposure to outdoor environmental conditions.

a) Simulation of Environmental Conditions

Accelerated weather (UV & Acid Rain) tests on several commercial sewing threads were conducted at Denkendorf Research Institute (Denkendorf, Germany) using the protocol in the following table. The climates of Southern Europe and the Southern United States were simulated via accelerated climate testing. Two simulated weather periods were tested: 9 days (equating to 2-3 years), and 18 days (equating to ~5 years). An acid rain mixture of sulfuric and nitric acids was used at a pH of 2.85. Humidity cycles were 20-100%, while temperature cycles were 0°-80 °C. Ultraviolet light Energy was set at 60 W/m².

[47] Pro-K Fluoropolymergroup, Technical brochure 3.1 Application of PTFE-polymers in oxygen systems, Sept. 2020, available at https://www.pro-kunststoff.de/assets/Merkbl%C3%A4tter%20und%20Co/TM%203.1%20Application%20of%20PTFE-polymers%20in%20oxygen%20systems.pdf.

The performance of the thread after cycles was determined through the following tests:

- Stress-Strain DIN EN ISO 2062
  Gauge Length: 250mm
  Crosshead Speed: 250mm/min
  Pretension: 0.5 cN/tex
- Titer DIN EN ISO 2060
- Number N at least 3 per condition

Stress-strain measures mechanical strength of the yarn. Titer is density (mass per unit length). Titer is needed to calculate tenacity, breaking force divided by the liner density, i.e., a strength measurement normalized for size. Elongation at yield and elongation at break are direct out puts from stress strain testing with tenacity, a calculated output

The materials tested were: GORE® TENARA® Sewing Thread M1000 KTR, GORE® TENARA® Sewing Thread M1000 TR- white, GORE® TENARA® Sewing Thread M1000 TR- black, Dabond® V92 polyester multifilament bonded natural white made from polyester, and NOMEX® NC- Tech 34 filament raw white made from M-aramid. The results of these tests which are presented in Figures 1 to 4 below demonstrate that PTFE thread performance in strength (tenacity) and elongation was unaffected by exposure to simulated environmental conditions. This confirms that the polymer did not degrade.

- **Figure 1** GORE® TENARA® Sewing Thread – shows retention of Tenacity after simulated UV & Acid Rain Exposure
- **Figure 2** Compares retention of Tenacity of GORE® TENARA® Sewing Thread with a NOMEX® NC- Tech 34 and Dabond® V92 polyester
- **Figure 3** Compares retention of Elongation at Yield of GORE® TENARA® Sewing Thread with a NOMEX® NC- Tech 34 and Dabond® V92 polyester
- **Figure 4** Compares retention of Elongation at Break of GORE® TENARA® Sewing Thread with a NOMEX® NC- Tech 34 and Dabond® V92 polyester

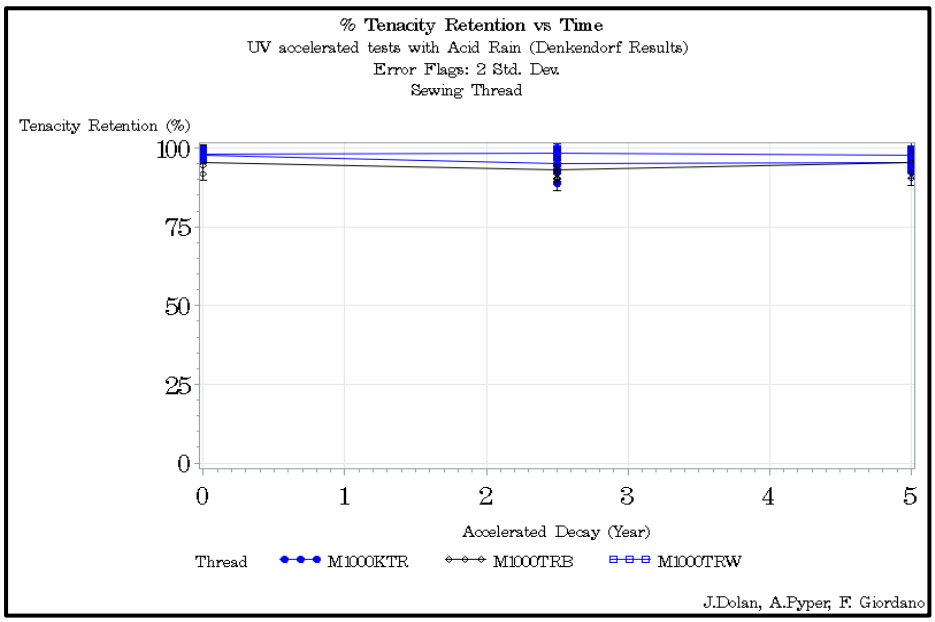

Figure 1 GORE® TENARA® Sewing Thread - Retention of Tenacity of UV & Acid Rain Exposure

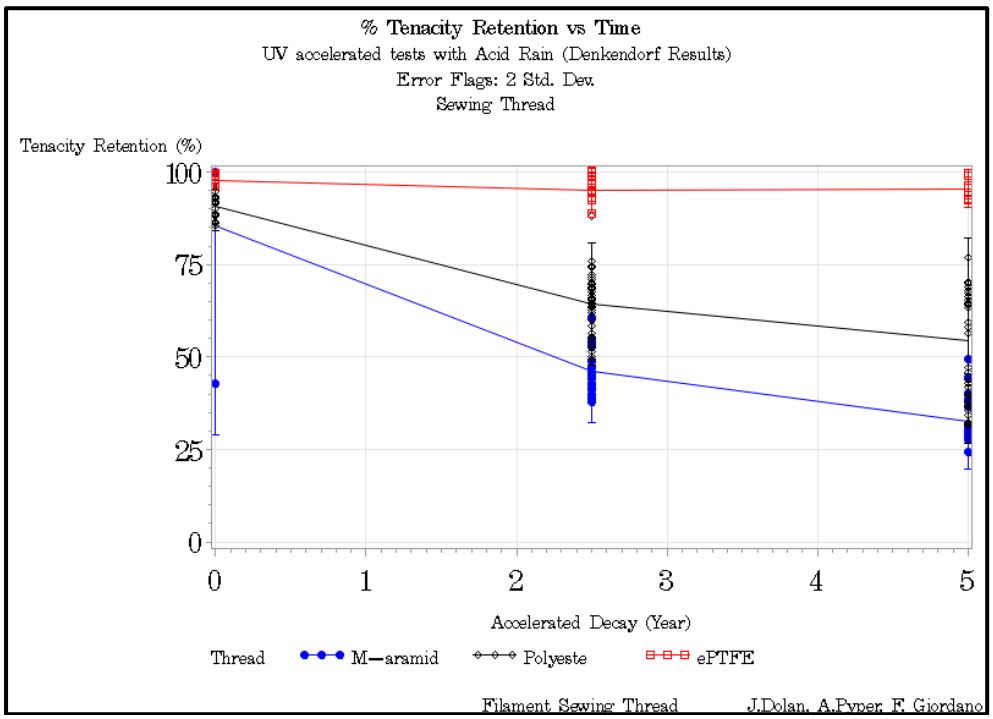

Figure 2 Retention of Tenacity: NOMEX® NC Tech 34 sewing thread, Polyester DABOND® V92 natural sewing thread, GORE® TENARA® Sewing Thread M1000KTR

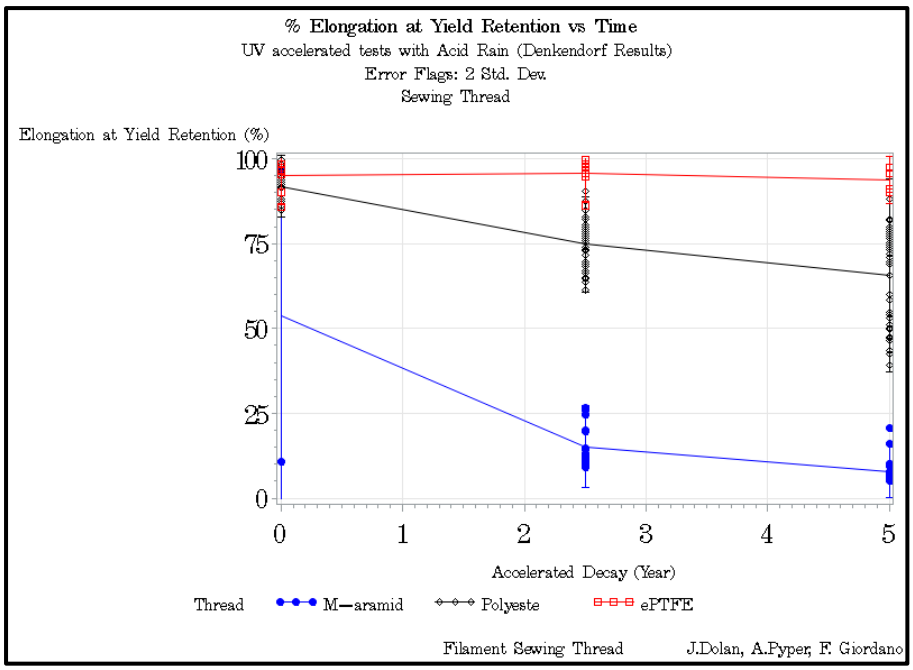

Figure 3 Retention of Elongation at Yield: NOMEX® NC Tech 34 sewing thread, Polyester DABOND® V92 natural sewing thread, GORE® TENARA® Sewing Thread M1000KTR

Elongation at yield is another output of stress strain testing (along with break strength). Tenacity (breaking force of yarn divided by linear density) is a calculated output and is a standard way of measuring strength of textile products such as yarn.

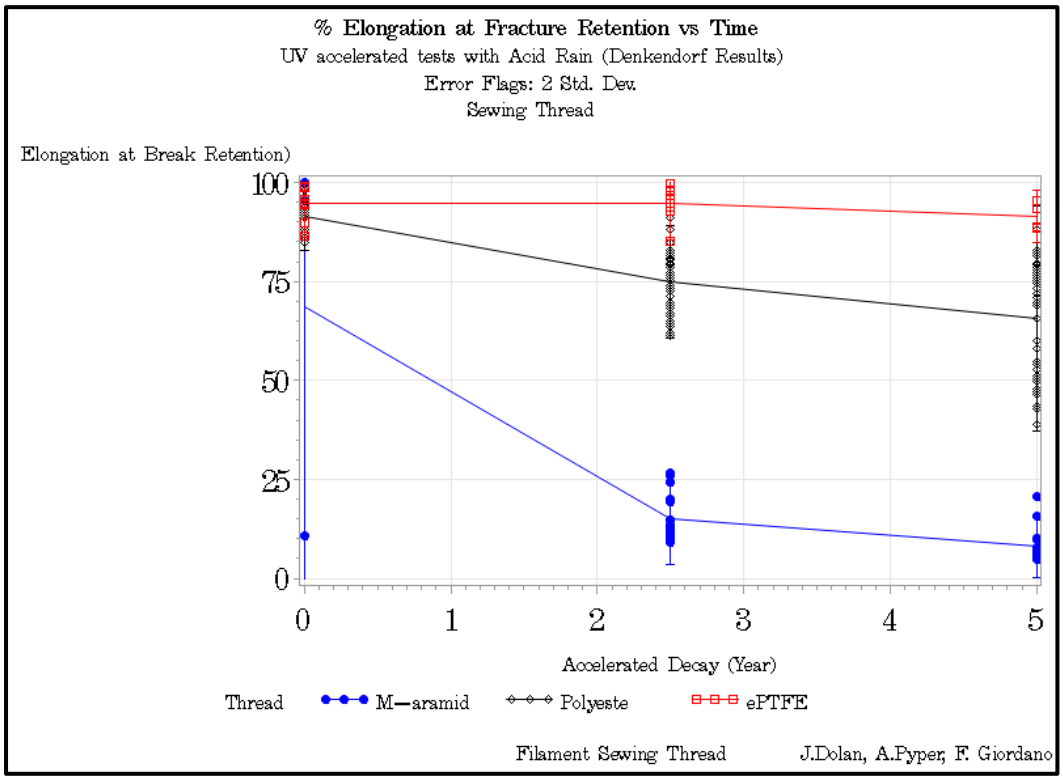

Figure 4 Retention of Elongation at Break: NOMEX® NC Tech 34 sewing thread, Polyester DABOND® V92 natural sewing thread, GORE® TENARA® Sewing Thread M1000KTR

b) Real-World Aging

The break strength of polyester (DACRON® thread) and natural/synthetic threads such as Eddcore thread made from cotton/polyester is reduced over time when exposed to sunlight and environmental elements such as rain, humidity as well as warm/cold temperature fluctuations. In particular, photons in sunlight break the bonds of the molecular chains resulting in the reduction of the thread's break strength. As sunlight duration increases, the loss of the thread's break strength increases.

Expanded polytetrafluorethylene (ePTFE) which is chemically the same as PTFE and has been mechanically expanded to increase porosity and strength, is not affected by photon damage therefore the break strength of an ePTFE thread is not compromised.

Figure 5 is a graph showing break strength retention of the three different threads that had been exposed to natural sunlight and environmental elements (›900 days) in Phoenix, Arizona. The results from the thread consisting of expanded polytetrafluorethylene, TENARA® Sewing Thread, maintained its break strength over a duration of ›1250 days, indicating the polymer was not degraded by sunlight, rain, humidity, warm/cold temperature exposure confirming the polymer did not degrade.

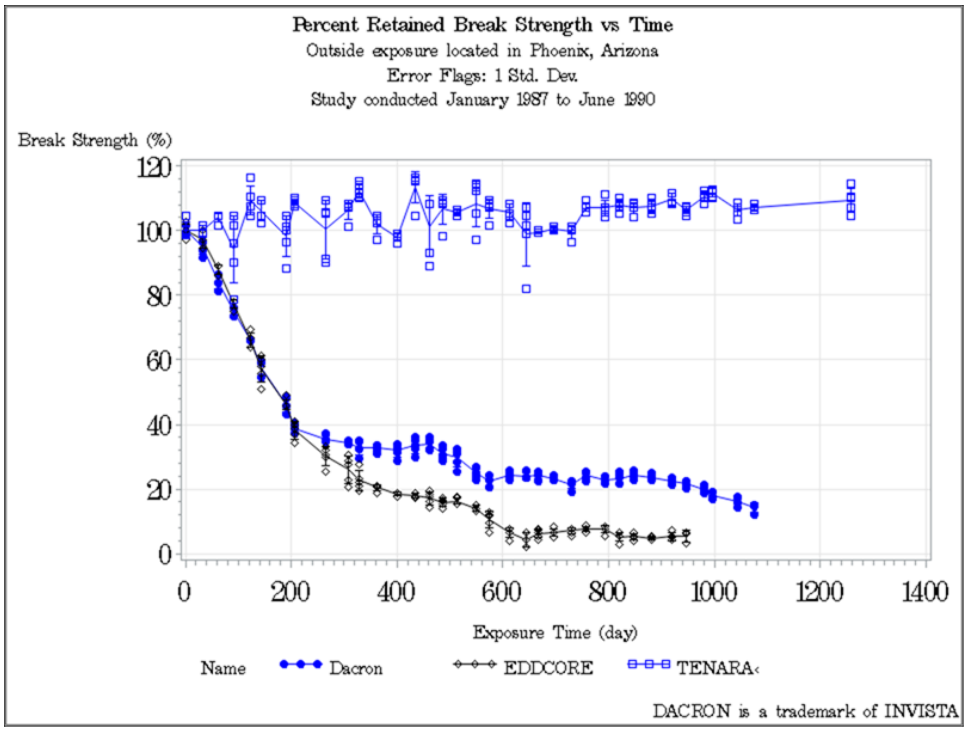

Figure 5 Break Strength Retention over Natural Sunlight & Environmental Exposure (Note: GORE® TENARA® Sewing Thread is a trademark of W. L. GORE & Associates)

The equation to calculate Break Strength Retention percent is:
$Break\ Strength\ Retention\% = 100*(Break\_Strength_{Non\ Exposed} - Break\_Strength_{Exposed}) / (Break\_Strength_{Non\ Exposed}$

The following real-world tests were performed in Phoenix, AZ (-112.01° Longitude, 33.43° Latitude) from January 1987 through June 1990. This test lasted 1,556 days. The humidity cycle was 16-45%. The temperature cycle was 7°-40° C. The ratio of sunlight to darkness was 44%. Threads were subjected to tensile tests for break strength and elongation% to failure. See Figures 6, 7, and 8.

Similar to lab testing, PTFE thread properties were demonstrated to be unaffected by exposure to challenging environmental conditions. In contrast, other polymers were significantly degraded under relevant environmental conditions. Additional data and analyses can be found in the submission made to the fire-fighting foam restriction process in 2022 (see Annex VI).

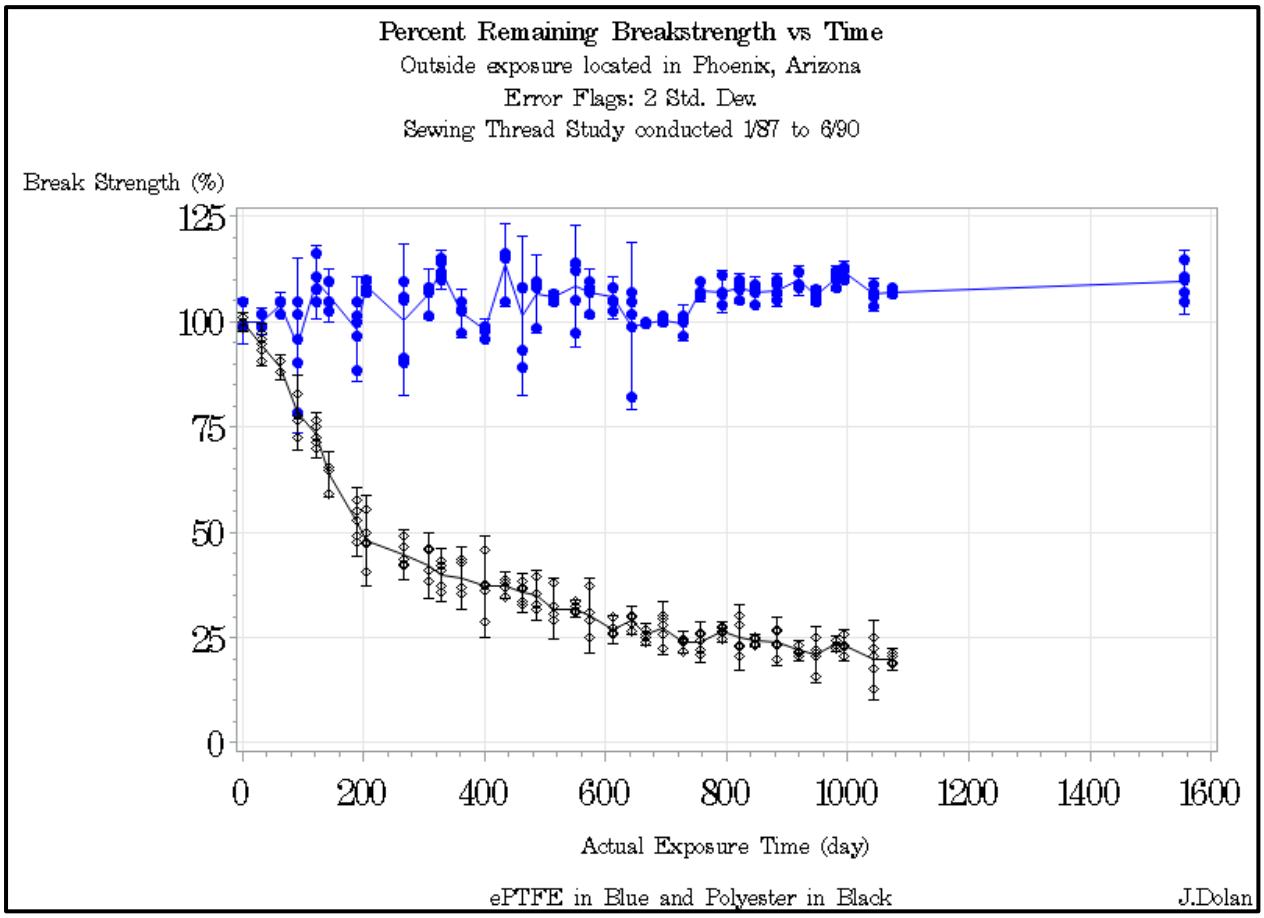

Figure 6 Retention% of Break- strength: Polyester DABOND® V92 natural sewing thread, GORE® TENARA® Sewing Thread M1000

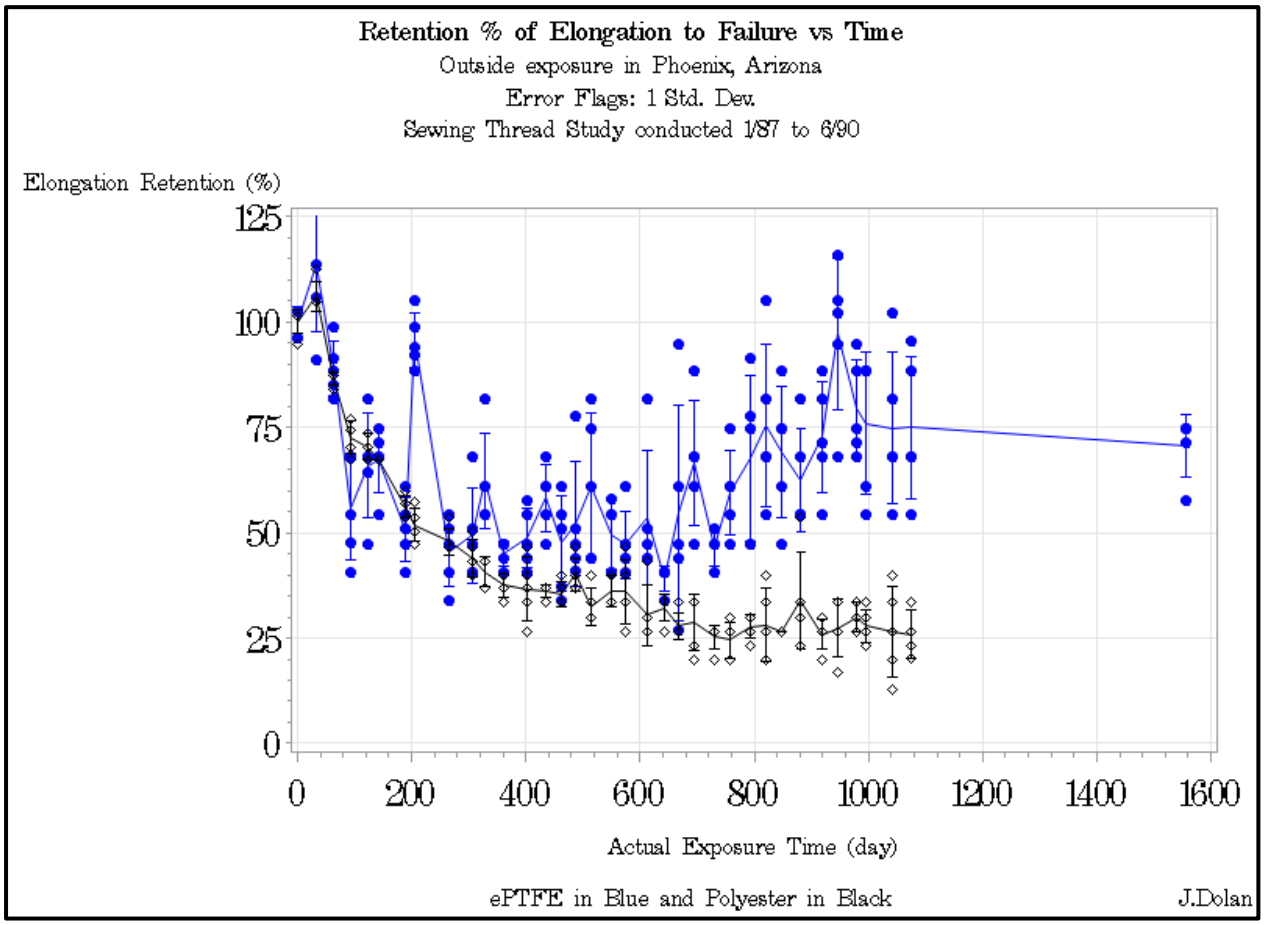

Figure 7 Retention% of Elongation to Break: Polyester DABOND® V92 natural sewing thread, GORE® TENARA® Sewing Thread M1000

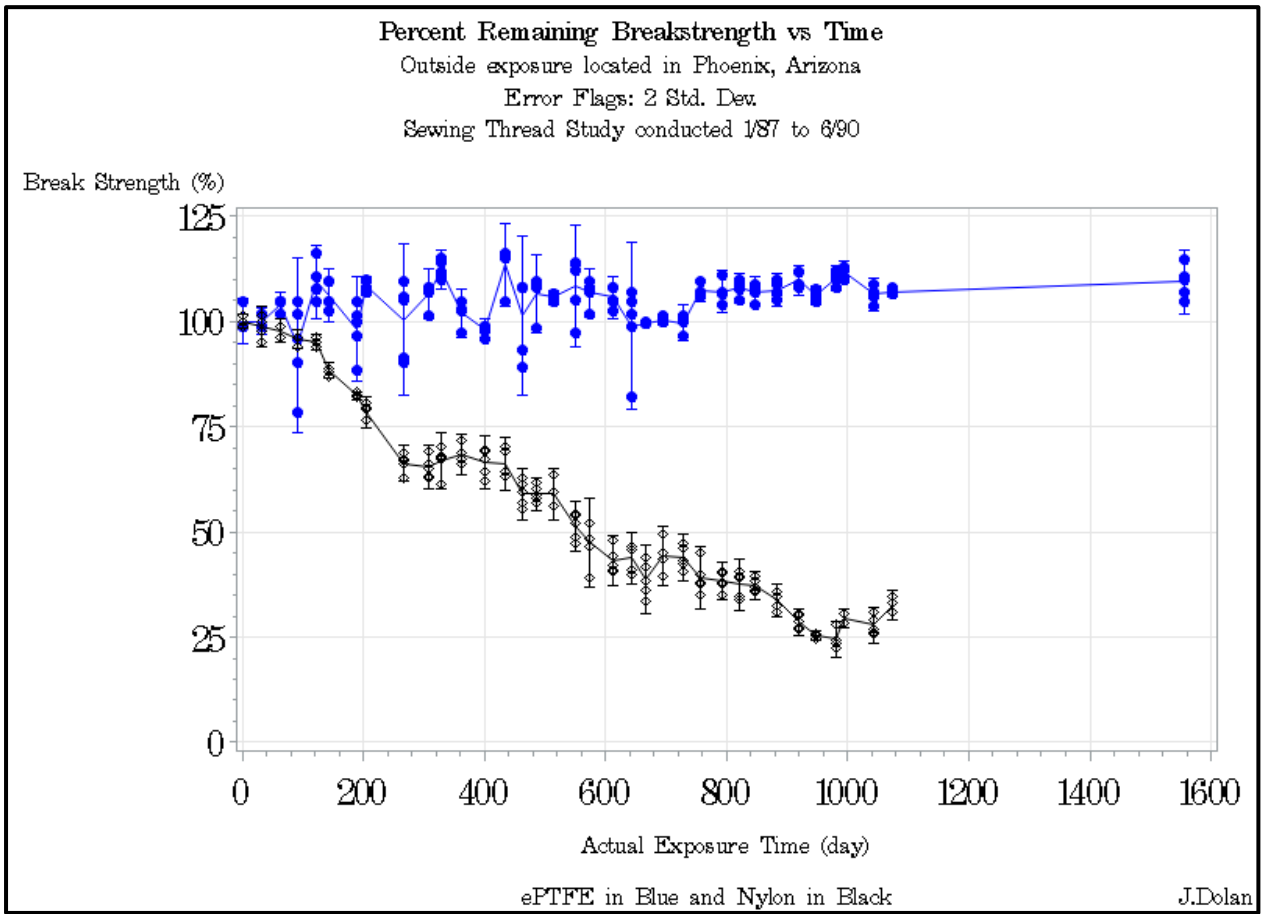

Figure 8 Retention% of Break- strength: Nylon BTS bonded, 1500 D sewing thread, GORE® TENARA® Sewing Thread M1000

Annex III – Overview of technically demanding applications where Gore intends to submit derogation requests

- Medical Devices
- Professional Apparel
- Aerospace and Defence Applications
- Semiconductor Manufacturing
- Chemical Manufacturing
- PEM Fuel Cells and PEM Electrolysers
- Specialty Wires and Cables
- Petroleum and Mining Industry
- Pollution Control and Dust Collection
- Heat Exchange Laminates
- Membranes Used for Venting of Medical Devices
- Products Used for the Processing and Delivery of Human and Veterinary Medicinal Products
- Technical Textiles
- Ingress Protection Vents for Vehicles and Vehicle Components
- Packaging Vents Used in Transport and Storage of Decomposing Chemicals
- Ingress Protection Vents for Communication Devices
- Ingress Protection Vents for Outdoor Electronic Applications
- Gas and Physical Sensors
- Battery Applications

Annex IV – Information on Gore's small-scale Polymerization Facility in Burgkirchen, Germany

I. OVERVIEW OF EMISSION CONTROL TECHNOLOGIES

Gore's site is equipped with state-of-the-art environmental controls including:

- Capture and recycling of monomers.
- A regenerative thermal oxidizer (RTO) with a caustic scrubber for air emissions.
- Activated carbon adsorption beds to treat water effluent.

II. MONITORING

Wastewater samples are collected and analyzed for traces of the used polymer processing aid daily in the on-site laboratory and a bi-weekly report is sent to the chemical park central wastewater treatment plant and to the local authorities.

In addition, the permit requires testing of the exhaust air and the soil to verify capture efficiency with regard to the processing aid.

III. OVERVIEW OF WORST-CASE EMISSION OF POLYMER PROCESSING AID

A summary of the annual emissions of the polymer processing aid of Gore fluoropolymer manufacturing facility in 2022 is shown in the Table below. **These emissions reflect worst-case scenario emissions calculated by Gore.** Monitoring of on-site emissions are often below analytical detection limits; the worst-case scenario emissions as used here represents a conservative estimation based on an assumption that emissions are just below detection limit. **Actual emissions of the polymer processing aid are expected to be significantly lower**. Additionally, further water treatment is carried out in the central wastewater treatment plant of the chemical park where the manufacturing site of Gore is located, which has not been accounted for in the emission estimates.

Worst-case annual emissions of fluorinated substances from Gore's fluoropolymer manufacturing facility in 2022	**Volume (tonnes)– worst-case**	**Control Device**	**Monitoring**
Air	‹ 0.0005	RTO, Scrubber	Temperature > 1000 °C
Water	‹ 0.00095	Activated carbon filters & site wastewater plant	Routine lab analysis
Annual total	**‹ 0.001**	-	-

Notes: Volumes given in tonnes and rounded to the first significant decimal. Total may therefore not sum up.

IV. WASTE HANDLING

The spent activated carbon beds are collected and thermally treated in a certified facility to regenerate the media. The facility continuously performs air monitoring with specialized maintenance restart leak testing, pursuant to a documented leak detection program.

The fluoropolymer scrap materials are shipped for thermal destruction at a certified treatment facility.

Annex V – Results of PFAS Measured: Incineration of PTFE and Wood (Paired t-testing)

Table 3
Results of all PFAS measured (ng/m3) and *P*-values for statistical comparison.

Abbrev.	Setting S1 (870 °C & 4 s)										
	Pair 1		Pair 2		Pair 3		Pair 4		Pair 5		p - value
	Control	0.3% PTFE	Control	0.3% PTFE	Control	0.3% PTFE	Control	0.3% PTFE	Control	0.3% PTFE	
PFHxA [PFC C6]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	163[b]	< LOQ	< LOQ
PFHpA [PFC C7]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	153[b]	156[b]	< LOQ
PFOA [PFC C8]	189[a]	194[c]	169[c]	179[c]	232[a]	302[c]	270[a]	354[c]	723[c]	184[a]	0.564
PFNA [PFC C9]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
PFDA [PFC C10]	< LOQ	128[a]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	153[b]	< LOQ	< LOQ
PFUdA [PFC C11]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	152[b]	< LOQ	< LOQ
PFDoA [PFC C12]	< LOQ	124[c]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	152[b]	< LOQ	< LOQ
PFTrDA [PFC C13]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
PFTeDA [PFC C14]	< LOQ	102[b]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	154[b]	< LOQ	< LOQ
PFBS [PFS C4]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
N-Me-FOSE alcohol	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ

Abbrev.	Setting S2 (1020 °C & 2.7 s)											
	Pair 6		Pair 7		Pair 8		Pair 9		Pair 10		Pair 11		p - value
	Control	0.3% PTFE	Control	0.3% PTFE	Control	0.3% PTFE	Control	0.3% PTFE	Control	0.3% PTFE	Control	0.3% PTFE	
PFHxA [PFC C6]	154[b]	< LOQ	< LOQ	136[b]	< LOQ	< LOQ	138[a]	< LOQ	< LOQ	< LOQ	118[b]	< LOQ	0.368
PFHpA [PFC C7]	< LOQ	< LOQ	< LOQ	135[b]	< LOQ	< LOQ	138[b]	< LOQ	< LOQ	< LOQ	116[b]	< LOQ	0.424
PFOA [PFC C8]	258[c]	189[c]	< LOQ	644[c]	< LOQ	137[b]	2743[c]	143[b]	143[b]	175[c]	413[c]	141[b]	0.407
PFNA [PFC C9]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	128[b]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
PFDA [PFC C10]	< LOQ	145[b]	< LOQ	133[b]	< LOQ	< LOQ	130[b]	< LOQ	< LOQ	< LOQ	117[b]	< LOQ	0.536
PFUdA [PFC C11]	< LOQ	< LOQ	< LOQ	133[b]	< LOQ	< LOQ	128[b]	< LOQ	< LOQ	< LOQ	115[b]	< LOQ	0.571
PFDoA [PFC C12]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	128[b]	< LOQ	< LOQ	< LOQ	115[b]	< LOQ	< LOQ
PFTrDA [PFC C13]	< LOQ	< LOQ	< LOQ	134[b]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
PFTeDA [PFC C14]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	131[b]	< LOQ	< LOQ	< LOQ	115[b]	< LOQ	< LOQ
PFBS [PFS C4]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	141[b]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ
N-Me-FOSE alcohol	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	136[b]	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	140[b]	< LOQ

[a] Only found in MeOH, all other concentrations were assumed as 1/2 LOQ.
[b] Only found on Filter, all other concentrations were assumed as 1/2 LOQ.
[c] Only found in MeOH & on Filter, all other concentrations were assumed as 1/2 LOQ.

Annex VI – Reference Number of submission to PFAS in Fire Fighting Foams Restriction Process

W. L. Gore GmbH has submitted hazards data on a set of fluoropolymers as part of the restriction process on PFAS in firefighting foams

Due to the file size limitation (20MB), documents had to be submitted through another file sharing and in batches. Gore believes the batches have been collected together for analysis. We list below the submission reference number and the date of each batch below to help retrieve those documents:

- 0da1b4d6-ff38-48db-abb8-daa7272aba92 (11.10.2022)
- f7aaf9e2-b710-4147-8824-68eb9b8d1fea (11.10.2022)
- 0b657618-993a-4fa2-8957-f3d477553a25 (11.10.2022)
- fbc86444-23a2-4c0c-ac0e-572502b2ddfc (11.10.2022)
- 667b597b-ca23-409d-b080-a56d54991c69 (11.10.2022)
- 4387a1bf-0535-4553-80cc-c87f2799d328 (11.10.2022)
- c9894726-45be-4048-82ee-b3955bcae4bc (11.10.2022)
- a0386a43-432e-4abd-9a6b-639023146980 (11.10.2022)
- 30682982-3a26-4fc3-bc11-285322004444 (11.10.2022)
- 32ba7e12-cb62-4418-951a-e4d0b2d53747 (20.10.2022)
- 6f025cfd-2156-4f57-a526-578a9bca8fda (20.10.2022)
- d2edbba2-999b-4c85-a6e8-758d597f0313 (20.10.2022)
- 758a2012-3659-418b-aa53-a1b82b518d91 (20.10.2022)
- 965759e2-4d7c-4672-9cc0-0f2a441e036e (20.10.2022)
- 08cf87e4-c1e3-4e1b-bc0d-88697ddfb612 (20.10.2022)
- e3a8c695-bc73-439e-b1cd-803594d344b4 (17.11.2022)

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NON-CONFIDENTIAL ATTACHMENT – pdfs of all references and reports are available on request.

W. L. Gore & Associates' Comments on Dossier Submitters' Draft EU REACH restriction on PFAS

Public consultation

Request for Derogation: Aerospace and Defence

July 2023

Gore appreciates the opportunity offered by the public consultation process to provide comments on the Proposal for a Restriction of Per- and polyfluoroalkyl substances (PFAS) (hereinafter "Restriction Proposal").

With this statement, we would like to explain why we believe that a derogation for aerospace and defence (hereinafter "A&D") – which as such is not covered in its entirety by the derogations in the Restriction Proposal – is needed and justified. Further, we would like to explain why this derogation should be time unlimited.

The conclusions from our submission are summarised as follows:

- It would be beneficial and justified to capture all uses of PFAS within the A&D sector under one derogation.
- It is vital to consider future A&D requirements that cannot be achieved without PFAS (e.g., higher voltages, increased electrical current, faster data rates, and improved sealing which enable miniaturization, weight reduction, and fuel efficiency in conventional and increasingly electrified aircraft).
- Material property screening of potential alternative materials as well as direct experimentation to evaluate alternatives have demonstrated that no alternative is currently able to meet required performance that would allow replacement of fluoropolymers in sealants, cables, and capacitors for aerospace and defence applications.
- It is unlikely that feasible alternatives will be found in the foreseeable future and using alternatives that do not meet the performance requirements to the same degree as PFAS is not an option in the A&D sector due to system performance, reliability, and safety concerns.
- Gore believes that the A&D supply chain are united in seeing the benefits of the combination of properties delivered by fluoropolymers to certify and sustain the safety of interdependent and interconnected systems that cannot be replaced for existing aircraft and defence systems.

I. Derogation Request

Considering the arguments and evidence presented below, Gore respectfully requests to include the following sector-specific derogation for aerospace and defence in Column 2, paragraph 6 of the proposed restriction:

Aerospace and defence

II. Description of the End Use

1. Selected Aerospace and Defence Applications

Aerospace and defence applications are varied, complex and often have some of the most demanding standards for performance, operating conditions, and reliability in equipment and vehicles. Within the vast array of critical Aerospace and Defence applications, Gore manufactures products for selected end uses. We are providing information on those uses well-known to us: Sealants, Cables & Cable Assemblies, and Capacitors. End uses include, but are not limited to, application in satellites, space exploration vehicles, civil and military aircrafts. They are presented to aid understanding of possible applications of PFAS (in our case mostly fluoropolymers) within the A&D sector but are not intended to present an exhaustive list of possible products/ applications of PFAS within that sector.

a. Sealants

Sealants are used to seal airframes, panels, and other structures both in civil and military aircraft. Aerospace sealants have a significant impact on airframe functionality, operational performance, and maintainability. Airframes that aren't properly sealed and protected can become damaged over time from mechanical forces and harsh contaminants — ultimately leading to more maintenance. Tapes and gaskets increase aircraft surface life because they effectively protect aircraft panels from vibration, corrosion, aggressive fluids, and more. Equipment manufacturers specify dry, lightweight sealants because they simplify aircraft assembly, increase manufacturing throughput, improve safety, and reduce lifecycle costs.

b. Cables & Cable Assemblies

Cables provide a nervous system-like network of reliable signal transmission within aircrafts to control communications, safety, and mission critical systems, such as flight controls, radar, and aircraft survivability equipment. A single aircraft, satellite, or vehicle will have numerous cables and cable assemblies, each with unique performance requirements based on its specific use in a complex system.

c. Capacitors

Capacitors are critical components needed to stabilize power supply in an aircraft to drive both auxiliary system power and flight control systems. The trend towards electrification of aircraft is further increasing performance requirements and expected operating temperatures.

2. Product Examples

Detailed descriptions of the type of products and their reliance on PFAS is provided below. The product examples are all Gore products, as details of comparable products manufactured by other companies are not publicly available. We believe that these products are representative of products manufactured and placed on the EU market by

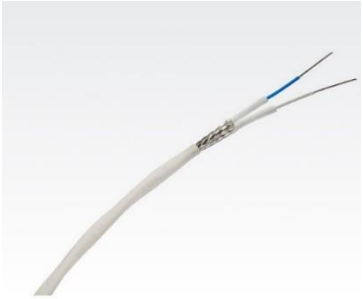
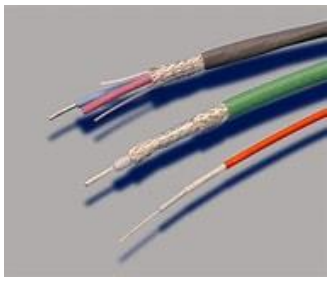
other companies but are not intended to present an exhaustive list of possible products/applications of PFAS within the A&D sector.

Based on the current proposal, only a few applications in Table 1 below might be provided with a derogation[1]; however, these products all require a derogation to ensure continued reliability of critical vehicles and equipment in the A&D sector:

Table 1. Selected Aerospace and Defence Products

Product	Illustrations	Description	
Gore® Skyflex® Aerospace Materials		Gaskets and sealants are used in aircraft structures to seal panels and protect surfaces mechanical forces and harsh environments that can severely damage aircraft structure. They protect against ingress or leak of fluids, minimise corrosion, reduce the impact of abrasion, and fill gaps. The materials make aircraft maintenance faster and simpler because they are lightweight, do not need to be cured, and are flexible to conform to any shape.	
Gore® Aerospace Data and Power Cables		Cables used in aircraft systems to deliver high quality signals even in demanding conditions[2].	
		Data cables	Compact, flexible, and routable cables designed to significantly improve system performance in an aircraft[3]. Fibre optic and copper high speed data cables transmit MIL-STD-1553, ethernet, CANBus, FibreChannel, IEEE-1394b, MIL-STD-1760, discrete signals, and other protocols to operate critical flight control systems, passenger support system, and mission systems equipment in Civil and Defence Aircrafts. Data cables provide a nervous system-like network of reliable signal transmission needed to protect soldiers and aircraft with fully functional and finely tuned aircraft

[1] Some applications might fall under the paragraph 60: "applications affecting the proper functioning related to the safety of transport vehicles, and affecting the safety of operators, passengers or goods until 13.5 years after EiF". As this derogation is for reconsideration and it is unclear how safety is defined in this context, we suggest a derogation for aerospace and defence.
[2] Gore (2021) GORE® Aerospace High Speed Data Cables. Accessed: 28/09/2021. Available at: https://www.gore.com/resources/aerospace-high-speed-data-cables-catalog
[3] Gore (2021) GORE® Aerospace High Speed Data Cables. Accessed: 28/09/2021. Available at: https://www.gore.com/hdraircraftcables

			survivability equipment and electronic countermeasures.
		Power cables	Used to power generators, operate flight controls, and support mission systems. Mission systems include radar and Aircraft Survivability Equipment such as Missile Warning Systems and Threat Jamming Equipment in Defence applications.
Gore® Microwave / RF Assemblies[4]		Used to transmit and receive analog radio frequency (RF) signals to maintain communications, operate radar, test mission systems, and feed Aircraft Survivability Equipment such as Missile Warning Systems and Threat Jamming Equipment in Aircraft and other Defence equipment. This product category also includes Microwave Cable Assemblies. With respect to modern electronic warfare (EW), defence forces must be able to promptly and accurately detect enemies and take appropriate actions before enemies do. Advanced radar technologies rely on microwave cables to enable this early detection capability.	
Gore® Space Cables and Assemblies.		Same properties as Aerospace Data and Power Cables and Microwave / RF Assemblies but designed to survive the harsh radiation, extreme temperatures, and vacuum of space.	
GORE™ High Temperature Capacitors		Capacitors deliver stable voltage and capacitance at elevated temperatures. Key performance characteristics include reliable self-clearing, low dissipation factor, and thermo-mechanical stability. This enables significant design advantages in the Aerospace industry to improve power density in line with the Electrification megatrend to reduce global emissions.	

[4] This product is also used in the electronics and telecommunications industry.

All of the PFAS used in these products are fluoropolymers which meet the criteria for Polymers of Low Concern (PLCs), under the definition provided by the OECD Expert Group on Polymers. The PFAS used for each product are shown in Table 2.

Table 2. PFAS used in Aerospace and Defence Products

Product	Type of PFAS	CAS	Is this PFAS a PLC
GORE® SKYFLEX® Aerospace Materials	PTFE	9002-84-0	Yes
GORE® Aerospace Data and Power Cables	PTFE	9002-84-0	Yes
	FEP	25067-11-2	Yes
Gore® Microwave / RF Assemblies	PTFE	9002-84-0	Yes
	PFA	26655-00-5	Yes
	FEP	25067-11-2	Yes
	ETFE	25038-71-5	Yes
Gore® Space Cables and Assemblies	PTFE	9002-84-0	Yes
	ETFE	25038-71-5	Yes
GORE™ High Temperature Capacitors	PTFE	9002-84-0	Yes
	ETFE	25038-71-5	Yes

III. Reference in Restriction Proposal

1. *Specific A&D needs are not addressed in the Restriction Proposal*

A&D applications are not discussed as a separate sector/use within the Restriction Proposal. The A&D sector relies on a broad range of PFAS applications covering, among many others, electronic components (such as cables and wires or capacitors) and sealants.

Various applications, also relevant to A&D, are described under transportation (E.2.10.) and electronics sections (E.2.11.) but those sections give very limited considerations to the specific needs of A&D.

Gore welcomes that the important function fulfilled by fluoropolymers used in transport (including aerospace) is recognised by the Dossier Submitters. A derogation for

'applications affecting the proper functioning related to the safety of transport vehicles, and affecting the safety of operators, passengers or goods until 13.5 years after EiF' have been proposed for reconsideration (Restriction report, RO2, paragraph 6o, page 8). We believe, however, that it is not sufficiently clear what type of specific applications would be covered, and whether it would cover military and space exploration applications at all.

For instance, the Restriction Proposal discusses mobile air conditioning (MAC) and refrigeration in military applications. It does not, however, recognize other essential applications of fluoropolymers such as sealants, wires and cables, or capacitors used in the defence sector on which we will elaborate in further sections of this document.

We welcome that the Dossier Submitters recognized the difference and more complex nature of military applications compared to civilian applications, namely the need to meet additional and more stringent performance criteria and the need to use equipment in hostile environments (Annex E, page 359-360). We believe the recognized difference also applies to other fluoropolymers applications within the defence sector, that has not been explicitly mentioned.

Also, it is recognized in the Restriction Proposal that aerospace standards require much longer approval-time and any new product introduction must consider separate quality management systems (*regulated under FIA and must confirm to ISOAS9100 and NADCAP systems*- see Annex E, page 354).

It would be beneficial and justified to capture all uses of PFAS within the A&D sector under one derogation. In the case of A&D, the need for a derogation is driven by the more complex and demanding performance and safety requirements of that sector.

2. *Assessment of alternatives has not considered the specific performance requirements of A&D*

Information on alternatives that may be relevant to PFAS applications within A&D are fragmented across transportation (E.2.10.) and electronics sections (E.2.11.).

Dossier Submitters recognized that in the area of electronics they '*received limited information on alternatives, however, does not fully understand whether these alternatives have the potential to be used broadly or can only be utilized in niche applications'* (Annex E, page 401).

Dossier Submitters recognized that *any alternatives to fluorinated polymers for sealing applications in transportation vehicles need to meet various requirements. They need to have a durability against lubricants, fuels, diesel, cooling agents and/or other fluids and have to provide good sealing properties over wide range of temperatures* (Annex E, page 351).

The feasibility of an alternative in specific applications (whether it is a cable or sealant) is critically dependent on its sector of use. We welcome the fact that the Restriction Proposal elaborates about alternatives available for cables and wires and sealants, but we would like

to point out and demonstrate in the following sections that they are not suitable and would lead to severe risks when applied in the A&D sector.

The Restriction Proposal understandably focuses on current applications of PFAS and often assesses whether there are working alternatives on the market, or promising alternatives in the innovation pipeline, that could replace those current uses. The Restriction Proposal introduced three possible timeline options that apply without discrimination to every end use sector. Those timelines are:

- Ban 18 months after EiF
- Ban 6.5 years after EiF
- Ban 13.5 years after EiF

However, when it comes to sectors of strategic importance like A&D, taking away a possibility to innovate with such unique and beneficial materials as fluoropolymers, eventually could lead to impairing the EU A&D industry.

It is vital to consider future A&D requirements (e.g., high voltages to facilitate further miniaturization, increasing current generating heat, more electric aircraft) when assessing suitability of alternatives.

IV. Need and Justification for a Derogation

A time unlimited derogation for Aerospace and Defence is needed and justified. Without a derogation, risk to passengers, aerospace staff and military personnel will increase as a result of the use of materials that cannot provide sufficient performance. Gore does not exclude the possibility of finding a breakthrough material that could display the properties and performances needed for those applications; however, no material that could replace fluoropolymers is in sight. Additionally, putting a time-bound restriction on the use of fluoropolymers in the A&D sector, without considering both current and future needs of that sector, also risks endangering EU market competitiveness and security. We propose that a derogation is justified based on the following points:

- The **performance requirements** for Aerospace and Defence applications.
- The **lack of availability of alternatives** that would provide the required level of performance.
- The **time required** for research and development to investigate and evaluate potential alternative materials, and if a feasible alternative is identified, the time required to identify, develop, test, and commercialize new A&D products.
- The **large socio-economic cost** of restricting the use.

1. Summary of Performance Requirements and Assessment of Alternatives

In September 2022, we provided a Use Assessment prepared by Eftec. The Use Assessment has been submitted to all 5 Dossier Submitters. Since this information was provided after the end of the Call for Evidence in September 2021, the Use Assessment is included as Attachment 3 listed in Annex II to this derogation request[5].

To make the information more easily available and to consider the information provided in the Restriction Proposal, we have summarized information on alternatives in Annex I to this document which also contains updated and supplementary information obtained after the Use Assessment was submitted. The information on alternatives is provided at a product type level, referring to the products described in the Section II above.

Below, we summarize the conclusions from Annex I for the three product areas in focus for this derogation request: Sealants, Cables & Cable Assemblies, and Capacitors

a) Sealants

i) Summary of Performance Requirements

Performance requirements include both physical and chemical properties. Sealants must demonstrate:

- Mechanical properties include strength, density, width, flexibility at low temperatures, and stability under storage conditions to be able to maintain a reliable seal between equipment and vehicle parts subject to mechanical stresses and vibration.
- Thermal stability across an extremely broad range of temperature conditions. For example, aircraft are subject to high temperatures when parked in hot environments and quickly travel to extreme altitudes where temperatures are quite low. Materials need to remain stable at conditions outlined by an external standard (AMS3255).
- Chemical resistance due to exposure to common aircraft fluids
- UV resistance due to environmental exposure
- Passing flammability requirements from industry standards
- Ability to be installed safely and reliably

ii) Why Fluoropolymers are used in Sealants

Fluoropolymer-based sealants demonstrate exceptional chemical, temperature, and UV resistance while maintaining sufficient mechanical strength. All assessed alternatives lead to significant disadvantages when compared to expanded PTFE sealants. Researched and tested sealants alternatives have reduced durability and longer maintenance time/increased downtime which could cause reduced aircraft availability. The most

[5] Since the UA has been created, we have also obtained additional information on use of fluoropolymers in capacitors.

common alternatives also lead to increased waste generation due to their shorter shelf life and non-reusability.

iii) Summary of Alternatives in Sealants

Polysulfide

Beside curing process difficulties[6] in comparison to PTFE and additional installation time, polysulfide sealants are not chemically resistant to technical fluids used in commercial aircraft (like LD-4 Hydraulic Fluid). They will also add weight to aircraft, and they are classified as Volatile Organic Compounds. Some polysulfides are classified as carcinogenic Cat.2 and STOT RE Cat.2 as well as Acute and Chronic Aquatic Toxicity Cat.1.[7]

Nitrile Rubber

Sealants made of nitrile rubber show limitations due to aging, especially under UV exposure which makes this material brittle, easy to break, and reduces its reusability. More frequent failures and increased waste have caused downstream users to request the change to PTFE sealants.

Polyurethane (PU) gel tape

PU sealants are not dimensionally stable under a mechanical load, leading to less reliable seals, replacement, and substantial waste. They are also higher weight than PTFE materials, resulting in higher fuel consumption and CO_2 emissions.

Silicone foams

Silicone foam material can tear and crack easily (leading to premature product failure and increased waste) and is susceptible to degradation from contact with fuel and hydraulic fluids.

A visual comparison of alternatives is shown in Table 3 below:

[6] Curing process susceptible to humidity and limited in time which makes it difficult to automate. Those points are explained further in Annex I

[7] See SDS in attachment 5

Table 3. Comparison of Alternative Materials for Sealant Applications in A&D

PTFE Sealants	Polysulfide Wet Sealants	Polyurethane Tapes	Gel Tapes
✓ Provides surface protection (abrasion, corrosion, vibration, anti-chafe)	△ Provides surface protection (abrasion, corrosion, vibration, anti-chafe)	✓ Provides surface protection (abrasion, corrosion, vibration, anti-chafe)	△ Provides surface protection (abrasion, corrosion, vibration, anti-chafe)
✓ Provide envrionmental sealing protection	✓ Provide environmental sealing protection	⊘ Provide environmental sealing protection	✓ Provide envrionmental sealing protection
✓ Repels aviation fluids like fuel, hydraulic (SKYDROL™), oil, de-icing	✓ Repels aviation fluids like fuel, hydraulic (SKYDROL™), oil, de-icing	△ Repels aviation fluids like fuel, hydraulic (SKYDROL™), oil, de-icing	⊘ Repels aviation fluids like fuel, hydraulic (SKYDROL™), oil, de-icing
✓ Remains in place under compression with no squeeze out	⊘ Remains in place under compression with no squeeze out	✓ Remains in place under compression with no squeeze out	⊘ Remains in place under compression with no squeeze out
✓ Non-curing with fewer process steps for easier and faster installation	⊘ Non-curing with fewer process steps for easier and faster installation	✓ Non-curing with fewer process steps for easier and faster installation	✓ Non-curing with fewer process steps for easier and faster installation
✓ Maintains protective performance over multiple open/close cycles	△ Maintains protective performance over multiple open/close cycles	✓ Maintains protective performance over multiple open/close cycles	△ Maintains protective performance over multiple open/close cycles
✓ Requires no operator certifIcations, special equipment or PPE	⊘ Requires no operator certifIcations, special equipment or PPE	✓ Requires no operator certifIcations, special equipment or PPE	✓ Requires no operator certifIcations, special equipment or PPE

b) Cables & Cable Assemblies

i) Summary of Performance Requirements

There is no single set of performance requirements for Cables and Cable Assemblies as a whole. Instead, the individual requirements vary by product type and in many cases are uniquely customized to the specific vehicle or system where the product will be used. These varied and demanding requirements require the availability of materials which can meet unique combinations of specifications. Cables and Cable Assemblies used in A&D applications must operate reliably over a long product life cycle that can reach beyond 30 years.

Key performance requirements include:

Dielectric constant (ε_r)

Dielectric constant is an important material characteristic which relates to the ability of the material to store electrical energy in an electrical field. Low dielectric constant values are necessary for high frequency or power applications to minimize electric power loss, enabling precise, consistent, and efficient signal transmission.

Service temperature range

Cables experience a wide range of operating temperatures from extreme conditions in varied climates, to low temperature at high elevation during flight and the extremes of space. As an example, cables must withstand the demanding A&D conditions above 150°C as highlighted in the Aerospace and Industrial Electrical Cable standard ANSI/NEMA WC27500 as published by NEMA (National Electrical Manufacturers Association). Some space applications can expose electrical components to temperatures well below -100°C.

Chemical resistance

The material must perform its function in harsh conditions and provide chemical resistance to oils, aircraft fluids, fuels, and other chemical substances.

Mechanical strength

The wires and cable materials must be highly durable and withstand frequent/rapid flexing, torsion, and pulling without compromising electrical performance under demanding environments (e.g., extreme temperatures).

Low coefficient of friction

The cable insulation and jacket layers must have a low coefficient of friction in order to decrease abrasion under continuous flexure and movement and during installation in aircraft and other systems.

ii) Why Fluoropolymers are used in Cables and Cable Assemblies

Fluoropolymers combine inherent electrical and mechanical properties with the unique ability to be processed into forms suitable for cable construction which are not available from other materials.

- Fluoropolymers like PTFE, FEP and PFA have a low dielectric constant of 2.1, where lower numbers enable higher precision and more reliable signal transmission.
- PTFE, in particular, can be processed into an expanded form which has an exceptionally low dielectric constant of 1.3.

Additionally, its maximum continuous service temperature (MCST) also enables:

- wide continuous use service temperature range, between -240 and +260°C

- good mechanical strength to withstand demanding mechanical and environmental challenges (i.e., withstanding handling, bending, torsion, and pulling without compromising electrical performance).

iii) Summary of Alternatives in Cables and Cable Assemblies

To operate in harsh and extreme conditions, cable applications need critical properties that only a small subset of potential materials can provide. Tables comparing materials' chemical stability, thermal stability and dielectric constant are provided in Annex I to exemplify the performance requirements. See Tables 5 and 6.

The materials discussed below may meet some of the performance requirements, but each has drawbacks or is unable to meet the necessary combination of requirements indicating they are not suitable for use in the A&D sector:

Polyimide

Besides its lack of flexibility, which complicates its use, this material displays a high dielectric constant, which limits its use in signal cables. It is also explicitly rejected as a material for applications where moisture is present, as humidity makes it even stiffer and increases the risk of breaks.

Polyesters, Polyethylene, Polyurethanes

Their max temperatures (80-125°C) mean they should not be used in aerospace applications as a significant drop in performance is typically observed over 80°C.

Moreover, they would require further additives for flame retardance[8]. In 1969, Notice 69-33 introduced in CFR (Code of Federal Regulations) Title 14 for Aeronautics and Space included a requirement to perform flame and burn tests to materials used in compartment interiors, cargo and baggage compartments, and electrical systems. This change has led to a replacement of less durable and worse performing materials with fluoropolymers. Therefore, any reversal to lower performing materials, such as those formerly used, is not an option as it would expose users (military, professionals and passengers) to increased, unacceptable risks.

Silicone

Although it allows for higher use temperature (180°C), silicones will be limited by their poor performance in signal/information cables due to their high dielectric constant.

Polyvinyl chloride (PVC)

PVC is the most popular jacket material for less demanding uses. However, in addition to its low resistance to abrasion and chemical substances, applications will be limited by its low Continuous Service Temperature (up to 80°C) and the outgassing property in thermal

[8] Some flame retardants are classified as PBT and therefore will be subjected to regulatory measures of their own.

vacuum conditions[9]. This material is not a feasible alternative for high performance or custom end uses found in Aerospace and Defence applications.

Alternatives are not able to maintain dielectric and other material properties within the required temperature ranges to assure system performance within environmental conditions that can include radiation, presence of chemicals, and other factors. They also have insufficient flame retardancy as required by European and U.S. Wiring Standards EN3475 and SAE AS22759.

c) Capacitors

i) Summary Performance Requirements

Critical A&D systems require capacitors to meet the power needs of complex systems reliably and consistently. Capacitor reliability improves overall system reliability. Technology systems used in A&D applications (e.g., aircraft) must qualify to meet minimum lifetime targets. Lifetime targets are becoming more challenging because the continued electrification of aircraft systems lead to a trend of higher operating temperatures. Should a film capacitor fail in service, functionality of the entire system could be lost. For example, this could impact the operation of critical systems such as braking or aileron control system (safety concern) or require the pilot to reduce power consumption to avoid further system losses.

Key performance criteria include:

Ability to self-clear

Clearing is an ability to isolate a fault (dielectric breakdown) from the rest of the device. This allows the capacitor to avoid a catastrophic and complete failure even when there is a dielectric breakdown somewhere in the capacitor. It leads the capacitor to have increased reliability and prevent system failure.

Low Dissipation Factor

Dissipation factor is a measure of the power lost travelling through a capacitor, mainly as heat. When materials have a high dissipation factor, the ability to deliver sufficient power is compromised and can cause excessive heating leading to reduced lifetime and reliability.

High temperature operating range

Electrical system operation, as well as environmental conditions, can expose a capacitor to elevated temperatures. Capacitors need to withstand these temperatures, in some cases, in excess of 200°C without failure or a significant change in electrical performance.

[9] Customers in aerospace sector have strict requirements on outgassing (especially under vacuum conditions)

ii) Why Fluoropolymers are used in Capacitors

Expanded PTFE technology uniquely combines reliable self-clearing, low dissipation factor, and thermo-mechanical stability. This improves reliability where capacitors are used today, and also enables further electrification of Aerospace systems which is a broader goal of the industry.

Capacitors are used in many applications that need to operate in a varied set of conditions. Therefore, there are a number of potential alternatives. The complete list of those potential alternatives is provided in Annex I where we also share their limitations and why those materials cannot be used in aerospace applications. In short, there are no known alternatives in the aerospace sectors that meet the power and reliability requirements, when considering the increasing power density and temperature conditions that the electrification of aircraft requires.

d) Alternatives Summary

As summarized above and shown in Annex I**, material property screening of potential alternative materials as well as direct experimentation to evaluate alternatives have demonstrated that no alternative is currently able to meet required performance that would allow replacement of fluoropolymers in sealants, cables and capacitors for aerospace and defence applications.**

2. Timeline

The A&D industry has been looking for alternative materials for cost saving opportunities for years without finding viable replacements for PFAS. Development, qualification, and transitions to alternative materials will require significant time and resources.

The Restriction Proposal only allows a transitional period of 13.5 years even in such cases where no alternatives are apparent. As pointed out on page 77 of the Restriction Dossier, this is based on the understanding of the Dossier Submitter that 13.5 years are *'normally sufficient for industry to take benefit from technical progress and to carry out scientific R&D activities to find and deploy technically and economically feasible alternatives'*.

Based on Gore's research and other available information, Section IV.1 confirms that no alternative materials are available at the time of writing and the combination of properties needed will be difficult to achieve in a new material (low dielectric constant, high service temperature, mechanical strength, chemical resistance, etc.). We will now underline the timeframe needed once a material with the suitable combination of properties has been discovered or invented for these applications.

Examples from the past, show that the time span to develop new materials can vary significantly. For example, the development of acrylic polymer took several decades. The process from the first synthesis of acrylic acid to the introduction of the commercial

polymer, was an 85-year journey.[10] The development of PTFE from the "accidental" discovery to a commercial product took about 10 years, from 1938 to 1948,[11] and then decades more to mature that technology into the materials used today. Development advances over this time have had to occur in polymerization, finishing, lubrication and blending, pelletization, and extrusion to develop forms usable in end products. In the absence of such an initial unexpected discovery, we can only speculate that developing a new polymer to commercial availability will take more than 20 years.

Using the example of Cables and Cable Assemblies, after identifying a material, the possible alternative materials will need further development in order to optimise them for specific application requirements. We estimate that this development stage could take 2 to 3 more years. There is also no guarantee that the new material and the associated manufacturing of that material would be preferable from an environmental perspective, as it would replace what is intrinsically a safe polymer.

Furthermore, any potential non-PFAS alternatives will need to go through a lengthy qualification testing process that is required for A&D substances to be approved. As an example, Gore is involved in a new standard qualification process for wires and cables with Society of Automotive Engineers (SAE) International, that already has taken circa 5 years. In 1969, CFR (Code of Federal Regulations) Title 14 for Aeronautics and Space as overseen by the FAA and NASA within the United Stated were amended with Notice 69-33. The notice stated, "requirements need to be considered in the initial design stages of an airplane, which is several years prior to the issuance of the type certificate, and to impose them on airplanes nearing type certification might require a substantial redesign of the airplane and would necessitate production-line type design changes" (page 23). Forty-four years later, the time to redesign and recertify aircraft will be impacted even more due to the additional complexity of interdependent systems that rely on fluoropolymer performance.

The final optimised material will then need to be manufactured into cable assemblies that can be evaluated and qualified both at a manufacturing and end-use level. Integration and qualification of cables into complex A&D systems is a complex and time-consuming activity. It can be even more challenging to qualify new materials as replacement parts in systems which are currently operational and may have a life of 20 or more years remaining.

[10] See https://www.ptonline.com/articles/tracing-the-history-of-polymeric-materials-part-20.
[11] https://www.teflon.com/en/news-events/history#:~:text=An%20Accidental%20Discovery&text=Roy%20J.,to%20form%20polytetrafluoroethylene%20(PTFE).

Table 4. Substitution Steps for Developing an Alternative to Fluoromaterials in Aerospace & Defence Applications

Steps for substitution	What activities does this step entail?	Time required for step
1. Identification and development of new material	Identify and develop suitable alternative materials. Product Development from lab discovery to pilot scale.	**Unknown** Estimate > 20 years
2. Product development an iterative stage of R&D, (re)formulation and lab testing	Optimise material for specific application requirements	2-3 years
3. Qualification and/or Validation - testing and validation with customers and/or external testers	Reliability testing of manufactured components.	2-5 years
4. Production - implementing the manufacturing plan for the alternative, including a possible pilot phase, regulatory approval, and modifications to the production line.	Supply chain development (new production capabilities and capacity for mass production).	2-5 years
5. Integration and qualification into end system or vehicle – Development and testing of product in-use with end device	Development cycle of new end device	3-7 years
Total		**Unknown** Estimated >29 years

3. Additional Information

a. Use Assessment

Additional Information can be found in the Use Assessment for A&D – Attachment 3, listed in Annex II to this derogation request. Among others, the following information is available in the Use Assessment:

- Market information
- PFAS use volumes

b. Social, Environmental and Economic Impacts

Components made using PFAS are necessary in the A&D sector to:

- Enable continued advances in the capability and reliability of aircraft, vehicles, and a range of electronic systems used in A&D applications

- Ensure the safety of passengers and the crew (or soldiers and space crew in space and defence industries)
- Reduce design and manufacturing costs for aircraft and vehicles
- Reduce operating costs due to increased reliability of components and reduced unplanned maintenance
- Lower the emissions from air travel by using lighter weight components
- Meet the regulatory requirements and industry standards.

Impact on Performance and Innovation of Critical Defence and Aviation Systems

For technically demanding uses with strict performance requirements, we believe a more in-depth and careful assessment of alternatives is needed. This is even more important for uses affecting people's safety and security, such as A&D, as the risk of failure is of much higher consequences. The risk related to reduction and withdrawal of A&D systems at various stages of development involving fluoropolymers, which would inevitably happen if a derogation is limited to 13.5 years, would jeopardize advancements in improved and more reliable defence systems as well as technologies that enable aircraft emissions reduction.

Risk of Component Failure leads to Increased Costs and Safety Risks

One of the key benefits of using PFAS in A&D products is increased performance due to their reliability, durability, and signal integrity. If PFAS can no longer be used, end products will be more impacted by electrical, mechanical, and environmental stress, making them more prone to wear and tear or damage. As a result, end-users will need to replace both the A&D products and end products (e.g., aircrafts) more frequently until a suitable alternative to PFAS in A&D products has been found. When aircraft or other equipment needs more frequent unplanned maintenance, it is not available for operational tasks which can have serious implications for aviation or defence capabilities. Product redesign and changes in downstream users' production processes will disrupt ongoing development efforts, which means that there is a risk of temporary production halt for products relying on PFAS-containing A&D products.

Availability of Spare Parts

It is also vital to ensure that spare parts made with PFAS are available for maintenance of both civil and military aircrafts and other vehicles/equipment as in the sector of A&D they have a service/shelf life of decades (40 years +). If restriction does not exempt A&D or forces producers to cease production, spare parts of the same specification will not be available. Alternative materials, if even developed, may not allow for a direct replacement within complex technologies of A&D resulting in premature obsolescence of parts or products. This would have huge economic, strategic (due to unavailability of functioning military equipment), and environmental (due to unnecessary waste and resource consumption) impact.

Annex I – Alternative Assessment

We would like to note that W. L. Gore & Associates has limited knowledge regarding hazards and risks presented by materials we do not manufacture or use. Information on hazards and risks of alternative chemicals presented below is based solely on desk research. All those chemicals are subject to REACH regulation and any applicable national workplace laws. Therefore, the information below is not to be seen as a judgement on the suitability of their use. We believe that before a restriction on the use of fluoropolymers, which are non-hazardous and non-bioavailable is implemented, a comprehensive comparative risk assessment throughout the entire lifecycle should be conducted on any potential alternatives.

Sealants

Performance requirements	- Tolerance to extreme temperature swings (Example: -73°C to 260°C per AMS3255B Class 1-4) - Chemical resistance and ability to seal against fuel, environmental fluids, and hydraulic fluids - Simple aircraft assembly and maintenance which leads to reduced cycle times and increased aircraft availability - Reusability and waste reduction compared to alternatives - Surface protection and high conformability - Qualified to customer specifications and industry standards - Mechanical strength, dimensional stability, and durability
Alternative materials assessment	**Polysulfide Sealants** Polysulfide does not have sufficient chemical resistance. It does not resist LD-4 (aircraft fluid), and is less resistant to water compared to PTFE-based products, leading to quicker failure over time resulting in more frequent maintenance Polysulfide needs to be cured. Polysulfide is applied as a liquid and the curing process is negatively impacted by temperature and humidity conditions. Once a pot of polysulfide is mixed, there is a specific time in which it must be used. Additionally, maintenance engineers may not need an entire pot but have to mix the entire pot. Both limitations generate additional waste. Also, viscosity between batches of liquid sealants can vary. These factors may prohibit use of automation in the manufacturing processes. Polysulfide is not suitable for every application where PTFE sealants are used. For example, it is not a suitable alternative in floorboard applications of the aircraft. Polysulfide is too tacky for use under floorboards – it becomes difficult to re-open the panel and any excess of the wet sealant (referred to as the “squeeze out”) can lead to production and cleaning problems when it gets onto unintended areas of the aircraft. Polysulfide use requires additional workplace controls. The solvent in polysulfide is a Volatile Organic Compound (VOC) and requires maintainers to work in a hood with

	proper air circulation. There is a high amount of effort needed to clean up sealed areas which entails the use of teams of operators who use large quantities of VOCs to remove excess or poorly placed cured sealant. This generates high VOC emissions. Polysulfide sealants are hazardous mixtures. US OSHA hazard classification: Acute Tox Cat 4 (oral and inhalation), Cancerogenic Cat 2, STOT RE Cat 2 EU SDS was not available. Polysulfide has a significantly longer installation and maintenance time. PTFE-based sealants enable surface protection and corrosion reduction can positively impact WIP times at bottlenecks. In a real case study[12] when various panels need to be reopened for maintenance multiple times, ePTFE sealants have shown great superiority to Polysulfide wet sealants, leading to a reduction of installation time from 50 to 4 hours. For detailed information including time analysis graphics please refer to: - Attachment 1- IMPROVING AIRCRAFT AVAILABILITY WITH ALTERNATIVE SEALANTS (Note that in the second graphic, MIL-S-8802 is synonymous with polysulfide) - GORE-SKYFLEX-Materials-Leonardo-Case-Study[12] Large amounts of disposal and transportation of waste: Polysulfide sealants are single-use and cannot be reused. Short shelf life also means that any excess mixture must be disposed of as hazardous waste. For all precautionary and risk management measures see SDS- Attachment 5 **Nitrile Rubber** Nitrile rubber may move in application, causing a risk to the aircraft and safety of the crew/passengers. It is not as conformable as PTFE sealants, so it might move within application and not seal if not properly installed. Nitrile rubber is not sufficiently UV resistant. Under UV exposure, it will break down and become brittle risking seal failure. Nitrile rubber is more complicated to handle for customers. Nitrile rubber is not reusable compared to PTFE gaskets so there is more waste generated. Nitrile rubber also has a higher weight than PTFE leading to higher weight of aircraft. Airbus had previously requested to change from nitrile rubber to PTFE-based sealants due to complicated handling work and deformations that has appeared when using nitrile rubber- Attachment 2

[12] https://www.gore.com/system/files/2020-07/GORE-SKYFLEX-Materials-Leonardo-Case-Study-M-345%20Trainer-05262020_0.pdf

	Polyurethane (PU) Gel Tape PU gels create additional waste: Gore is aware of companies using a PTFE scrim or PTFE release layer with PU Gel tape. This approach still relies on fluoropolymers and can squeeze out in the application a failed seal, safety risks and premature replacement. They are not recoverable or reusable, leading to waste. PU lead to other installation and aircraft performance challenges. Gels take more time to replace in application compared to 100% PTFE sealants. Additionally, they are higher weight than expanded PTFE leading to higher weight of aircraft. **Silicone Foams** Safety and waste: Silicone sealants can tear and crack easily leading to sealing deficiencies and premature replacement. If the seal fails and fluids leak into areas of the aircraft, this could cause mechanical damage to the airplane and take of aircraft out of service more frequently. Silicone foams are specific to floorboard applications. They cannot be used in all applications where PTFE sealants can be used due to their low tensile strength. They are not able to withstand vibrations and high compression in other areas of the aircraft. Silicone foams hold moisture and do not resist fuel or hydraulic fluids like PTFE sealants. They have retained moisture and trapped dirt in application. **Only PTFE sealants are able to meet the combination of mechanical and chemical properties required for sealants in A&D applications.** See further information in the sections below and in Attachment 4 – Sealant Technologies in Commercial Aircraft

Cables and Cable Assemblies

Performance requirements	Cables used in A&D applications are often custom designed to unique performance requirements for a specific type of vehicle, aircraft or satellite system which may differ from a similar system in the same end use. The user of these cables specifies the electrical signal performance and the physical conditions it must withstand. These physical demands can include attributes such as torque/crush/kink resistance, abrasion resistance, dust/moisture resistance, performance over a wide temperature range, chemical resistance, high flex, and high connector pull strength. Cables achieve these performance attributes though a combination of the inherent properties of the materials used, plus the design and construction techniques used

	by the manufacturer. Cables have overall electrical performance requirements such as: - ultra-low attenuation of microwave/RF and high-speed differential signals over distance to provide adequate signal transmission with physical, environmental, and electrical challenges of A&D end uses - smaller phase/amplitude change over temperature to provide adequate signal transmission with physical, environmental, and electrical challenges of A&D end uses - shorter time delay of microwave/RF signal over distance to provide adequate signal transmission with physical, environmental, and electrical challenges of A&D end uses - lower capacitance over distance to enhance precise and accurate microwave/RF signal transmission Both electrical and physical performance of the cables are influenced by the inherent properties of the materials used. Key material properties include: - Low dielectric constant values are necessary for high frequency or power applications to minimize electric power loss, enabling precise, consistent, and efficient signal transmission - Wide continuous use service temperature range (i.e., -240 to +260°C, typical) to provide adequate signal transmission with physical, environmental, and electrical challenges - Low outgassing in thermal-vacuum conditions to provide adequate signal transmission with physical, environmental, and electrical challenges of A&D end uses - Adequate mechanical strength to withstand demanding mechanical and environmental challenges - Resistance to abrasion - Resistance to water/oil/chemical substances - Radiation resistance See characteristics listed in section titled: “Alternative materials known or discussed in Restriction Proposal and performance of such materials” for specific performance ranges. For example: A microwave/RF cable assembly, made with fluoropolymers, has overall operating temperature derated to -160 to +200°C to account for self-generated heating from microwave signal(s) being transmitted in the worst-case scenario (e.g., highest operating temperature @ +200°C with highest possible microwave power being transmitted). If a microwave/RF test cable assembly is made with non-PFAS materials, its overall operating temperature will have to be derated further (e.g., -25 to +85°C). **This reduced temperature range is not sufficient to accommodate the temperature range for civil and military aircrafts, and spaceflight vehicles.**

Alternative materials known or discussed in Restriction Proposal and performance of such materials

Cables and Cable Assemblies in A&D applications require materials to meet combinations of performance requirements simultaneously which eliminates many materials from being feasible. Table 5 below summarizes the performance of various materials against A&D requirements.

Table 5. Comparison of Performance Characteristics

Comparison of Performance Characteristics of Various Materials for Typical Aerospace Requirements

Known performance characteristics are approximate.

	Characteristic	Typical Aerospace Requirements	Materials							
			Fluoropolymers	Polyimide	Polyester	Polyethylene	Polyurethane	Silicones	PVC	Foamed Polyethylene
	Max Temperature[1,2]	200 C								
	Min Temperature	-65 C; Cold Bend EN3475-406								
	Flammability, Toxicity	EN3475-407, EN3475-602								
	Chemical Resistance[3]	EN3475-411								
	Arc Tracking	MIL-STD-2223				?	?	?		?
	Hydrolitic Stability	EN3475-412								
	Long-term Thermal Stability[1]	EN3475-416								
	Dielectric Constant[4]	Low Er for Smaller, Lighter Weight Cables								
	Cut-through Resistance /Abrasion Resistance	EN3475-503/EN3475-501								
	Flexibility (Stiffness and Springback Force)	AS4373-707 (Gore experience)								
SPACE FOCUSED	Low Loss Over Broad Temperature Range[5]	See Dielectric Constant Over Temperature Range								
SPACE FOCUSED	Outgassing	ASTM E595 TML ≤ 1% (Gore Expertise)								
SPACE FOCUSED	Radiation Resistance	Cross-linked ETFE performance unique	Cross-linked ETFE Specific							

Legend: Meets Requirement | Marginal Performance | Does Not Meet | Unknown

Sources of Information

(1) - "Max Temperature - Thermal Index. The thermal index is computed usin the projected 15,000 hour life based on the ASTM D3032, Section 14. The minimum thermal index shall be 200 C" (Ron Solomon, June 1991, *New Insulation Constructions for Aerospace Wiring Application* s (WL-TR-91-4066 Volume 1). St. Louis, Missouri,: McDonnel Douglas Corporation. o. 15). (Lectromec.2016)

(2) Use of Cables on Aircraft - Lectromec (Link: https://lectromec.com/use-of-cables-on-aircraft-part-1/)

(3) rating for Chemical Resistance taken from Chemical Resistance Chart PN 41-6018/rev. C (Emerson Process Management, 2010; Link: https://studylib.net/doc/18540781/chemical-resistance-chart---emerson-process-management: https://studylib.net/doc/18540781/chemical-resistance-chart---emerson-process-

(4) Dielectric constant: for microwave cable assemblies' dielectric material, smaller dielectric constant values are more desirable because it concurrently enables ultra-low attenuation of microwave/RF signal over distance, smaller phase/amplitude change over temperature, shorter time delay of microwave/RF signal over distance, and lower capacitance over distance to enable precise and accuurate microwave/RF transmission

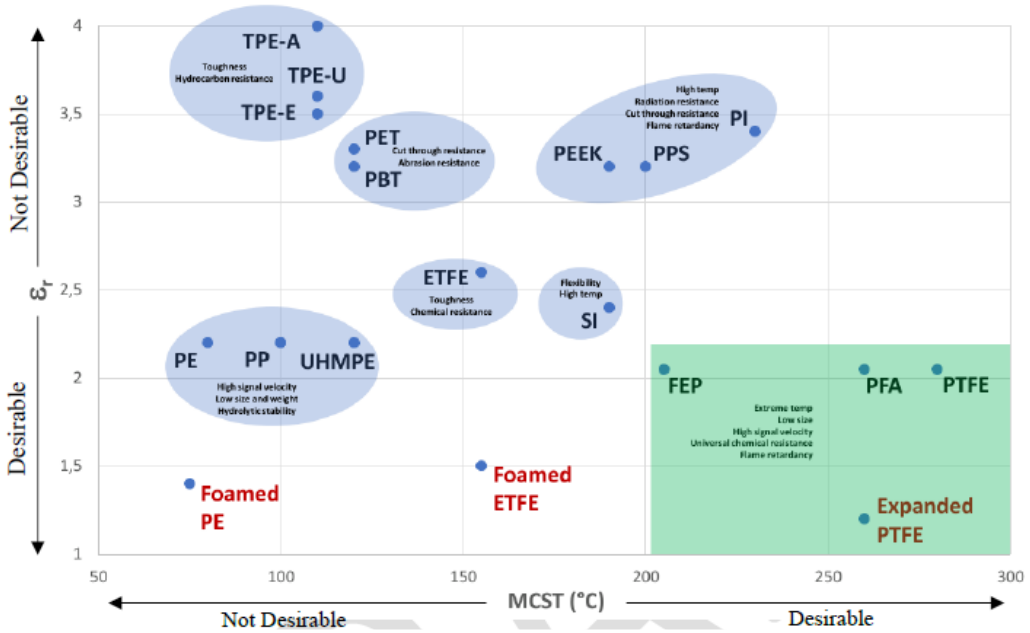
(5) The sustainable use of PTFE in Wire and Cable, Gore Internal White Paper, Amadeus Wiesemann, November 2022.

Dielectric Constant and Temperature

Having a sufficiently low dielectric constant eliminates most alternatives from consideration as alternatives is A&D Cable applications. Additional requirements such as temperature and chemical resistance eliminate the remaining non-fluoropolymer alternatives. This point is further highlighted in Figure 1 below, which demonstrates that fluoropolymers have the required combination of dielectric

constant rating and maximum continued service temperature (MCST) for A&D applications to provide adequate signal transmission with physical, environmental, and electrical challenges.

Fig. 1: Dielectric Constant (ε_r) vs. Maximum Continuous Service Temperature (MCST)



Chemical Resistance

Table 6 below shows chemical resistance of a range of polymers to the broad list of fluids, fuels, and cleaning solvents that are commonly used in the Aerospace industry as defined by Table 17 of SAE AS 22759, which is a broadly used Cable standard. Only fluoropolymers are sufficiently resistant to a broad range of chemicals, including hydrocarbons which are particularly relevant to A&D applications.

Table 6. Chemical Resistance of Polymers[13]
Note: PTFE is referred to as TFE

	ETFE	FEP/TFE/PFA	FLPE	FLPP	HDPE	LDPE	PC	PETG	PP	PVC	TPE***
Acids, Dilute or Weak	E	E	E	E	E	E	E	G	E	E	G
Acids, **Strong/Concentrated	E	E	G	G	G	G	G	N	G	G	F
Alcohols, Aliphatic	E	E	E	E	E	E	G	G	E	G	E
Aldehydes	E	E	G	G	G	G	G	G	G	G	G
Bases/Alkali	E	E	F	E	E	E	N	N	E	E	F
Esters	G	E	G	G	G	G	N	G	G	N	N
Hydrocarbons, Aliphatic	E	E	E	G	G	F	G	G	G	G	E
Hydrocarbons, Aromatic	G	E	E	N	N	N	N	N	N	N	N
Hydrocarbons, Halogenated	G	E	G	F	N	N	N	N	N	N	F
Ketones, Aromatic	G	E	G	G	N	N	N	N	N	F	N
Oxidizing Agents, Strong	E	E	F	F	F	F	F	F	F	G	N

*Not for tubing chemical resistance (except PVC) **Except for oxidizing acids (See oxidizing agents, strong) ***TPE gaskets

EXCELLENT	GOOD	FAIR	NOT RECOMMENDED
30 days of constant exposure causes no damage. Plastic may tolerate for 30 years.	Little or no damage after 30 days of constant exposure to the reagent.	Some effect after 7 days of constant exposure to the reagent. The effect may be crazing, cracking, loss of strength or discoloration.	Immediate damage may occur. Depending on the plastic, the effect may be severe crazing, cracking, loss of strength or discoloration, deformation, dissolution or permeation loss.

Additional notes on each alternative material:

- **Polyimide**
  - Prone to arc tracking after exposure to water (humidity)
  - High dielectric and stiff nature of the material makes polyimide not feasible for signal cables
  - Aircraft Wiring Degradation Study performed by Raytheon Technical Services Company LLC on behalf of Federal Aviation Administration, U.S. Department of Transportation concluded that "*Aircraft wiring systems should be designed to minimize the risk of wires being subjected to a tighter than 10-times dynamic bend. The use of PI (Polyimide) or PV wire in high moisture level areas is not a recommended safe practice because of the significant role that moisture plays in the aging of those wire types.*" (Raytheon Technical Services Company LLC , 2008, p. 92)
- **Polyesters**
  - Max temperature of 125°C makes polyesters a poor choice in Aerospace applications
  - Cut through performance[14] is significantly lowered above 80°C

	○ Additives needed for flame retardance (additives may be substances of concerns themselves – like bromides) (Afirm Group, 2018) ○ Not resistant to typical fluids and chemicals seen in Aerospace Applications • **Polyethylene** ○ Max temperature of 80-120°C makes polyesters a poor choice in Aerospace and Defence applications ○ Cut through performance is poor ○ Additives needed for flame retardance (additives are substances of concerns themselves – like bromides) (Afirm Group, 2018) • **Polyurethanes** ○ Max temperature of 120°C makes polyurethanes a poor choice in Aerospace applications ○ Cut through performance is poor at all temperatures ○ Additives needed for flame retardance (additives are substances of concerns themselves – like bromides) (Afirm Group, 2018) • **Silicones** ○ Temperature range up to 180°C ○ Cut through resistance is poor ○ High dielectric constant and poor loss tangent of silicones means they are not feasible for signal cables • **Polyvinyl chloride (PVC)** ○ Not a viable alternative, does not meet any of the performance criteria ○ Similarly as in case of Polyamide Aircraft Wiring Degradation Study concluded that the use of PV wire in high moisture level areas is not a recommended safe practice (PV is defined as Polyvinyl Chloride/nylon) (Raytheon Technical Services Company LLC , 2008) ○ Additionally, ANSI/NEMA WC 27500-2020 (American National Standard for Aerospace and Industrial Electrical Cable Section 3.8.2.5 concludes that "Polyvinyl chloride shall not be used for aerospace purposes." (Standard available from National Electrical Manufacturers Association, under copyright) • **Foamed Polyethylene** ○ Max temperature of 8 -120°C makes polyesters a poor choice in Aerospace applications ○ Cut through performance is poor ○ Additives needed for flame retardance (additives are substances of concerns themselves – like bromides and halogens) (Afirm Group, 2018)
R&D activities conducted	Gore has tested polyimide insulated aircraft wiring in a commonly used Teflon®/Kapton®/Teflon® variant. Gore's R&D showed that the Kapton® layer can

[13] Eason, M., & Vogel, R. (2022, May). Sealing Devices and the need for PFAS. Valve World, 20-22.
[14] A wire/cable's ability to withstand compression damage, which is one of the most common means for damage to a wire/cable on an aircraft

	be exposed through moderate abrasion whereby the Kapton is susceptible for corona discharge to occur leading to arc tracking and ultimately fire.
Conclusion	**Only fluoropolymers are able to meet the combination of electrical, mechanical, thermal, and chemical properties required for Cable and Cable Assemblies in A&D Applications.**

Capacitors

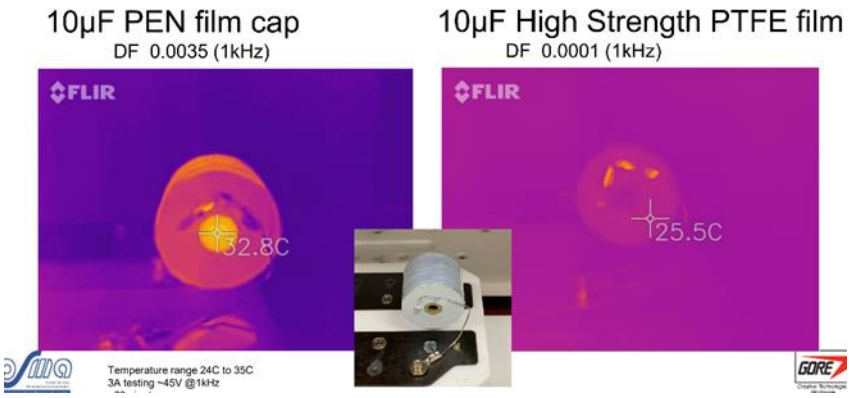
Performance requirements	Traditionally, the use of secondary power within civil aircraft has fallen into three general categories, Hydraulic, Pneumatic, and Electrical power. Current trends are seeing manufacturers move towards replacing traditional secondary hydraulic and pneumatic power systems with electrical alternatives. Electrical aircraft could achieve lower fuel consumption and emissions. However, before full electrification is feasible there are still numerous reliability issues to be resolved; especially within power electronics. The primary stressors affecting the reliability of several components within power electronics systems, such as printed circuit boards (PCBs), semiconductors, and capacitors are temperature-related (Wileman, Aslam, & Perinpanayagam, 2021). It is therefore necessary for capacitors in the aerospace sector to meet the following improved performance characteristics: - Low Dissipation Factor – a materials ability to self-heal when under charge and resist sudden catastrophic failure[15] of a capacitor. A high dissipation factor indicates high energy loss and lower lifetime reliability. - High breakdown strength over temperature - High Insulation Resistance over broad temperature range - Low dielectric loss over temperature - Low dielectric loss over wide frequency range - Stable capacitance over wide range of temperatures and voltages **An analysis focused on dissipation factor and temperature resistance is sufficient to demonstrate the lack of alternatives to fluoropolymers.** See presentation: High temperature Capacitor Applications in More Electric Aircraft presented at Applied Power Electronics Conference 2018 (W.L. Gore & Associates, 2018)
Alternative materials known or discussed in Restriction Proposal and performance	<u>Alternative Material Technologies – Ceramics and Metallized Film</u> A variety of high temperature capacitor dielectrics exist such as ceramics (MLCCs) and Electrolytics, however, these suffer catastrophic failure risk from fracture or loss of electrolyte respectively. Metallized film capacitors exhibit a self-clearing phenomenon whereby excursions of electrical stress can be accommodated without catastrophic failure, making this type

[15] Catastrophic failure is defined as a total loss of capacitance. Catastrophic failure implies collateral damage to the rest of the system resulting in down time and unscheduled field service

of such materials	of capacitor preferred for the aerospace industry. However, conventional film dielectrics are temperature limited. Common Aerospace design approach for power electronics leverages metallized film capacitors using polypropylene (105°C temp limit) as the dielectric in combination with an active cooling system. To cool the capacitors, power is bled from the jet engine to power a liquid-cooling system comprising coolant pumps, tanks, heat exchangers, ducts & tubes which adds system weight, which reduces overall engine fuel efficiency and increases carbon emissions. Increasing electrification in the design on aircraft no longer makes this option available. For more details on cooling systems for aircraft power systems see (Debabrata Pal, 2017). **Neither Ceramic nor metallized film capacitors can meet the temperature and reliability requirements for A&D applications.** [redacted] [redacted] [redacted]

Figure 3 (below) shows an exemplary visual comparison of dissipation factor and self-heating between PEN and PTFE film. The lighter colour seen in the PEN film cap indicates it is operating at a higher temperature due to its high dissipation factor. Generally, a 10°C increase in operating temperature will reduce component lifetime by about 50%. Thus, the hotter cap will degrade faster and be more likely to fail during use.

Figure 3. Comparison of Operating Temperatures of PEN and PTFE films



In Table 7, we present some key disadvantages of various materials when used in extremely harsh environments such as A&D, including a column which describes its current application. We also included materials applied in Oil & Gas Downhole tools, to present their deficiencies, in case they were considered for A&D applications.

Table 7. Performance Challenges with Alternate Materials in A&D Capacitors

Non-Fluorinated Alternative Material	Material Type	Application	Disadvantages
Class 2 Ceramics (X7R)	Ceramics	Power conditioning in downhole tools	Fail catastrophically; susceptible to fracture from shock & vibration
Class 1 Ceramics (C0G)	Ceramics	Sensors, resonant circuits	Temperature stable but very low capacitance density due to the lack of BaTiO2 loading
Wet Tantalum	Hermetically sealed tantalum with electrolyte	Power conditioning in downhole tools	Fail catastrophically; susceptible to overvoltage/reverse current surges. Typically low max voltage ~125V.
Polypropylene (Treofan)	film (PP)	Aircraft power conditioning when combined with cooling systems	Limited to ~105°C. Available since the 1950's. Dominant film capacitor dielectric. Dissipation factor 2x PTFE. The added weight of cooling systems required to utilize PP film will disallow the Aircraft industry

				from meeting global emissions goals.
	Polyimide (Kapton)	film (PI)	Space power electronics	Typically thick film/foil format; poor clearing; Dissipation factor 20X PTFE. Poor DWV leading to large form factor (poor energy density)
	Polyethylene Terephthalate (Mylar)	film (PET)	Widely used but not often in aircraft power systems	125°C max temp. Widely used but not in high current applications. Dissipation factor 50X PTFE.
	Polyphenylene Sulfide (Torelina)	film (PPS)	Marketed as HT film dielectric but sees little use above 125C	Largely replaced polycarbonate in the 1980's. Limited to 125°C. Poor clearing. Dissipation factor 180X PTFE. (self-heats significantly)
	Polyethylene naphthalate (Teonex)	film (PEN)	Marketed as HT film dielectric but sees little use above 125C	Introduced ~2012 as HT capacitor film but limited to 125°C. Dissipation factor 35X PTFE.
	Polyetherimide (Ultem)	film (PEI)	Marketed as HT film dielectric but sees little use above 125C	Marketed for use at 150°C but little adoption above 125°C. Dissipation factor 22X PTFE.
	Polycarbonate	film (PC)	Precision capacitors, RC circuits	125°C max temp. Widely used but not in high current applications. Dissipation factor 50X PTFE.
	Polycharge	Polymer deposition	Traction inverters	Mostly focused on automotive market, but capability is up to 140°C. Dissipation factor 25X PTFE. Not generally available.
	Elecrolytic (CDE high temp)	Aluminum elecrolytic	Power conditioning in downhole tools	Fail catastrophically due to the evaporation of electrolyte, which leads to increased ESR, thermal runaway & shorting. Struggles to survive at high temperatures. Has a low max voltage (~300V).

Additional References:

For an overview of film dielectric materials, see publication (Foster, James C General Electric Company, 1990)

See presentation: High temperature Capacitor Applications in More Electric Aircraft presented at Applied Power Electronics Conference 2018 (W.L. Gore & Associates, 2018) to see the detailed comparative analysis of performance of alternative materials

Also see a publication in Elsevier that provides an overview of the significant technical challenges required to meet the proposed 80% reduction in CO_2 emissions by 2050 (Clean Sky2). This paper cites industry surveys which specifically call for necessary

	development into capacitors for harsh environments (high temperature) required to meet these goals.
R&D activities conducted	Gore has tested PTFE, PPS (polyphenylenesulfide), PEN (polyethylene naphthalate), and PEI (polyetherimide) films for dielectric lifetime based on an analysis of reliable self-clearing. Each of these film dielectrics are marketed as suitable in the 125–150°C range and were regarded the latest advancements in higher temperature film dielectrics. PTFE film substantially outperformed the other options at 150°C, by achieving 3 times higher lifetime. PEN and PPS films demonstrated catastrophic failure above 125°C and PEI demonstrated catastrophic failure above 150°C. PTFE film demonstrated reliable clearing as high as 225°C. Clearing is an ability to isolate the fault (dielectric breakdown) from the rest of the device. Note: In the above study, the older high temperature capable films introduced in the 1950's were not included such as PI (polyimide), PC (polycarbonate), and PET (polyethylene terephthalate) due to the well-established, market-recognized drawbacks of poor clearing (PI), high self-heating (PET), and general un-availability (PC). In another study performed in 2018, PTFE film was tested in a capacitor form to demonstrate the impact of a low loss dielectric (low dissipation factor). PEN (polyethylene naphthalate) material was used for comparison, as this was the latest/emerging high temperature film dielectric marketed at the time. PTFE film achieves up to 3.5 times greater current handling capability because of the lower power loss characteristics of the film. (See poster summarizing the results- attachment 6)
Conclusion	**Material property screening and experimental results confirm that PTFE film uniquely combines reliable self-clearing, low dissipation factor, and thermo-mechanical stability that is required for Capacitors in A&D applications. Alternative materials are unable to meet the performance requirements.**

Annex II – Overview of attachments supporting the request

Reference	Document Title
Attachment 1	- IMPROVING AIRCRAFT AVAILABILITY WITH ALTERNATIVE SEALANTS
Attachment 2	- Replacement of Nitrile Rubber inquiry
Attachment 3	- Final Use Assessment A&D
Attachment 4	- Sealant Technologies in Commercial Aircraft
Attachment 5	- SDS for Polysulfide Part A and Part B (two PDF documents)
Attachment 6	- PEN vs Gore Capacitors_ECTMApril2018

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Together, improving life

W. L. Gore & Associates' Comments on Dossier Submitters' Draft EU REACH restriction on PFAS

Public consultation

Request for Derogation: Medical Devices

June 2023

Table of Contents

I. Derogation Request

Gore appreciates the opportunity offered by the public consultation process to provide comments on the Annex XV Proposal for a Restriction of Per- and polyfluoroalkyl substances (PFASs) (hereinafter 'Restriction Proposal').

With this statement we would like to explain why we believe that a derogation for implantable medical devices and Class IIb and Class III[1] invasive medical devices within the scope of Regulation (EU) 2017/745 is needed and justified.

Considering the arguments and evidence presented below, Gore respectfully requests to modify the following application-specific derogation for medical devices in paragraph 6 b. of the proposed restriction as follows:

By way of derogation, paragraphs 1 and 2 shall not apply to fluoropolymers and perfluoropolyethers for use in:

> **b. implantable medical devices and Class IIb and Class III invasive medical devices within the scope of Regulation (EU) 2017/745.**

Since we suggest that hernia meshes are included in the derogation for implantable medical devices, paragraph 6.h. considered for hernia meshes should be deleted.

Since "tubes and catheters" is an imprecise definition and the proposed derogation above utilizes the device classification terminology from MDR, paragraph 6.c should be deleted, unless there are other uses of tubes intended by the Dossier Submitters and not included in the proposed derogation above.

II. Need and Justification for Derogation Modification

In recommending the derogation for medical devices currently in the restriction proposal, the Dossier Submitters recognized both the critical nature of implantable and invasive medical devices and the challenge with identifying and commercializing alternative materials. Gore believes that modification of the proposed derogation is needed and justified to adequately account for the reality of developing, testing and commercializing an alternative non-PFAS implantable or invasive medical devices. The proposed modifications are based upon the following considerations, which are supported by the evidence provided in this document:

1. Extend derogation period to reflect the actual development timelines of implantable and invasive medical devices and patient risk from removing existing devices from the market

The restriction proposal's recommendation of a 13.5-year derogation is not technically or economically feasible. Ability or timeline for identification of a material which exhibits the same exceptional, proven qualities of fluoropolymers in medical devices is unknown and unpredictable. There are no equivalent alternatives to

[1] Class I, IIa, IIb, III Medical Devices – The risk-based classifications of medical devices in the EU per EU MDR 2017/745, ranging from Class I for the lowest-risk devices to Class III for the highest. This risk-based system of device classification takes into account the vulnerability of the human body and the potential risks associated with the devices. 'Classification rules' are set out in Annex VIII of Regulation (EU) 2017/45 on medical devices (MDR).

fluoropolymers for many implantable and invasive medical devices available today. The Dossier Submitters "concluded that the evidence is sufficiently strong that technically and economically feasible alternatives are not generally available for the quantities required for use in implantable medical devices and that the substitution potential is low."[2] With the uncertainty about alternative materials, it will take in excess of 20 years to develop, clinically test, gain approval for and commercialize a single redesigned product in the EU market, considering historical experience[3] and the regulatory environment[4] (i.e., EU MDR 2017/745) for a typical implantable or invasive medical device. The restriction proposal will impact hundreds of medical devices used in the EU. This further lengthens the product replacement timeline beyond 20 years because all these products will need to be redesigned and re-evaluated simultaneously.

The burden of this lengthy and costly process to develop, test and commercialize new medical devices will be borne by medical device companies, regulatory bodies, government and the health infrastructure (ultimately the tax payers). Further explanation of these resource requirements and the potential impact upon them is shown in [redacted]

2. Clarify the scope of medical devices to include Class IIb and Class III invasive devices in line with the Medical Device Regulation

Invasive medical devices provide patients with a wide range of critical, lifesaving and risk reducing medical therapies, but are not clearly included in the restriction proposal. Successful use of the implantable devices requires the use of invasive medical devices (such as introducer sheaths and catheters), which also require fluoropolymer materials. These invasive devices are as important to include in derogations as the implants they support. Without the availability of these Class IIb and Class III invasive devices, many of the implantable medical devices included in the initial derogation would either be unusable or require additional procedures that increase cost to the hospital and carry additional safety risk for patients. Examples of these invasive products proposed for derogation inclusion are listed in [redacted]

3. Include hernia mesh in the scope of the derogation based on additional evidence provided

The restriction proposal seeks additional information regarding hernia meshes. Gore provides evidence to support that currently available alternatives are not technically and economically feasible for substitution, and therefore should be treated consistently with other implantable medical devices. Therefore, Gore requests that the exclusion of hernia meshes from the derogation in paragraph 6.b be removed. See [redacted]

4. Fluoropolymers provide unique functionality in implantable and invasive medical devices

Fluoropolymers are a commonly used class of materials in the medical device and pharmaceutical industries with an extensive documented track record of utility and safety (over 45 years on the market). These materials are used

[redacted]

in critical device components due to their inherent properties, including durability, mechanical strength, inertness, thermal stability, and resistance to chemical, biological, and physical degradation.

Fluoropolymers used in these applications meet the criteria for Polymers of Low Concern (PLCs), under the definition provided by the OECD Expert Group on Polymers[5]. They are non-toxic, not bioavailable, not bioaccumulative, not mobile in the environment and pose no potential for long-range transport (LRT).

5. Significant socio-economic impact of regulated implantable and invasive medical devices which use fluoropolymers

The suggested derogation is crucial to continuing to protect the health and rights (per Article 35 of the EU Charter of Fundamental Rights) of hundreds of thousands of European patients per year. Hundreds of life-saving or life-improving therapies for multiple high-risk disease states rely on the unique and proven properties of fluoropolymers. Even in cases where alternatives exist, they typically have significant adverse tradeoffs or do not cover diverse patient populations. Continued access to these therapies is essential to the overall health of the EU and global population.

Implantable and invasive medical devices are already highly regulated and evaluated for patient safety. Reimbursement decisions demonstrate that they have been assessed to have unique value compared to alternative treatment options. Existing regulations (e.g., EU MDR 2017/745 Annex 1) and international standards (e.g., ISO 10993 series) require comprehensive evaluations of biological safety. These regulations also establish a robust regime under which implantable and invasive medical devices are rigorously evaluated for safety, efficacy, and economic value. The established system of medical device regulation in the EU is further rationale to consider medical devices differently in the scope of a REACH restriction. Additional information on approval requirements is listed in Section IV.a.

We also believe the estimates of material use and potential emissions for implantable medical devices have been over estimated, creating a further disparity between the societal costs and perceived benefits of restricting fluoropolymers in implantable and invasive medical devices.

III. Brief Description of the End Use

In the Restriction Proposal, implantable medical devices are discussed in detail with references to many end uses, including Table A.99 in Annex A, and Section E.2.9 in Annex E. The Dossier Submitters concluded that the evidence is sufficiently strong that technically and economically feasible alternatives are not generally available for the quantities required for use in implantable medical devices and that the substitution potential is low. This section provides additional information on the end use of implantable medical devices.

In addition to implantable medical devices, the Dossier Submitters provided a limited discussion of other devices that are used in surgery and other procedures when addressing tubes and catheters. **"Tubes and catheters" is an incomplete consideration of the range of necessary devices that are required for state-of-the-art patient care,** but

[5] OECD (2009). Data analysis of the identification of correlations between polymer characteristics and potential for health or ecotoxicological concern. OECD Task Force on New Chemicals Notification and Assessment, Expert Group Meeting on Polymers; 2007 Mar; Tokyo, Japan. Paris (FR)

not clearly included in implantable devices. Such Invasive Devices are discussed in [redacted] for more clear inclusion in the derogation. There may be other uses of "tubes" in medical device applications beyond implantable and invasive devices about which others may have more information.

a) Patient Treatments and Device Considerations

Implantable and invasive medical devices (within scope of this derogation request) are used in high-risk applications to improve the health and wellbeing of patients suffering from a broad range of critical conditions and diseases. Many fluoropolymer-based medical devices, including those products described herein, have an extensive clinical history showing safety and effectiveness. We do not have detailed information on other medical device manufacturers who use fluoropolymer-based devices, however we can speak to nearly 45 million Gore implants worldwide, including around 9.5 million implants in the EU, spanning 45+ years of clinical use. Approximately [redacted] Gore medical devices are sold in the EU annually, which corresponds to nearly 114,000 lifesaving and life-improving medical procedures. [redacted]

To highlight the criticality of continued patient access to implantable medical devices and the uniqueness of specific implantable medical products to treat certain medical conditions and/or patient populations, the following two examples are provided.

Pediatric Shunts

Cyanotic congenital heart defects are defects affecting the structure of the heart which are present at birth and result in cyanosis, a below-normal oxygenation of the blood. Infants with cyanosis are frequently termed "blue babies" because the condition may result in a bluish discoloration of the skin. Depending on the nature and severity of a cyanotic congenital heart defect, staged palliative repair surgery may be indicated[6]. GORE® PROPATEN® vascular grafts configured for pediatric shunt are frequently used as part of the first stage of repair to shunt (provide) blood to the lungs. This supplemental blood flow to the lungs is life saving and intended to provide a means of increasing blood oxygenation to stabilize the infant until they can withstand a subsequent, more permanent repair.

A common vascular graft failure mode is thrombosis, especially small diameter vascular grafts of less than 6mm[7]. GORE PROPATEN Vascular graft Configured for Pediatric Shunt (3-6 mm) are designed to resist thrombus formation using a Heparin based surface modification technology. In 2018, a physician sponsored retrospective analysis demonstrated an 82% reduction in shunt occlusion and shunt related mortality in pediatric patients with cyanotic congenital heart defects[8]. The use of ePTFE grafts to palliate cyanotic defects has become routine based on their excellent performance and ease of use. Prior to the availability of ePTFE grafts, surgeons would connect the artery supplying oxygenated blood to the arm

[6] P. Syamasundar Rao. Diagnosis and Management of Cyanotic Congenital Heart Disease: Part I. http://medind.nic.in/icb/t09/i1/icbt09i1p57.pdf

[7] Begovac PC, Thomson RC, Fisher JL, Hughson A, Gällhagen A. Improvements in GORE-TEX® Vascular Graft performance by Carmeda® BioActive Surface heparin immobilization. European Journal of Vascular & Endovascular Surgery 2003;25(5):432-437

[8] Ashfaq A, Soroya MS, Iyengar A, Federman M, Reemtsen BL. Heparin-Coated Grafts Reduce Mortality in Pediatric Patients Receiving Systemic-to-Pulmonary Shunts. Pediatric Cardiology. 2018;39(3):473-477.

directly to the artery carrying blood to the lungs; sacrificing blood flow to the infant's arm. This technique (Baylock-Taussig shunt) is now considered outdated since the availability of ePTFE shunts.

Without ePTFE grafts, surgeons would have no available grafts to treat these babies [redacted] and untreated cyanosis could result in infant death. No synthetic alternatives have emerged as clinically successful. This highlights the unique biocompatibility of ePTFE in blood-contact applications, and the need for it to remain on the market for use in medical device applications.

Septal Occluders

Septal Occluders are another example of a critical need raised by the German Association for Pediatric Cardiology and Congenital Heart Disease. The Association personally appealed to medical device manufacturers to provide essential implantable devices due to critical shortages of occluder devices needed to treat neonatal and pediatric patients[redacted].

The GORE® Septal Occluder is an implantable medical device requiring minimally invasive surgery which provides unique benefits to doctors closing atrial septal defects (heart defect) and patent foramen ovales (hole between the upper chamber of the heart). Many of these patients are newborns or young children. While there are alternatives available, it is important to note that Gore's devices differ from competitors because the material design and characteristics allow for treatment of a wider range of atrial septal defects across a broader spectrum of patients. Alternative products use large amounts of woven metal in their devices which may cause the device to erode through the heart and aorta. This requires open heart surgery to correct which increases the risk of complications and death. The expanded PTFE-based device uses a minimal amount of metal to produce a softer, more conformable device which decreases the chances of eroding through the heart and therefore reducing the need for further, more risky surgery.

b) Medical Device Uses

Gore only manufactures devices used in a few of the sub-uses identified by the Dossier Submitters. However, this should be considered just a sampling of the devices that warrant derogation pursuant to an implantable and invasive medical devices derogation. Even though every type of medical device is not articulated explicitly, the rationale for derogation applies to the entire universe of devices in use or in development regulated by the MDR. For additional detail on devices within those sub-uses where Gore has direct experience, commercially available medical products are summarized in Table 1, including examples of the disease states treated and fluoropolymer materials used.

Table 1. Summary of Selected Sub-uses of Implantable and Invasive Medical Devices

Type of Device		Example Disease States Treated (Simplified)	Fluoropolymer Materials Used
Implantable Medical Devices*	Interventional cardiac occluders	Atrial septal defects (ASDs) (i.e., a hole in a wall between the heart's upper chambers)	• PTFE occluder material • [redacted]
	Interventional endoprostheses	Aneurysms (i.e., a bulge in a blood vessel caused by weakening of the vessel wall) Peripheral Arterial Disease (PAD)/Critical Limb-Threatening Ischemia (CLTI) (i.e., loss of blood flow to lower limbs due to narrowing/blockage of blood vessels, may result in limb amputation)	• PTFE or PTFE/FEP grafts and covers that serve as a biocompatible blood conduit [redacted]
	Surgical vascular grafts	Diseased (e.g., PAD/CLTI- above) or injured (e.g., due to ongoing dialysis) blood vessels that need replacement or bypass	• PTFE graft base tube [redacted]
	Cardiovascular patches	Pediatric and adult patients born with a heart defect requiring patching to repair.	• PTFE biocompatible material/surface [redacted]
	Hernia meshes	Repair of hernias (i.e., bulge of an organ or a part of an organ through the wall of the cavity that normally contains it)	• PTFE biocompatible material/surface [redacted]
	Surgical sutures	Close wounds and attach devices or tissues to other tissue. Replace heart valve connective tissues.	• PTFE monofilament suture
Non-Implantable (Invasive) Medical Devices**	Introducer sheaths	Often used to insert or deploy implantable medical devices such as some of those listed above. Often enable minimally invasive endovascular (as opposed to open/surgical) procedures.	• PTFE sheath liner [redacted]
	Balloon catheters		• PTFE balloon protector
	TIPS needles		• FEP needle protector

*Class III per EU MDR 2017/745
**Class IIb and III per EU MDR 2017/745

[redacted]

New Device Development

In addition to commercially available devices, there are numerous new devices in development that may provide therapeutic solutions where device options do not currently exist. Examples of ongoing development work include, but are not limited to, expanded or next-generation offerings of some of the Table 1 products, as well as implanted membranes to deliver cell replacement therapies.

There are multiple unmet needs, known to Gore, that may be addressed by ongoing implantable device developments that may provide critical lifesaving and risk-reducing medical treatment and may help prevent serious risks and complications, such as the following (non-exhaustive list):

- The need for open surgery which typically corresponds with:
  - Additional risk of infection (often corresponds with higher morbidity)
  - Increased procedural time (often corresponds with increased length of exposure to anaesthesia)
  - Increased hospital stay length (often corresponds with higher healthcare practitioner burden, higher risk of infection or reintervention, increased emotional/mental health impacts, and significantly increased financial cost of treatment)
- Amputation of limbs due to peripheral vascular disease (narrowing/blockage of peripheral arteries)
- Tissue erosion, or other adverse interactions of the implant with the patient's organs/native tissue
- Reinterventions (additional surgeries/procedures) needed due to failed, or otherwise inadequate, prior procedures/treatments
- Stroke due to rupture of aneurysms (bulging, weakened area of a blood vessel) or due to septal defects (hole in a wall between the heart's upper chambers)
- (Premature) Death due to disease progression

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By: OAH on 11/28/2023
Michael Blume Attachment

Minnesota Pollution Control Agency

Subject: Solvay Response to "Planned New Rules Governing Reporting by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS)"

November 20, 2023

Solvay America, Inc. ("Solvay") appreciates the opportunity to provide the following comments to the Minnesota Pollution Control Agency open rulemaking entitled, "Planned New Rules Governing Reporting by Manufacturers Upon Submission of Required Information about Products Containing Per-and polyfluoroalkyl substances (PFAS)." Solvay seeks to be a partner to build an economy that is diverse, resilient, and competitive while meeting economic, national security, environmental, and climate objectives.

Solvay is a global leader in advanced materials and specialty chemicals. Our tailor-made products are critical for creating lighter-weight aircraft, electric vehicles, renewable energy installations, semiconductors, consumer goods, healthcare, and other essential products for a more sustainable society. In the United States, Solvay employs over 5,600 people working in 35 sites across 25 states. Our U.S. footprint includes our composite materials manufacturing site in Winona, Minnesota where we have 265 employees. This site is critical to the American aerospace and defense industrial base and provides irreplaceable materials for military and civilian applications.

We support all measures to keep the public safe, and our air and water resources clean for generations to come. We applaud the state's actions to find ways to appropriately regulate PFAS. Further, we are encouraged by many of the specific steps that would address some of the more common and higher-risk routes of potential environmental and human health exposure. As a global leader in fluoropolymer manufacturing, Solvay 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.

Solvay's Partnership with the U.S. Department of Energy

In October 2022, Solvay 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 fluoropolymer production facility in Augusta, GA.[1] This facility has the potential to provide enough polyvinylidene fluoride (PVDF) 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.

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[1]See https://www.energy.gov/sites/default/files/2022-10/DOE%20BIL%20Battery%20FOA-2678%20Selectee%20Fact%20Sheets%20-%201_2.pdf

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

Solvay 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 Solvay'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 Solvay 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 soluble in water, nonmobile, nonbioavailable, nonbioaccumulative, and nontoxic."[4] Due to these properties, many of these substances are unable to penetrate biological structures, are not water soluble, and do not transform into legacy PFAS, like PFOA and PFOS. 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]

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[2] http://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf

[3] For example, see Solvay'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.

[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.*

Over the last several years, Solvay invested millions of dollars to advance our technology where we now produce all of our fluoropolymers in the U.S. without the use of fluorosurfactants. Fluorosurfactants are non-polymeric process aids that help ingredients work together in manufacturing some fluoropolymers and historically included PFOA and PFNA that are among the PFAS substances under the most intense spotlight. Solvay was able to invent a next generation, more sustainable range of specialized fluoropolymers without the use of fluorosurfactants while keeping the unique properties of these products, as required for special applications.[6]

One of the biggest threats to Solvay'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."[7]

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.

Confidential Business Information (CBI)

Solvay 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 Solvay's materials is a key differentiating factor between competing articles in the marketplace. As such, our

[6] https://www.solvay.com/en/innovation/science-solutions/pfas.
[7] *See https://www.acq.osd.mil/eie/eer/ecc/pfas/docs/reports/Report-on-Critical-PFAS-Substance-Uses.pdf*

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).

Solvay 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, Solvay recommends the following for consideration or to be included in a final rulemaking:

Duplicative State and Federal Reporting:
Moreover, the 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.

Solvay 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 delaying this rulemaking until the information required by the EPA is available for consumption. 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:
Solvay 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.[8] 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.

Data and Report Formatting:
The statute instructs the MPCA to collect, "the amount of each PFAS, identified by its chemical abstracts service registry number" and, "a brief description of the product, including a universal product code (UPC), stock keeping unit (SKU), or other numeric code assigned to the product." Solvay requests that the MPCA allow respondents to use alternatives to chemical abstracts service registry (CAS) numbers, specifically the unique five-digit accession number (ACCNO) and a generic chemical name for each confidential chemical identity on the TSCA Inventory. Accession numbers are a key mechanism for industry and government to collaborate on chemical policy while maintaining sensitive and proprietary information secure.

Furthermore, in many cases, an UPC or an SKU may not be available for respondents and the available uniquely identifying information is considered a "trade secret," e.g. the combination of material grade and customer. The MPCA should provide respondents the flexibility to generate or be assigned a unique numeric code in lieu of an UPC or SKU.

[8] 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 11/28/2023
Steve Barthel Attachment

MINNESOTA GROCERS ASSOCIATION

1360 Energy Park Drive, Suite #110 • St. Paul, MN 55108 • 651-228-0973 • 1-800-966-8352 • www.mngrocers.com

To: Minnesota Pollution Control Agency (MPCA)
Date: November 28, 2023

Subject: PFAS in Products Reporting Rule

The Minnesota Grocers Association (MGA) appreciates the opportunity to submit comments regarding the Minnesota Pollution Control Agency's (MPCA) drafting of rules governing the reporting by manufacturers of required information about products containing per-and polyfluoroalkyl substances (PFAS).

The MGA is the only state trade association representing the food industry of Minnesota from farm to fork. We have over 300 members with over 1,300 locations statewide. Our association includes retailers, food producers, manufacturers, brokers, and wholesaler member companies. The MGA is tasked to support and represent industry while advancing the common good of our great state.

As a statewide trade association that supports an industry that is greatly impacted by these rules, we believe that the final guidance needs to create a reasonable structure that can be executed in real world situations. They should be concise and mindful of the multiple layers of supply chain that are affected by the outcomes.

We ask the MPCA to create a working group/committee of stakeholders to consult and provide guidance as the rules are developed. By engaging and consulting with those directly involved in the manufacturing and distribution of products containing PFAS we can build a structure that safely and responsibly produces rules which achieve the stated goals while avoiding misperceptions, disruptions, and unintended consequences.

It is critically important that Minnesota does not become a regulatory island. This can be achieved by building off the work of the Environmental Protection Agency (EPA), and states that have already begun implementation of similar PFAS regulations. Creating uniformity for manufacturers and distributors will avoid confusion, redundancies, and allow for consistency in compliance.

As part of the ongoing work there are several definitions within the law that require clarification. The definition of PFAS cannot be too broad and must discern between different threat levels - there are many variables within the manufacturing process. The definition should also be consistent and not conflict with federal definitions used under Toxic Control Substances Act (TSCA) or used by the Food and Drug Administration (FDA).

To foster successful implementation of new reporting rules and to create awareness for both businesses and consumers, we urge the MPCA to include multiple educational opportunities, issue clear guidance, and develop realistic timelines for enactment.

We appreciate the opportunity to provide comments and look forward to participating in the formation and implementation of the new rules. Please do not hesitate to contact me with any questions.

Sincerely,

Jamie Pfuhl
President
Minnesota Grocers Association

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Advanced Medical Technology Association

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November 28, 2023

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 PFAS in Products Reporting Rule

To Whom It May Concern,

AdvaMed, the MedTech Association, submits this letter in response to the Minnesota Pollution Control Agency's (MPCA) Request for Comment to the pre-draft of the regulation to implement the PFAS in Products Reporting Rule ("the Rule") as directed by Minnesota Session Law - 2023, Chapter 60, H.F. No. 2310. AdvaMed is the largest national trade association representing nearly 450 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 the first state 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).

PFAS in Medical Technology

Per- and polyfluoroalkyl substances, known as PFAS, are a broad class of over 10,000 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 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 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's 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.

Reporting and Compliance Challenges

In a supply chain that is eight to ten 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 never be able to achieve 100% disclosure to MPCA. While this information is provided to 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.

It may take device manufacturers upwards of several years to even identify where in the supply chain regulated PFAS substances occur before they can attempt to mitigate and change their processes. There is no "commercially available" technique that can assess all 10,000+ PFAS chemicals at one time.

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 10,000 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 10,000+ 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.

Many medical technology manufacturers are global companies already complying with EU REACH requirements and reporting mandates for several years. AdvaMed recommends that MPCA review how the EU Waste Frame Directive and the associated SCIP database is structured and consider harmonizing its reporting mandates to ensure continuity, accuracy, and utility of the reported data.

Response to Questions in RFC

Please find below AdvaMed's responses to MPCA's specific questions and additional comments on the pre-draft of the PFAS in Products Reporting Rule.

Are there definitions in subdivision 1 for which clarification would be useful to understanding reporting responsibilities?

AdvaMed seeks clarity on the following definitions:

A. Clarify whether a "medical device" falls under subcategory O and whether this includes a device and drug combination product such as a syringe filled with medicine.
    1. MPCA must clarify if the manufacturer of the drug or manufacturer of the device is responsible for reporting data for the combination product.

B. Definition of "Perfluoroalkyl and polyfluoroalkyl substances" or "PFAS":
    1. Will the MPCA publish a list of PFAS and corresponding CAS numbers that are included within the statutory definition for purposes of reporting?
    2. Are PFAS polymers covered by the statutory definition?
    3. Would a substance such as CAS 771-56-2, which is a fluorinated aromatic, with each carbon atom of the ring containing just **one**

fluorine atom (i.e., one C-F bond, per carbon atom--there are no -CF2- or -CF3 groups), be included in the statutory definition of PFAS (i.e., would the carbon atoms of this ring be regarded as "fully fluorinated")?

C. Definition of Product:
    1. Does the definition of "product" include a product's packaging? Based on legislative definition, a product's packaging is not included in the definition. If MPCA asserts otherwise, please provide legislative justification.
    2. Does the definition of "product" include products used for research and development (e.g., clinical trials of FDA regulated products, such as medical devices, laboratory testing, and other scientific experimentation)? Based on the legislative definition, it appears that products that are in the research and development or clinical trial phase are out of scope of the reporting rule. If MPCA asserts otherwise, please provide the legislative definition. This clarification would align with other chemical reporting rules, including EU REACH.

Are there terms or processes in subdivision 2 for which clarifications will help reporting entities determine reporting status or data-gathering process?

AdvaMed seeks clarity for the level of due diligence required of a manufacturer and the communication required with their supply chain, specifically, when it comes to (1) complex products/components that are already pre-assembled and, (2) when determining "intentionally added PFAS".

If a manufacturer of a complex article (e.g., a surgical console) sources parts manufactured by another entity, the complex article manufacturer should not be responsible for reporting intentionally added PFAS within the part manufactured by another entity. If this scenario of reporting is required, due diligence (requesting information from the supplier) should be sufficient to satisfy the requirement.

Depending on the depth of supply chain communication required for complex article manufacturers, sufficient time will be needed to map supply chains, if a manufacturer needs it.

If a PFAS substance was added to a material several layers upstream in the supply chain (e.g., wire coating), the process to discover that and report its presence will be onerous. Specifically, when a manufacturer has no knowledge of the presence of a PFAS substance and has not included its use in any product specification, this should not be considered "intentionally added". Of note, the Environmental Protection Agency's (EPA's) response to comments in the recently published and final TSCA PFAS Reporting Rule (Federal Register Vol. 88, No. 195, pg. 70516)

indicates that a manufacturer of articles should rely on "reasonable inquiry within the full scope of their organization" but isn't obligated to survey the entire supply chain in order to discover uses of PFAS in their articles.

The MPCA should include a "known to or reasonably ascertainable by" the manufacturer standard of care for purposes of identifying and reporting products that contain "intentionally added PFAS," - similar to what EPA recently adopted in the TSCA PFAS reporting rule. According to EPA, "known to or reasonably ascertainable by" is defined to include "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. EPA states that this reporting standard requires reporting entities to evaluate their current level of knowledge of their manufactured products as well as evaluate whether there is additional information that a reasonable person, similarly situated, would be expected to know, possess, or control. This reporting standard "carries with it an exercise of due diligence, and the information-gathering activities that may be necessary for manufacturers to achieve this reporting standard may vary from case-to-case."

Examples of types of information that are considered to be in a manufacturer's possession or control or that a reasonable person similarly situated might be expected to possess, control, or know include files maintained by the manufacturer, such as marketing studies, sales reports, or customer surveys; information contained in standard references showing use information or concentrations of chemical substances in mixtures, such as a safety data sheet or a supplier notification; and information from the Chemical Abstracts Service. If particular information cannot be derived or reasonably estimated without conducting further customer surveys, it would not be "reasonably ascertainable" to the manufacturer.

EPA also notes that if a manufacturer does not have actual data (e.g., measurements or monitoring data) to report, the manufacturer should consider whether "reasonable estimates" of such information are ascertainable. "Reasonable estimates" may rely on approaches such as mass balance calculations, emissions factors, or best engineering judgment. If manufacturers do not know or if they cannot reasonably make estimates for certain data elements, except for production volumes, they may indicate such information is "not known or reasonably ascertainable" to them in lieu of the requested estimate or range.

The EPA's PFAS reporting approach acknowledges the complexity of supply chains, particularly for product components, that suppliers will seek to protect their confidential business information pertaining to formulation, and the challenges that manufacturers may have in testing product components that are purchased from a supplier and used in the manufacturer's product (such as complex diagnostic tools and robotic instruments)

We recommend that MPCA adopt EPA's reasonable standard. Failing to do this will result in the definition of "intentionally added" becoming exceedingly difficult to determine independently. It will also result in it being nearly impossible to subsequently verify whether one or more suppliers in the supply chain "intentionally added" the substance without disclosing it to the manufacturer.

Based on broad legislative definition of PFAS, there also is likelihood that a covered PFAS may not have a CAS number. Also, a manufacturer of a product component may indicate that PFAS is present but may not include the detailed information for purposes of protecting confidential business information. The MPCA's regulations must consider these issues (which are similar to the issues identified by the EPA when it adopted its "known to or reasonably ascertainable by" the manufacturer standard for reporting under TSCA).

Given the challenges with complex medical technologies described above, identifying intentionally added PFAS in product components, and challenges in reporting PFAS amounts as discussed below, AdvaMed urges MPCA to consider a delayed timeline for reporting PFAS in certain complex products such as medical technology and, in particular for, "product components". Component suppliers will likely focus on their own compliance before providing necessary information to their customers. Their reports may inform full product reporting for medical technology manufacturers and will help avoid duplicative reporting. Additional time to implement reporting for "product components" will ease the regulatory compliance burden while still providing MPCA with reports on products containing intentionally added PFAS.

AdvaMed seeks clarity from MPCA on what a commercially available analytical method means. We recommend that a method which is developed and validated by the manufacturer qualify under the Rule. AdvaMed believes that this flexibility should be maintained, as different companies have different approved methods to test the thousands of types of medical devices and technology that manufacturers sell in the state of Minnesota.

Under Subd. 2(a) "Information required", AdvaMed seeks clarity on the following points:

1. For (1), would providing the UPC alone, be enough to satisfy a "brief description of the product?" We recommend defining this field to ensure consistency, e.g., IVD/MD or something more descriptive from a technical file.
2. For (2), what does purpose mean? Is it the function of the PFAS in the product or its component (e.g., to provide lubricity) or is it the role that this function then plays in the product (to allow insertion into the vasculature, without perforating the blood vessel)?

3. For (3), manufacturers need more information on what it means to report PFAS "falling within a range". As noted above, a manufacturer confirming exact concentrations or concentration ranges in products or product components obtained from suppliers has challenges. The MPCA should consider the elements EPA's TSCA PFAS reporting approach when testing data from suppliers is not available.
    a. Please confirm whether "amount" means the weight (i.e., in grams, kilograms, etc.), volume (i.e. ml, liters, etc.) or the concentration of PFAS (i.e., percentage, parts per million, etc.)?
    b. Can the quantity be a range or less than (<) mass quantity? ECHA recommends a tiered approach where total fluorine is measured and if it is above a certain threshold then further investigation on PFAS is conducted (see page 184, reference[1]).
    c. Does amount of PFAS refer to the total amount in each product SKU? Is it the total amount of PFAS summarized across all sales of a product category each year?
    d. AdvaMed requests clarity for a de minimis standard or threshold for "intentionally added PFAS". Certain testing methods could trigger the presence of PFAS even if it's from the testing container and not the product itself.
4. For (4), does the contact person need to be a US employee?
5. For (5)(b), does this mean that approval must be sought on a case-by-case basis, or will MPCA provide guidance for products can be combined and reported under a common category. For example, what if a given category of devices has the same essential ingredients, but those ingredients vary in concentration, results in many unique SKUs--could these be combined and reported as a category?
6. For (5)(c), as referenced above, what constitutes a significant change? Does significant change mean change of PFAS chemical or increase/decrease of PFAS in the product?

In Subdivision 2(b), there is the potential to report by type of product or category rather than each individual product. However, it requires the approval of the commissioner. Clarification is needed regarding the logistics of this approval process and the limitations within this process. For instance, would all product types or categories have to have the same PFAS substance(s) at the same concentration or within the same range? For example, if a hypothetical company knows that the entire line of their instruments use PTFE tubing and gaskets, could this be reported once?

What will be considered a "significant change" when providing updated reports? Will it be based on a new type of PFAS or concentration changes? For article manufacturers, a small change in concentration of a component supplied several layers upstream may be difficult to verify.

How should the MPCA balance public availability of data and trade secrecy as part of the reporting requirements?

AdvaMed respectfully requests that the amount of PFAS (production volumes, concentrations, etc.) that is reported to MPCA not be disclosed in any public-facing database. This type of information can be used to back-calculate and ultimately estimate the sales of that product, which is confidential business information. This may harm a given manufacturer's competitive advantage if their competitor were to have this knowledge. Additionally, we would request that the name of the responsible person and their associated contact information also be protected as confidential, and therefore not disclosed publicly, otherwise the public disclosure may lead to individual violations of privacy.

AdvaMed requests that manufacturer names, product identifiers, confidential formulas, UPC etc., should not be shared publicly. If any data is shared with the public, the MPCA should summarize and anonymize the data to the extent practical to avoid inadvertently disclosing any data that could be used to identify specific products or companies, at least in the case of B2B or professional use.

Are there any terms used in subdivision 3 that should be further defined or where examples would be helpful?

AdvaMed would appreciate MPCA providing examples for Declarations of Compliance from suppliers and supplier engagements language, especially in cases when a manufacturer of a complex article is responsible.

Under the requirements for waivers and extensions, we recommend that manufacturers should be allowed to use composition data for products already disclosed under federal regulation as justification for requesting a waiver.

Are there specific portions of the reporting process that should not be defined through guidance or the development of an application form?

We recommend that MPCA refrain from specifying the method a manufacturer uses to develop reporting information. It would be inefficient to define any parameters beyond those which have been set by the EPA.

Other questions or comments relating to reporting or the process of reporting?

AdvaMed seeks further details regarding how MPCA will protect the confidentiality of the information manufacturers submit.

Regarding the format for reporting, will MPCA develop a separate electronic portal for submission? For example, the New England Waste Management Officials Association (NEWMOA) uses a secure portal for Mercury reporting. AdvaMed recommends that MPCA allow any online reporting method to be tested and give manufacturers the opportunity to provide feedback on the electronic portal before data reporting goes into effect on January 1, 2026. This will help avoid confusion, mis-reporting, or other technical issues that could be addressed in advance.

Regarding the cost of compliance and testing, AdvaMed recommends that MPCA allow for manufacturers to reference out to the PFAS manufacturer if they have reported already to avoid duplication.

Conclusion

In closing, we offer two final recommendations below.

First, in addition to assisting in the technical aspects of reporting with this RFC, 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.

The Department of Defense recently reported to Congress that "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." 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.

Second, we urge 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 confidentiality 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 in advance of drafting the formal PFAS in Products Reporting Rule. We look forward

to working with MPCA and being a technical resource on this complex and precedent setting rulemaking.

Sincerely,

Roxy Kozyckyj
Director, State Government & Regional Affairs
AdvaMed

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Minnesota 55164-0620

Re: Planned New Rules Governing Data Collection for the Minnesota PFAS in Product Program (Implementation of Amara's Law)

Revisor's ID Number R-4828
OAH Docket No. 65-9003-39507

Dear Commissioner Kessler,

The Association of Equipment Manufacturers (AEM) appreciates the opportunity to comment on the Minnesota Pollution Control Agency's (MPCA) announced intent to begin rulemaking; *PFAS in Products Reporting Rule*, hereafter referred to as the Planned 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.

AEM is the North American-based international trade group representing off-road 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 off-road 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.

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 requests that MPCA take into consideration the following points:

1. Provide adequate and appropriate amount of time for the off-road equipment manufacturing industry to identify, collect, and report the data regarding PFAS found in this industry.
2. Harmonize the definition of PFAS with EPA's structural definition.
3. Clarify definitions and provide industry with a reporting threshold to enable the data collection efforts.
4. Adopt the EPA's model for Confidential Business Information (CBI) protections.
5. Provide clarity regarding processes and procedures for requesting an extension of the reporting deadline and waiving information requirements with the commissioner.
6. Clarify the process for defining and determining the "currently unavoidable use" for PFAS.

Provide adequate and appropriate amount of time for the off-road equipment manufacturing industry to identify, collect, and report the data regarding PFAS found in this industry.

The recently promulgated Minnesota Session Law[1], passed by the Minnesota State Legislature, requires all manufacturers of a products sold, offered for sale, or distributed in the state of Minnesota that contain intentionally added PFAS to submit number of data points to the commissioner of the MPCA by January 1, 2026. This data includes, a brief description of the product, the functional use of the PFAS included in the product or product components, the quantity of PFAS, assigned chemical abstract service (CAS) number, the identification information of the manufacturer, and any other information requested by the commissioner.

Any timeline to comply with the obligations of the Planned Rule need to account for the tremendous work needed to gather, collate, and submit the required data. The definition of PFAS[2] adopted in Amara's law is overly broad, unnecessarily including thousands of individual PFAS substances under the scope of coverage. The lack of a de minimis threshold ensures manufacturers need to account for trace amounts of PFAS in their products, which may require expensive lab testing to confirm.

Furthermore, currently existing analytical test methods for detecting PFAS and overall global laboratory testing capacity cannot possibly accommodate the sheer volume and variety of PFAS across all industries as required under this rule. There are no standard test methods found to measure PFAS in most uses of electronics and electronic equipment incorporating semiconductors, fluorinated gases and refrigerants, medical devices, oil gas and mining applications, metal plating, flame retardants and resins. In total, there are only standard methods for detecting between 10 and 30 different unique PFAS chemicals out of the over 14,000 different PFAS known to exist. Moreover, the typical cost for a battery of tests to identify the chemical composition on an individual solid component costs roughly $10,000 for a final report. With around 250 different product types in the off-road sector, each containing roughly 100,000 different components, and roughly 1,000 different equipment manufacturers required to test their products to determine the location, type, and quantity of PFAS; the total cost of testing will exceed the total value of the entire off-road industry by orders of magnitude. The total testing costs to industry in general will be much higher, as this estimate is only applicable to the off-road equipment sector.

Therefore, the PFAS definition in Amara's Law promulgates an overly broad, costly, and impossible reporting requirement, which duplicates and potentially conflicts with an ongoing EPA PFAS reporting rule recently promulgated[3] at the Federal level. This definition, as written, leaves no viable compliance pathway for companies looking to sell into the State of Minnesota.

Next, as AEM indicated in their comments on the EPA's PFAS recordkeeping and reporting rule,[4] full compliance would take a minimum of three (3) years to achieve (See Annex I below). This estimate is based on several assumptions, such as *de minimis* reporting thresholds, a limited and pre-defined list of PFAS substances, and CBI provisions for industry to realistically comply with this timeline. The off-road equipment industry builds hundreds of products, some with as many as 100,000 unique parts, purchased from a supply chain that can run up to 20 layers deep. Furthermore, the off-road industry does not currently possess an industry wide reporting system, similar to those found in other sectors. AEM's member companies are working on evaluating their supply chains to

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[1] Minnesota Session Law - 2023, Chapter 60, Article 3, Section 21, (Minnesota Statutes 116.943) Subdivision 2

[2] "'Perfluoroalkyl and polyfluoroalkyl substances' or 'PFAS' means a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom."

[3] https://www.federalregister.gov/documents/2023/10/11/2023-22094/toxic-substances-control-act-reporting-and-recordkeeping-requirements-for-perfluoroalkyl-and

[4] https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0549-0158

determine whether and to what extent PFAS chemicals are contained in their current product offerings. However, most companies in the wider supply chain remain unaware of the host of new PFAS reporting requirements seen at the global level. Many of these same companies do not have the subject matter expertise to report on the chemical composition of the articles they manufacture. The lack of a *de minimis* provision and the thousands of unique chemicals that fall under the PFAS family only exacerbates these challenges. The complexities of the off-road industry's supply chain combined with the widespread supplier education issues will foster widespread data quality problems, resulting in missing, poor, and inaccurate data from the equipment manufacturing sector.

These issues, endemic throughout the supply chain, are compounded by the compliance and operating environment many of these companies operate in. The off-road industry does not specify parts and components based on chemical or material content. Parts are specified for safety and performance characteristics. For this reason, the manufacturing supply chain lacks the data infrastructure needed to collect this information on short notice, which is only exacerbated by the sheer number of PFAS chemicals that exist (>10,000 unique chemical entities). Furthermore, smaller manufacturers of components often do not store chemicals above the reporting thresholds required under the EPA's CDR or SARA Section 313 reporting rules. As a result, many companies in our supply chains never cultivated the systems or expertise needed to gather and store the relevant chemical data for the components and parts they manufacture and distribute. Other companies, who do manufacture PFAS chemicals and may understand the reporting requirements, have little to no CBI protections leaving them hesitant to share their data until rules come into force. To protect their businesses, many bulk chemical manufacturers choose to conceal the composition of their products, delaying and complicating downstream reporting, making data collection an impossible task in the timeframes outlined in Amara's Law.

Recommendation:

The off-road equipment sector needs an appropriate amount of time to identify, collect, and report the data regarding PFAS found in the off-road equipment sector. Without an appropriate transition period, the data collected will be low quality and unreliable for the purposes of crafting future responsible public policy. The minimum time equipment manufacturers would need to comply with this rule is three (3) years. This estimate is based on several assumptions, such as *de minimis* reporting thresholds, a limited and pre-defined list of PFAS substances, and CBI provisions for industry to realistically comply with this timeline. Deadlines for reporting that provide inadequate lead times produce unintended consequences, including both under-reporting and over-reporting of PFAS in products.

Harmonize the definition of PFAS with EPA's structural definition

Definitions in subdivision 1:

The definition of PFAS found in subdivision 1 of the Minnesota Session law is overly broad and will create confusion for reporting entities. The definition used in subdivision 1 states that "'Perfluoroalkyl and polyfluoroalkyl substances' or 'PFAS' means a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom."[5] This definition will include tens of thousands of different unique chemical entities, many of which do not have Chemical Abstract Service (CAS) registry numbers. In contrast, the EPA uses a more distinct and workable definition in their PFAS

[5] Minnesota Session Law - 2023, Chapter 60, Article 3, Section 21, (Minnesota Statutes 116.943) Subdivision 1 (p).

Recordkeeping and Reporting Rule[6]. The EPA defines PFAS as including at least on the following three structures:

• R-(CF_2)-CF(R′)R″, where both the CF_2 and CF moieties are saturated carbons;

• R–CF_2 OCF_2 -R′, where R and R′ can either be F, O, or saturated carbons; and

• CF_3 C(CF_3)R′R″, where R′ and R″ can either be F or saturated carbons.

Harmonizing reporting standard definitions with other regulatory bodies helps industry comply with rules. Limiting the number of reportable chemicals also gives reporting entities an achievable goal to meet. AEM recommends that MPCA refine and harmonize this definition with that of EPA.

Clarify definitions and provide industry with a reporting threshold to enable the data collection efforts

Definitions in subdivision 2:

Under subdivision 2 (3), the law states:

> *"[…] 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 […]."*[7]

"*[F]alling within a range approved for reporting purposes by the commissioner."* This phrasing is unclear to AEM and our member companies. Does this range refer to a reporting threshold? If so, what process would the commissioner use to determine an appropriate reporting threshold? Answers to these questions would provide a tremendous amount of regulatory clarity to industry.

Furthermore, as stated above, current analytical test methods for detecting and identifying PFAS chemicals, especially test methods for identifying PFAS chemicals in articles and solid materials, remain extremely limited. Product manufacturers will not be able to use these existing test methods to produce any useful information at scale for reporting purposes. The only current method available to industry is to survey the supply chain for any chemical data they may have. With these considerations in mind, providing a useful reporting threshold or *de minimis* concentrations would help reporting entities with their compliance responsibilities.

Recommendation:

To support industry's compliance with these procedures, please provide guidance and definitional clarity on the language in Subdivision 2 (3). Furthermore, to make it possible for industry collect and report useful data to the MCPA, please provide a viable reporting threshold for regulated entities.

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[6] https://www.federalregister.gov/documents/2023/10/11/2023-22094/toxic-substances-control-act-reporting-and-recordkeeping-requirements-for-perfluoroalkyl-and

[7] Minnesota Session Law - 2023, Chapter 60, Article 3, Section 21, (Minnesota Statutes 116.943) Subdivision 2 (3).

Having a *de minimis* threshold concentration, is extremely useful and provides tremendous clarity when asking for information from suppliers.

Adopt the EPA's model for Confidential Business Information (CBI) protections

Trade secret information creates complex issues for reporting entities at the end of the supply chain. Most chemical manufacturers do not reveal CBI chemical identity information until they are legally required to do so. This significantly slows down the AEM members' efforts to collect information in order to prepare to timely comply with the reporting requirement. Without adequate legal protection of CBI, or a regulatory mandate requiring chemicals manufacturers to provide data to their customers and other actors further down the supply chain, the chemical manufacturers will not reveal the identity of the PFAS substances they manufacture and sell, making compliance with the subject rule impossible for the original equipment manufacturers (OEMs).

This ensures that OEMs, with supply chains that run up to 20 layers deep, will need to wait until that information can filter down through the supply chain to the end-product manufacturer. Assuming the supply chain has the sophistication to handle and communicate this information, this entire process can take months and in some cases years to yield results. However, despite this practical impossibility, based on the requirements in Amara's Law, OEMs will, in the meantime, still be liable for the products they sell, maintenance, and service in Minnesota.

Recommendation:

To provide product manufacturers with a viable compliance pathway, the MPCA needs to ensure companies can communicate their CBI data in a safe and effective process. AEM suggests that MPCA adopt the EPA's model for CBI protections. This action would provide clarity and certainty for industry when working to comply with new legal and regulatory requirements.

Provide clarity regarding processes and procedures for requesting an extension of the reporting deadline and waiving information requirements with the commissioner

Definitions in Subdivision 3[8]:

Under Subdivision 3:
"(a) *The commissioner may waive all or part of the information required under subdivision 2 if the commissioner determines that substantially equivalent information is already publicly available. The commissioner may grant a waiver under this paragraph to a manufacturer or a group of manufacturers for multiple products or a product category.*

and

(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 requirements."*

Recommendation:

AEM requests clarity regarding these processes and procedures for requesting an extension of the reporting deadline and waiving information requirements with the commissioner. As demonstrated

[8] Minnesota Session Law - 2023, Chapter 60, Article 3, Section 21, (Minnesota Statutes 116.943) Subdivision 3.

in the above sections, the off-road equipment industry is very complex and may require additional time to adequately comply with the provisions in Amara's Law. Understanding how this process works, and what the procedure will be for making these types of requests will provide clarity and certainty for the off-road equipment sector.

Clarify the process for defining and determining the "currently unavoidable use" of PFAS

Under Subdivision 5(c), products containing intentionally added PFAS will be restricted from sale or distribution in the state of Minnesota, unless the commissioner has determined by rule that the use of PFAS in a product is a currently unavoidable use. The term "currently unavoidable use" is defined in subdivision 1(j) to mean that 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.

Equipment manufacturers design their products to last for decades under extremely harsh, demanding, and arduous work environments crucial for the operation and success of the U.S. economy. Equipment materials, parts, and components need to meet rigorous design and testing requirements to ensure critical product functions continue to operate safely and effectively on the jobsite. With their many useful chemical and physical traits, PFAS provide crucial characteristics necessary to meet various equipment design challenges and regulatory requirements.

Properly manufactured equipment must meet various design characteristics to ensure they operate in a safe, reliable, continuous, and efficient manner. The mechanical functions inside a off-road vehicle exposes parts and components to various stressors:

- Pressure - various systems, such as the hydraulic and engine systems, experience extreme pressure environments up to 500 bar.
- Temperature - the engine compartment and exhaust system operate at temperatures as high as 800 °C.
- Chemical - seals interact with various fluids, requiring a high degree of chemical and corrosion resistance to ensure the continued operation of exposed parts.
- Mechanical – machines possess a high degree of mechanical wear and tear, sealing parts must survive the shear forces due to the mechanical movement of the equipment.

PFAS are the only chemical family known to provide the combination of thermal stability, chemical resistance, low frictional characteristics, and sealing capabilities required to operate in this harsh machine environment. Several PFAS chemicals, known broadly as fluoropolymers, which include Polytetrafluoroethylene (PTFE), Fluoroelastomer (Viton), and Polyvinylidene fluoride (PVDF) possess many of these crucial chemical traits and have no known substitutes, making them irreplaceable for the off-road equipment industry. Some of these parts, components, and systems using irreplaceable PFAS chemicals include (but are not limited to): sealing technologies, fluids, friction devices, electronics and electronic components, and alternative power applications, among others.

Replacing PFAS with inappropriate material substitutes would compromise the functionality of corresponding parts and components, ensuring increasing failure rates, fluid leaks, safety issues, and shorter vehicle lifetimes.

<u>Recommendation:</u>

Due to the variety and criticality of PFAS used in the off-road equipment sector, AEM requests that MCPA clarify the process for defining and determining a "currently unavoidable use" case for PFAS.

This effort will provide clarity and regulatory certainty for industry, not to mention the benefit of safety and continuity for the U.S. economy.

Summary of Requests:

The off-road equipment manufacturing industry recognizes the importance of uncovering the presence and usage related to PFAS chemicals. Additionally, off-road equipment manufacturers understand the value in collaborating with policymakers to communicate the needs of industry during crucial rulemaking decisions. To ensure new rules meet their objectives with accurate and complete data, AEM requests that MCPA:

1. Provide adequate and appropriate amount of time for the off-road equipment manufacturing industry to identify, collect, and report the data regarding PFAS found in this industry.
2. Harmonize the definition of PFAS with EPA's structural definition.
3. Clarify definitions and provide industry with a reporting threshold to enable the data collection efforts.
4. Adopt the EPA's model for Confidential Business Information (CBI) protections.
5. Provide clarity regarding processes and procedures for requesting an extension of the reporting deadline and waiving information requirements with the commissioner.
6. Clarify the process for defining and determining the "currently unavoidable use" for PFAS.

AEM Appreciates your consideration of these comments.

Please feel free to contact me 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)

Annex I: Time and Cost Analysis

Many current PFAS applications have no known chemical alternatives available for use in non-road products. Their unique blend of properties and characteristics make them essential to the continued operation of the non-road industry. Even with PFAS chemicals providing this essential functionality throughout industry, AEM's member companies recognize the environmental and health concerns of some of the substances in this chemical group and remain dedicated to finding safe chemical alternatives where possible. Despite this awareness and commitment to change, any transition away from PFAS will require time and resources to achieve.

The following section details the time and cost assumptions, as well as detailed descriptions of the current logistical challenges associated with the industry wide phase-out of PFAS chemicals:

Table 1: Summary Timeline to Identify, Validate, Test and Recertify a Product Containing PFAS Materials

ACTIVITY	TIME
IDENTIFICATION	
IDENTIFY ALL SUBSTANCES CLASSIFIED AS PFAS FROM REG. LIST	6 months
IDENTIFY HIGH RISK COMPONENT TYPES	8 months
CREATE LIST OF AT-RISK PARTS AND SUBCOMPONENTS	6 months
UPDATE INTERNAL DATA COLLECTION AND COMPLIANCE SYSTEMS	9 months
SUPPLIER COMMUNICATION AND TRAINING	9 months
REQUEST DATA FROM SUPPLIERS	20 months
FORMAT DATA, CHECK ACCURACY & STORE DATA	2 months
TOTAL	60 months
VALIDATE AND TEST	
VALIDATE PFAS PRESENCE WITH SUPPLIER	6 months
INVESTIGATE ALTERNATIVE MATERIAL	15 Months
PROCURE PROTOTYPE MATERIALS	12 Months
COMPONENT VALIDATION OF NEW MATERIAL	15 Months
PRODUCT VALIDATION WITH NEW MATERIAL COMPONENTS	24 Months
TURN INVENTORY TO PURGE SUPPLY CHAIN & ENSURE COMPLIANCE	12 Months
TOTAL	84 months
RECERTIFICATION	
RECERTIFICATION	12 Months
TOTAL	156 Months

Analysis Assumptions

The following sections attempt to identify the resource costs associated with an industry wide transition away from the use of PFAS chemicals. Certain assumptions are required in order to establish a believable estimate associated with this effort. The importance of the following assumptions undergirding Annex I cannot be overstated.

Assumptions:

1. This timeline assumes a limited list of around a dozen chemicals under assessment at any one time.
    a. There is a designated list to reference.
    b. Available time to prepare for the phase-out work.
2. PFAS substances have identifiable, functional, and economic alternatives
3. The alternative is available and scalable to production quantities
4. Supply chain delays are minimal or non-existent
5. The testing and development cycle experiences no delays, or unexpected roadblocks

Identification:

The first step in highlighting the inherent risks of PFAS for the non-road industry is the lack of a common universal baseline for the total number of substances of concern. Various global regulatory and governmental agencies possess unique lists of known PFAS substances. These lists range from a few dozen to over ten thousand unique PFAS entities. To complicate this issue further, different references from academic research, regulatory agency activity or incoming legal requirements use different descriptions of PFAS to define their scope. Some of these definitions are narrower requiring multiple adjacent carbon atoms with a varying number of attached fluorine atoms to the larger chemical structure, to the broadest definition which includes any compound whose structure contains at least one carbon atom attached to a fluorine atom. This definitional difference introduces confusion to the marketplace hampering a company's efforts to identify the total number of PFAS compounds in their products. Before any largescale identification effort takes place, universal agreement on one definition and one list would help provide clarity and reduce complexity.

A second challenge in addressing global PFAS exposure risks, is the sheer number of PFAS substances identified through various stakeholder group research. Even with one universal agreed upon definition of PFAS, having a single list that still requires industry to identify and account for over 10,000 unique chemical substances is an extremely challenging task. Requiring companies to account for long lists of chemicals of concern, without corresponding *de minimis* relief provisions, takes time, effort, and resources to accomplish. Keeping future chemical lists focused on high risk PFAS, instead of the entire substance family would help industry identify and track important substances of concern.

While not solely unique to the non-road equipment industry, the issue of supply chain education and communication presents a substantial challenge to global OEMs. Historically, the non-road industry had very little expertise and history regarding the collection and storage of data for chemical management regulations. This educational issue, endemic throughout the supply chain, is compounded by the wider compliance environment many of these companies operate in. Smaller manufacturers of components often do not store chemicals above the reporting thresholds required under US law (e.g., CDR, SARA 313 reporting rules. As a result, many companies in our supply chains never cultivated the systems or expertise needed to gather and store the relevant chemical data for the components and parts they manufacture and distribute. Their task is made more difficult due to the confidential business information (CBI) protections many bulk chemical manufacturers utilize to conceal the composition of their products, making downstream reporting extremely challenging to accomplish. Additionally, International suppliers follow various global regulations which differ from each other, deepening the data collection obstacles faced by the global supply chain. Absent a data reporting system adopted globally across our industry sector that can track and monitor chemical substances throughout the supply chain, it remains an extraordinarily difficult task for a single OEM to know the chemical composition of the articles they currently market.

Table 2: Estimated Timeline for the Non-Road Equipment Industry to Comply with the Data Collection and Reporting Requirements of the EPA's PFAS Final Rule

ACTIVITY	TIME
IDENTIFY ALL SUBSTANCES CLASSIFIED AS PFAS FROM REG. LIST	6 months
IDENTIFY HIGH RISK COMPONENT TYPES	8 months
CREATE LIST OF AT-RISK PARTS AND SUBCOMPONENTS	6 months
UPDATE INTERNAL DATA COLLECTION AND COMPLIANCE SYSTEMS	9 months
SUPPLIER COMMUNICATION AND TRAINING	9 months
REQUEST DATA FROM SUPPLIERS	20 months
FORMAT DATA, CHECK ACCURACY & STORE DATA	2 months
TOTAL	60 months

From the timeline listed in Table 2, obtaining data from 80% of the supply chain would take a minimum of 60 months to complete. This estimate assumes that upstream suppliers provide high quality chemical information to downstream manufacturers. The scale and complexity of the global supply chain will challenge this estimated timeline. Response rates will differ based on supply chain knowledge gaps, unfamiliarity with chemical regulations, the absence of pre-established systems for collecting material data, as well as the issues associated with CBI protected chemical products. The contrasting formats and methods used to distribute chemical data throughout industry further complicate this project. Some industries, like the automotive industry, use an established system (IMDS) to collect material disclosures for their parts and components. This system uses known CAS numbers, established *de minimis* reporting thresholds, and other criteria to assist in tracking chemical substances in articles. The non-road industry does not possess a system like this, nor do they utilize a common format to collect the required information. Full material disclosures collected on the common formats are received on average 25% faster than "non-standardized" or company specific formats. The uncoordinated and inexperienced nature of the global supply chain creates immense compliance obstacles for OEMs, which will challenge a manufacturer's ability to meet these estimated timelines.

Alternatives and Substitutes

For most PFAS, there are no currently known technical or economically feasible alternatives used in non-road equipment that do not compromise safety, durability, or reliability of the finished product. AEM members produce equipment designed to consensus safety standards and subject to third party certifications, customer requirements, and regulatory testing obligations. Changes to materials and formulations which affect fit, function, performance, or safety must undergo extensive testing to ensure new designs meet internal quality benchmarks, design specifications, and regulatory requirements. The sheer variety of applications and functionality provided by PFAS chemicals make it difficult to estimate the time needed to identify, test, and qualify alternative chemical substances for each end use.

Table 3: Timeline to Identify, Validate, and Test Alternative Substances after Likely Viable Alternatives are Identified

ACTIVITY	TIMELINE FOR EQUIPMENT MANUFACTURING INDUSTRY
VALIDATE PIP PFAS PRESENCE WITH SUPPLIER	6 months
INVESTIGATE ALTERNATIVE MATERIAL	15 Months

PROCURE PROTOTYPE MATERIALS	12 Months
COMPONENT VALIDATION OF NEW MATERIAL	15 Months
PRODUCT VALIDATION WITH NEW MATERIAL COMPONENTS	24 Months
TURN INVENTORY TO PURGE SUPPLY CHAIN & ENSURE COMPLIANCE	12 Months
TOTAL	84 months

Estimated timelines assume suitable alternative materials exist, that manufacturers do not encounter dead ends during these assessments, and that current supply chain issues throughout the world do not hamper shipping and transportation timelines. Furthermore, the timeline estimates assume the total number of PFAS substances used in non-road equipment is a manageable size. The higher number of PFAS substances used in the components and systems of the end-product, the longer the timeline will be.

Testing and material validation requirements often take the longest time to complete when assessing new material adoption. Non-road equipment operates in some of the most demanding and severe environments over a product life cycle measured in decades. Such equipment is subject to various fire safety and flammability regulatory requirements set by a variety of domestic and international regulatory agencies. Beyond various mandatory requirements[9,10,11,12,13,14], manufacturers must perform a host of safety, durability, and performance tests to ensure their products meet industry standards, internal quality specifications, as well as customer and regulatory requirements.

Due to the prevalence of PFAS throughout industry, manufacturers will likely see these substances present within different systems of their products. Manufacturers would need to conduct simultaneous redesign work on various alternative substances across multiple product platforms, resulting in different batteries of tests across a wide swath of machine types. Of course, manufacturers can run changes to multiple systems simultaneously, but they cannot implement changes across all product lines simultaneously as test cells, qualified staff, and other resources are all limited.

Testing and Re-certifying Components and End Products

Due to the efficacy of using PFAS in high stress environments, many equipment manufacturers will likely find this substance present in critical parts used in their engine and emission control systems. Engine emission sensors, as an example, designed for non-road equipment to comply with the Clean Air Act, likely rely on PFAS to survive the high-pressure environment in the engine compartment. Any identified alternative materials will require expensive and time-consuming in-house and third-party certification testing before the product can satisfy the current regulatory standards governing its safety and performance.

9 Flammability Test for Motor Vehicle Interiors, 49 § C.F.R. 571.302(1998)
10 Fire Protection and Prevention, 29 § C.F.R 1926.24(2000), Fire Prevention, 29 § C.F.R 1926.151(2001)
11 Fire Resistant Hydraulic Fluids, 30 § C.F.R 35(2012), Requirements for the Approval of Flame-Resistant Conveyor Belts, 20 § C.F.R 14(2008), Fire Protection 30 § C.F.R 75.1100, Fire Protection, 30 § C.F.R 77.1100, Fire suppression systems for diesel-powered equipment and fuel transportation units, 30 § C.F.R 75.1911
12 Recommended Fire Safety Practices for Rail Transit Materials Selection, U.S. Department of Transportation, https://www.transit.dot.gov/sites/fta.dot.gov/files/docs/NASFM_Recommended_Practices.pdf, 2008
13 49 CFR 216, 223, 229, 231, 232, 238 – Passenger Equipment Safety Standards – correct citation
14 Flammable Fabrics Act, Public Law 83-88; 67 Stat. 111, June 30, 1953

The EPA, as part of their *General Compliance Provisions for Highway, Stationary, and Nonroad Programs*[15], identifies emission-related components in Appendix I to Part 1068. Changes to these critical components and systems require engine manufacturers to conduct a battery of emissions tests to ensure the equipment still meet national emission standards. Generally, a single engine platform requires around four years of development, or roughly the timeline associated with the cadence of engine emission regulatory changes. Depending on the prevalence of PFAS in these crucial emission control systems, manufacturers may need to undergo complete engine emission recertifications across all their product lines. As stated in the previous section though, manufacturers can run changes to multiple systems simultaneously, but they cannot implement changes across all product lines simultaneously as test cells, qualified staff, and other resources are all limited. Furthermore, changes to the engine may force design changes to the end-product, lengthening the entire process for the manufacturer.

As shown in Table 4 below, AEM's member companies estimate the industry would need a total of 12 months to recertify their products under current US emission requirements. This estimate assumes that material changes to critical engine control systems would not require a full engine redesign and recertification. If this assumption proves incorrect, the likely timeline for full recertification under the law would take between 4 to 8 years to fully complete.

Table 4: Timeline to Test and Re-Certify End Products

ACTIVITY	TIMELINE FOR EQUIPMENT MANUFACTURING INDUSTRY
RECERTIFICATION	12 Months

Total Time and Costs:

The total time and costs associated with identifying, substituting, and testing their products is significant. The above estimates are based on various crucial assumptions: presence of alternatives, availability of supply, minimal supply chain disruptions, as well as a flawlessly executed validation and certification process. If these assumptions are correct, the entire effort will take at least thirteen (13) years to finish for a single batch of PFAS chemicals. However, this estimate assumes ideal conditions, and in the aftermath of the pandemic supply chain disruptions, with the added logistical challenges of collecting the necessary information, and the need for supplier education, this effort will take much longer than the timeline listed in Annex 1.

[15] 40 CFR Chapter I, Subchapter U, Part 1068

Coalition of Manufacturers of Complex Products

November 28, 2023

Katrina Kessler, Commissioner
Minnesota Pollution Control Agency
520 Lafayette Rd, St Paul, MN 55155

Via eComment at https://minnesotaoah.granicusideas.com/

Re: Planned New Rules Governing Reporting by Manufacturers on Products Containing Per-and polyfluoroalkyl substances ("PFAS"); Revisor's ID Number R-4828; and Associated Fees; Revisor's ID Number R-4827

Dear Commissioner Kessler:

The Coalition of Manufacturers of Complex Products ("Coalition") respectfully submits the following comments on proposed regulations and fees implementing Minnesota Session Law - 2023, Chapter 60, H.F. No. 2310, An Act to establish reporting requirements and rulemaking for Products containing PFAS. The law establishes a requirement for manufacturers to notify the Minnesota Pollution Control Agency ("MPCA") of any product for sale in the State that contains intentionally added PFAS, and submit certain information, starting on January 1, 2026.

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 ("HVAC-R") and water heating equipment, electronics, and their replacement parts. Coalition members serve and support nearly every major sector in the nation, providing critical products for government agencies, the US 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 purposes of this proposed rule, the Coalition supports:

- **Reporting for a single list of high priority PFAS.** The grouping of thousands of PFAS chemicals by chemical definition creates regulations that are too complex to comply with or to enforce. Use of a list of reportable Chemical Abstracts Service Registry Numbers ("CASRNs") is needed.

- **Excluding refrigerants and fluoropolymers from reporting.** These are often critical ingredients in complex goods and do not meet the criteria to be classified as persistent, bioaccumulative and toxic substances ("PBT") or "forever chemicals."

- **Permit coordinated supply chain reporting.** In recognition of supply chain complexity, a coordinated supply chain reporting mechanism should be proposed to allow chemical manufacturers to report and exempt complex consumer and durable goods manufacturers from reporting. Manufacturers should be allowed to notify their suppliers that their components are

in products sold in Minnesota, and have the supplier notify directly on that basis. Reported data should be limited to information that is known or reasonably ascertainable and downstream manufacturers should not be penalized if information cannot be obtained. Products should be grouped for reporting and in assessing fees, which should be capped at only what is necessary to carry out the program. A coordinated supply chain reporting mechanism should allow chemical manufacturers to report and exempt complex consumer and durable goods manufacturers from reporting.

- **Regulations that apply a risk-based approach to consider both hazard and exposure.** To best protect human health and the environment, a risk-based approach focuses limited agency resources on the highest priorities based on actual environmental, health, and safety risk of chemistries, not just the mere presence of a substance. Workable and reasonable regulations should exclude *de minimis* levels, replacement parts, large-scale manufacturing equipment, and critical uses.

- **Clear timelines to identify unavoidable uses.** The State should focus any immediate products bans on high emissive uses of high risk PFAS regulated under the Stockholm Convention on Persistent Organic Pollutants and the U.S. Environmental Protection Agency's ("EPA's") contaminants of concern on the ("UCMR 5") list. Up to five years after the rulemaking on unavoidable use regulations should be allowed for complex product and equipment manufacturers to evaluate the availability, cost, safety, and reliability of potential alternatives.

In addition, with respect to MPCA's request for comments, we provide the following responses:

1) **Are there definitions in subdivision 1 for which clarification would be useful to understanding reporting responsibilities?**

   Subd. 1(l) defines "intentionally added" to mean 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. Subd. 2(a) clarifies that only "intentionally added PFAS" are reportable. MPCA should include in its regulations provisions to exclude the presence of chemicals that do not provide functionality to components or equipment (*e.g.*, contaminants). MPCA may wish to further refine reporting requirements to exempt products which qualify as "articles" containing *de minimis* levels of PFAS. The Coalition suggests that a *de minimis* level could be further clarified as PFAS in quantities of less than 0.1% by weight of the final product.

2) **Are there terms or processes in subdivision 2 for which clarifications will help reporting entities determine reporting status or data-gathering process?**

   To implement the requirement in Subd. 2(a)(1) to describe products with a universal product code, we ask that MPCA allow flexibility to use any variety of internationally used product classification codes such as Harmonized Tariff System ("HTS") code or the European Union Substances of Concern in Products ("SCIP") database, or the Global Product Classification ("GPC") brick code.

   Subd. 2(a)(3) directs reporting only as to the amount of each PFAS "identified by its chemical abstracts service registry number." Regulations should confirm that MPCA interprets that PFAS subject to the reporting requirement of the law are limited to those that have a CASRN. Specifically, the Coalition asks MPCA to establish a list of reportable PFAS chemicals that meet the definition in the legislation, with their specific CASRNs included.

Subd. 2(a)(3) also calls for reporting "the amount of each PFAS . . . in the product, reported as an exact quantity determined using commercially available analytical methods or as falling within a range approved for reporting purposes . . ." The Coalition supports being able to provide a concentration range, as this information will be more readily available.

Subd. 2(a)(5) allows MCPA to request additional information beyond that enumerated in the statute. The Coalition thinks the information elements that are listed there are sufficient for MPCA to form an understanding of the presence of PFAS in products in commerce in Minnesota. We urge MPCA to be reasonable and judicious and not require additional information beyond that which is already required to be reported by the statute.

Subd. 2(b) permits MPCA to allow a manufacturer to supply information for a category or type of product rather than for each individual product. The Coalition believes it is more expedient and efficient for MPCA to propose conditions under which such reports will be accepted rather than requiring approvals on an individual company basis. MPCA's regulations also should permit grouping of products for purposes of fees.

3) **How should MPCA balance public availability of data and trade secrecy as part of the reporting requirements?**

MPCA's regulations should ensure that reportable information is protected. It would be helpful to clarify which types of information can be claimed as confidential and to provide a simplified process for substantiating those claims, if necessary.

4) **Are there any terms used in subdivision 3 that should be further defined or where examples would be helpful?**

Subd. 3 allows MPCA to waive all or part of the information requirements if substantially equivalent information is already publicly available. The Coalition asks MPCA to define "substantially equivalent" information and consider formal waivers from the outset for the federal reporting rule elements. MPCA should also explore agreements with other states to reduce duplicative reporting. The Northeast Waste Management Officials' Association, Inc. ("NEWMOA"), which consists of members from state environmental agencies from Maine, Connecticut, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont, released draft model PFAS legislation on May 2, 2023. The draft legislation specifically advances the concept of an interstate clearinghouse. Minnesota should consider this interesting option for structuring reporting.

5) **Are there specific portions of the reporting process that should not be defined through guidance or the development of an application form?**

The Coalition supports providing flexibility in guidance and forms to address the concerns and areas specified above.

The Coalition greatly appreciates the consideration by MPCA of the following comments regarding this involved issue.

1. **Regulations should be consistent with the statutory requirement which only applies to chemicals with a CASRN. The Coalition asks MPCA to provide a single list of PFAS chemicals by CASRN for which reporting is required.**

PFAS is a broad term that refers to the family of perfluoroalkyl and polyfluoroalkyl substances, synthetic organic compounds having carbon and fluorine. The term is defined differently by policymakers. It was coined to address chemicals that may create similar concerns to perfluorooctanoic acid ("PFOA") and perfluorooctanoic sulfonate ("PFOS"), called "forever chemicals" due to their longevity in the environment and the human body (persistence and bioaccumulation).

Subd. 1(p) defines "perfluoroalkyl and polyfluoroalkyl substances" or "PFAS" to mean "a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom." This is by far the broadest PFAS definition in terms of scope. The grouping of thousands of PFAS chemicals by this chemical definition creates regulations that are too complex to comply with or to enforce.

Recognizing these challenges, Subd. 2(a)(3) directs reporting only as to the amount of each PFAS "identified by its chemical abstracts service registry number." Regulations should confirm that the MPCA interprets that PFAS subject to the reporting requirement of the law are limited to those that have a CASRN. Specifically, the Coalition asks MPCA to establish a list of reportable PFAS chemicals that meet the definition in the legislation, with their specific CASRNs included. This is how manufacturers downstream identify and search for ingredients in their products – by CASRN. Complex product manufacturers are not in the business of understanding or interpreting a complex chemistry definition or recognizing chemical structural diagrams. They make (or merely assemble) equipment, not chemicals. Because the statute only expects reporting for chemicals with CASRNs, having a list will make reporting clear and efficient. MPCA should provide the regulated community with the necessary information to aid in accurate reporting.

We recognize that EPA maintains lists of chemicals considered to be PFAS and direct the regulated community to this website. In association with the federal reporting requirement on PFAS, EPA expects to publish a single list. The current federal webpage contains several links to lists of PFAS, in many cases identified by CASRNs, that have been already compiled by EPA, the Organization for Economic Cooperation and Development ("OECD"), KEMI the Swedish Chemicals Agency, and community efforts. However, EPA's webpage currently lists over 12,000 PFAS chemicals. To survey supply chains for this entire of family of chemicals could take decades. Testing for all those chemicals in hundreds, thousands, or even tens of thousands of parts and components is literally impossible. We recommend that MPCA follow the EUs Global Declarative Substance List ("GADSL") which recently identified a list of around 500 priority PFAS chemicals.

2. **Coordinated reporting to reduce the significant challenges for complex supply chains.**

According to Subd. 2, the new proposed requirements will need to ask manufacturers to report a universal product code ("UPC"), stock keeping unit ("SKU"), or other numeric code assigned to the product, as well as the purpose for which PFAS are used in the product, including in any product components. The amount of each PFAS, identified by its CASRN in the product must also be reported, either as an exact quantity determined using commercially available analytical methods or as falling within a range approved for reporting purposes by the commissioner. Manufacturers must also provide their name and address, as well as the name, address, and phone number of a contact person for the manufacturer. Finally, any additional information requested by the Commissioner as necessary to implement the requirements of the PFAS reporting provisions must be provided.

Complex goods are sold through several multi-step supply chain pathways including by distribution and through retailers. The quantity and type of equipment sold into specific states is unknown. This complexity is likely to result in over- or under-reporting or simply incorrect information. Complex supply chains make it difficult to know which party will be the "responsible" reporting entity as the company which markets the product and whose name appears on the product label may be different. For products sold directly to distributors and not directly to retailers or individuals, it will be virtually impossible for the original equipment manufacturer ("OEM") to report on sales into Minnesota. International marketing companies further confound responsibilities as to whether the importer or others in the supply chain will have reporting obligations and could lead to over- or under-reporting.

When manufacturers have initiated supply chain inquiries for other regulated chemicals, on average, approximately 30% of suppliers respond to repeated requests for information. Many companies have had lower levels of response. Based on past and current experience, complex product manufacturers require additional time beyond that which is contemplated in the proposed rule to survey their complex, often international, supply chains for the presence of specific chemicals in the components, parts, and raw materials that they purchase. They often face an initial lack of responsiveness from suppliers, as well as claims that the chemical make-up of components is a trade secret.

We ask MPCA to consider if it is possible to avoid the need for these often-protracted negotiations and still obtain the information the rule requires. On the basis of past experience, the Coalition recommends two alternatives. First, the Coalition encourages MPCA to implement accountability and enforcement requirements that ensure suppliers inform downstream manufacturers of components and parts containing PFAS. Suppliers should disclose the use of PFAS to downstream customers well in advance of the reporting deadline, so that companies subject to reporting have the information needed to report on articles containing chemicals of interest. Second and alternatively, we ask MPCA to allow manufacturers of complex products and equipment to notify their suppliers that their components are in products sold in Minnesota, and have the supplier notify MPCA directly on that basis. Manufacturers could report a list of suppliers that have been notified and the response that they have received as to whether that suppliers' components contain PFAS or not and separately report the absence of a response along with contact information for all suppliers. The Coalition suggests that a six-month period would be reasonable to notify suppliers and that another six months to one year should be allowed to report the information to the MPCA. Even in cases where a component manufacturer may not separately sell the component in Minnesota, the component that these companies manufacture is nonetheless in commerce when it is in a final product that is distributed in the State. Companies that sell components to complex product manufacturers do so knowing that the parts are intended to be installed in final products that may be sold throughout the United States, if not the world.

Providing reporting options like this will reduce duplicative reporting or incomplete information due to claims of intellectual property concerns. It would allow for more streamlined reporting and facilitate determinations about quantities and locations of PFAS. Hopefully, MPCA can determine a pathway responsive to these considerations in developing the reporting structure.

3. **Consider exemptions from reporting for fluoropolymers, refrigerants, and *de minimis* quantities in complex products and equipment.**

PFAS have a wide variety of different properties. Due to this variation, it is inappropriate to require reporting for all PFAS as a single group. Risks associated with one member of the class should not be attributed to other members of the PFAS class without clear scientific justification. Furthermore, the grouping of thousands of PFAS chemicals creates regulations that are too complex to comply with or to enforce and thus not reasonable, practical, or achievable. The Coalition urges MPCA to exempt refrigerants and fluoropolymers from reporting altogether. These are often critical ingredients in complex

goods which do not meet the criteria to be classified as PBTs or "forever chemicals." Fluoropolymer coatings and products resist heat, oil, stains, grease, and water, which increases product lifespan and reliability and prevents fires and corrosion. Hydrofluorocarbons ("HFCs") were commercialized to replace ozone depleting substances in the 1990s. Many HFCs, especially those with high global warming potential ("GWP") are regulated under the Kigali Amendment to the Montreal Protocol, as short-lived climate pollutants ("SLCPs"). HFCs are short-lived and do not meet the criteria to be classified as PBTs or "forever chemicals." SLCPs are regulated because they are particularly impactful in addressing climate change because of their relatively short lifetimes of as little as days to as much as decades compared to carbon dioxide which remains in the atmosphere from 300 to 1000 years.

Subd. 1(l) defines "intentionally added" to mean 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. Subd. 2(a) clarifies that only "intentionally added PFAS" are reportable. MPCA should include in its regulations provisions to exclude the presence of chemicals that do not provide functionality to components (*e.g.*, contaminants). MPCA may wish to further refine reporting requirements to exempt products which qualify as "articles" containing *de minimis* levels of PFAS. The Coalition suggests that a "*de minimis*" level could be further clarified as PFAS in quantities of less than 0.1% by weight of the final product.

Chemicals in plastic parts and electrical components are widely used across a broad range of manufactured articles globally. OEMs have limited visibility and control over complex, multi-tiered, global supply chains. MPCA should confirm in regulations that when components in complex products and equipment are manufactured at the same facilities producing other components for industries that intentionally contain reportable substances, the potential for unintentional, cross-contamination in *de minimis* quantities does not trigger reporting for the component or the final product in which it is installed.

We also would like to point out the balance of considerations which support a *de minimis* exemption for intentionally added PFAS, below which reporting would be exempt for "articles". The Occupational Safety and Health Administration ("OSHA") Hazard Communication Program ("HazCom") exempts businesses from reporting ingredients on safety data sheets ("SDS") in *de minimis* quantities.[1]

Due to the complexities of the international, multi-tiered supply chain, determining a presence below the threshold of 0.1 % by weight is very difficult. Manufacturers must rely on the accuracy of reporting from every supplier throughout the entire supply chain on trace amounts of a chemical, even those that are present unintentionally. There is little, if any, evidence to suggest that the presence of trace amounts of a chemical in an article can contribute to exposure, which must be considered in any risk determination. Furthermore, there has been much scientific debate over whether it is actually possible to achieve 100% confidence in any formulation.

Levels of chemical below a threshold of 0.1% do not tend to appear in global chemical management systems, like the International Material Data System ("IMDS") used by the automotive industry.[2] In the

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[1] OSHA provides a 0.1% cutoff for inclusion of certain hazardous chemicals on safety data sheets ("SDS"). It is difficult for companies to identify a *de minimis* amount of a substance in a product below the OSHA call-out. The difficulties associated with reporting would be lessened if companies were not required to exceed their current responsibilities to self-identify small quantity ingredients.

[2] The IMDS is viewed as the global standard for reporting material content throughout the automotive supply chain and for identifying which chemicals of concern are present in finished materials and components. The automotive industry has made significant investments in this data system in order to track compliance with global regulations impacting their products. The threshold for reporting for this system is 0.1% by weight. The

European Registration, Evaluation, and Authorization of Chemicals ("REACH") Regulation, European Union ("EU") and European Economic Area ("EEA") producers and importers of articles may be subject to notification if their article contains a substance on the EU Candidate List *only* if the listed substance is present above a concentration of 0.1%. Inclusion of a 0.1% *de minimis* threshold has proven to be effective in allowing the EU to focus on chemical manufacturing and use scenarios where the volume of the chemical is significant enough to pose a concern for exposure.

As a result, many downstream companies in complex supply chains do not currently have robust tracking systems for ingredients under this threshold, including certain PFAS chemicals. We are suggesting that MPCA may want to exempt articles that contain only *de minimis* quantities of 0.1% by weight or less to allow for a practicable regulation that is reasonably implementable.

Coalition OEMs have limited visibility and control over complex, multi-tiered, global supply chains and have spent considerable time in attempting to assess the potential presence or absence of chemicals in their supply chains. The intimate knowledge of the chemicals comprising components is with either component manufacturers or their suppliers and often will not be shared due to confidential business information ("CBI") concerns. This lack of transparency hampers the ability of manufacturers to be fully knowledgeable and in control of the chemistry of components. It is unrealistic for OEMs to mandate that their suppliers analyze each of the thousands of components to determine the presence or absence of chemicals in every component.[3] A *de minimis* threshold makes ingredient tracking more manageable. In many cases, *de minimis* quantities serve as a reasonable proxy for low potential exposure.

We ask MPCA to consider additional definitions that recognize the complex supply chains associated with the products and equipment manufactured by Coalition members. The term "article" is a well-understood regulatory term defined by EPA (40 C.F.R. § 720.3(c)) and OSHA (29 C.F.R. § 1910.1200(c)). In addition, there are definitions for the terms "complex consumer goods" and "complex durable goods" in the Toxic Substances Control Act ("TSCA") that largely capture the complexity of the final products our companies manufacture:[4]

> *"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."*
>
> *"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."*

Potential exposure to chemicals contained in components and final products that meet these definitions is low, given that they are often embedded in a polymer matrix in a component that is enclosed in a final equipment product and the chemicals are not intended for release into the environment.

IMDS now has over 15 years of data compiled relying on a *de minimis* level of 0.1%. The presence of any chemical below this threshold is not required to be reported in IMDS.

[3] For example, EPA's Economic Analysis conservatively estimates that the cost of testing <u>just</u> children's products for the presence of PIP (3:1) would likely exceed $0.5 billion.

[4] See Section 6(c)(2)(D)(ii)(I) and (II) of TSCA.

MPCA should articulate that at least the following options, and potentially others, are acceptable mechanisms to document compliance with the recordkeeping requirement of the regulation. Requirements for record retention should be no greater than five years. Specific guidance regarding recordkeeping will ensure that OEMs and the entire supply chain are well-prepared for compliance with the regulation, such as:

- Documentation sufficient to demonstrate that the finished article does not include more than *de minimis* levels such as a certificate of compliance from suppliers;

- Manufacturing specifications such as specification drawings noting that components cannot include more than *de minimis* levels of controlled substances; or

- Commercial contracts for components or sub-assemblies limiting the presence of PFAS chemicals to less than 0.1% by weight.

The Coalition notes that labeling requirements go beyond the statutes requirements and should not be included. They are not an effective form of communication with consumers or end-users, because Coalition products are often in machine rooms or remote locations generally hidden from view.

4. **The Coalition asks MPCA to exempt replacement parts for complex products with long life spans from product bans.**

Subd. 5(c) of the law provides a ban on products containing PFAS as of January 2032. Subd. 8(3) excludes the sale or resale of a used product. Consistent with this exclusion, we ask MPCA to include in the regulations an exemption for replacement parts for complex final products that are designed prior to the date of the ban, for products that have a lifespan of many years such as refrigeration and heating equipment. These products are found in manufacturing facilities, commercial outlets, retail stores, and residential homes. Again, the risk of release of PFAS to the environment for these products is extremely low. We think an exemption for replacement parts would make the administration of this rule more reasonable without compromising the safety and well-being of the citizens of Minnesota.

5. **Avoiding additional and duplicative reporting.**

Subd. 2(a)(5) allows MCPA to request additional information beyond that enumerated in the statute. The Coalition thinks the information elements that are listed there are sufficient for MPCA to form an understanding of the presence of PFAS in products in commerce in Minnesota. We urge MPCA to be reasonable and judicious and not require additional information beyond that which is already required to be reported by the statute. Moreover, Subd. 3 allows MPCA to waive all or part of the information requirements if substantially equivalent information is already publicly available. The Coalition asks MPCA to consider formal waivers from the outset in the regulations which recognize the federal reporting rule elements and explore agreements with other states to reduce duplicative reporting. NEWMOA's draft model PFAS legislation specifically advances the concept of an interstate clearinghouse. This may be an interesting option for structuring reporting for Minnesota to consider.

6. **The Coalition encourages MPCA to allow flexibility in the use of internationally used product classification codes.**

The Coalition members manufacture thousands of models (and hundreds of thousands of components and parts) with safety and reliability at the forefront of their designs to protect consumers from unreasonable risk. Manufacturers should be able group products in categories to simplify reporting, as there are many similar products that can be grouped together. To implement the requirement in Subd.

2(a)(1) to describe products with a universal product code, we ask that MPCA allow flexibility to use any variety of internationally used product classification codes such as the HTS code or the European Union Substances of Concern or SCIP database, or GPC brick code. To ease this new reporting burden, companies should be required to use an international product classification code but should not be required to use a single option. Without allowing for the range of currently used reporting systems, reporting will be even more challenging.

7. **Reporting should be based on concentration of each PFAS in a product, as an alternative to the total amount of each PFAS, and testing should not be routinely required.**

Subd. 2(a)(3) calls for reporting "the amount of each PFAS . . . in the product, reported as an exact quantity determined using commercially available analytical methods or as falling within a range approved for reporting purposes . . ." The Coalition supports being able to provide a concentration range, because this information will be more readily available. The use of range reporting is accepted practice in many reporting programs and reduces the need to identify and protect formulations as CBI. Testing for thousands of product SKUs is prohibitively expensive. Regulations that permit the alternative of providing an estimated concentration range would help to alleviate this burden. Moreover, the best source of this information is the entity that added the chemical to the component, part, or raw material. This requirement further highlights the need to have the option for reporting by knowledgeable suppliers rather than by manufacturers assembling supplied parts.

8. **The Coalition supports regulations to protect CBI and trade secrets.**

MPCA's regulations should ensure that reportable information is protected. It would be helpful to clarify which types of information can be claimed as confidential and to provide a simplified process for substantiating those claims, if necessary. Products that create value are often guarded by companies through alternative means than a patent. It is important for MPCA to strike the right balance between maintaining U.S. competitiveness and public right-to-know, so as not to disclose so much information that the disclosure empowers competitors to plunder technologies without compensation or the same level of investment in time and resources.

9. **The Coalition supports grouping products for reporting and fee administration.**

Subd. 2(b) permits MPCA to allow a manufacturer to supply information for a category or type of product rather than for each individual product. The Coalition believes it is more expedient and efficient for MPCA to propose conditions under which such reports will be accepted rather than requiring approvals on an individual company basis. MPCA's regulations also should permit grouping of products for purposes of fees. A separate fee should not be required for each of the thousands of SKUs that manufacturers of complex products and equipment manage. It would be cost-prohibitive if every component, equipment model, packaging type, and replacement part would require that a fee be paid to MPCA. That level of fees is unlikely to be necessary to administer the reporting requirements. Fees should be capped at a level necessary to administer the program.

10. **MPCA should prioritize proposing reasonable procedures and criteria for unavoidable use determinations.**

The Coalition supports eliminating non-essential uses of PFAS and promoting safer alternatives. At the same time, the Coalition thanks Minnesota for understanding that there are currently essential uses of PFAS chemicals that provide important safety and performance features in complex products in internal components and parts, such as resistance to high temperatures. Ultimately, high performance solutions must be available commercially and in sufficient quantities to meet market demand, at a cost that is

sustainable to consumers and end-users, especially for critical products to society. Companies far downstream in the supply chain from their suppliers and from the information that they need in order to comply will require sufficient time to transition to an alternative chemical—if one exists—which in many cases could take years.

The Coalition is supportive of a process by which MPCA is able to determine by rulemaking that an application of PFAS is "currently unavoidable." For MPCA's consideration, the Coalition urges consideration of the same criteria that EPA must utilize under Section 6(g) of TSCA for considering exemptions for "critical or essential" uses of chemicals. The EPA Administrator may, as part of a rule promulgated under Section 6(a) of TSCA, or in a separate rule, grant an exemption from a requirement of a section 6(a) rule for a specific condition of use of a chemical substance or mixture, if the Administrator finds that—

(A) the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure;

(B) compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or

(C) the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

It would be appropriate for Minnesota to consider aligning with the federal criteria for "critical or essential use." Moreover, the Coalition supports allowing up to five years after the rulemaking on unavoidable use regulations for complex product and equipment manufacturers to evaluate the availability, cost, safety, and reliability of potential alternatives.

Subd. 5(c) allows MPCA to determine by rule that the use of PFAS in the product is a currently unavoidable use, by specifying specific products or product categories. The Coalition urges MPCA to include a list of recognized unavoidable uses up-front in a proposed regulation. This list should include complex consumer goods and complex durable goods as defined above in these comments. Commercial and consumer products such as appliances, electronics, vehicles, vessels, and heating and cooling systems must meet strict performance and safety standards. These products may be engineered in a way that requires inclusion of PFAS, depending on its definition, with lifetimes up to 50 years. When present, the PFAS is 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 Therefore, these products do not present a known exposure risk to PFAS.

Sufficient notice must be provided to stakeholders to ensure process transparency and the ability to engage in comment opportunities. Even simple, singular chemical phaseouts for complex durable goods requires a minimum of three to seven years, or five years on average, *if* a feasible alternative has already been identified. If alternative analyses must be performed, additional time will be necessary. Due to the difficulties associated with the chemical substitution process (which includes the high socio-economic cost of identifying chemicals in a complex, global, mutli-tiered supply chain, trying to find an alternative (if one is available), and then launching the complicated process of product redesign which includes, research, development, testing, and implementation) there is a great risk of unforeseen disruptions to supply chains and business continuity with all the associated economic impacts. To best protect human health and the environment, a risk-based approach should focus limited agency resources on the highest

priorities based on actual environmental, health, and safety risk of particular chemistries, not just the mere presence of a substance.

11. **The Coalition appreciates MPCA's continuing open dialogue regarding all policy issues associated with this challenging regulation.**

Coalition members support efforts to minimize exposure to hazardous chemicals. However, there are certain aspects of the regulation under consideration that may be unattainable which apply to components or articles with limited potential for exposure. Manufacturers that distribute final products in Minnesota face tremendous difficulty identifying or reporting on the presence of PFAS in components because other parties add them to the product. In addition, without a specific list of CASRNs, or procedures in the rule for assistance from suppliers and exemptions for unavoidable uses, the rule could create confusion for those who must comply. It is also important to allow companies to continue to sell replacement parts and equipment critical for life-saving climate control and ventilation and for cold chains for vaccines into Minnesota.

* * *

The Coalition thanks MPCA for consideration of these comments. We welcome the opportunity to discuss these comments with you and answer any questions from MPCA. Please do not hesitate to reach out to Martha Marrapese, Partner, Wiley LLP at mmarrapese@wiley.law or 202-719-7156.

Respectfully Submitted,

Coalition of Manufacturers of Complex Products

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RECEIVED
By: OAH on 11/28/2023
Amanda Hagan Attachment

November 28, 2023

Animal Health Institute (AHI) Response to Request for Comments on: (1) 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; and (2) Planned New Rules Governing Fees Payable by Manufacturers Upon Submission of Required Information about Products Containing Per- and polyfluoroalkyl substances (PFAS), Revisor's ID Number R-4827

Thank you for the opportunity to provide feedback on the planned PFAS rules for submission of required information about products containing PFAS and associated fees. AHI is the U.S. trade association for research-based manufacturers of animal health products – the medicines that keep pets and livestock healthy. While some PFAS chemistries are known to be harmful, the active ingredients in animal health products are just the opposite: they have gone through federally-required, rigorous safety testing before reaching the market, including evaluating the safety effects on the animal, humans, and the environment.

AHI members develop, manufacture, and distribute a range of animal health products, including pharmaceuticals, biologics (including vaccines), flea and tick preventatives, and medical devices (including diagnostics), to veterinarians, pet owners, and food animal livestock owners. PFAS, when defined as a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom, can include the active ingredient in oral flea and tick medications, federally-regulated packaging components of biologics and medical devices, as well as the active ingredients in topical flea and tick products and collars.

No current alternatives to PFAS are available for these products, making the use of PFAS unavoidable and, in fact, vitally important for the public health. For example, some active ingredients approved by the U.S. Food and Drug Administration (FDA) and U.S. Environmental Protection Agency (EPA) are fluorinated molecules that are administered in animals, either orally or topically. Other veterinary products contain fluorinated molecules as essential, functional parts of their administering components (e.g., vaccine syringes) that are federally evaluated and approved with the underlying health product.

Unlike human drugs and medical devices (including diagnostics), which are all regulated by FDA, our members' animal health products are overseen and regulated by three distinct federal agencies:

- Small molecule pharmaceuticals and medical devices (including diagnostics) at FDA under the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. §§ 301 *et seq.*). Evaluating that an animal drug product is safe is paramount to and required for FDA approval. All PFAS regulated as animal drugs go through this rigorous process. FDA review involves evaluation of safety to the animal and of the food products made from the treated animal if the drug is for use in food-producing animals. ***FDA's required review process also evaluates the drug's impact on the environment and the safety of the people who will give the drug to the animal or who may come in contact with the drug.*** Additionally, the FFDCA provides FDA regulatory oversight of

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medical devices (including diagnostics) intended for animal use. Animal device manufacturers must assure that devices are safe, effective, and properly labeled.

- Biologics (including vaccines and certain diagnostic kits) at the Animal and Plant Health Inspection Service (APHIS) within the U.S. Department of Agriculture (USDA) under the Virus-Serum-Toxin Act (VSTA) (21 U.S.C. §§ 151-159). The VSTA authorizes USDA to review and license animal biologics manufacturers and their products; ensures animal biologics are pure, safe, potent, and effective; and requires every biologic to obtain a license and undergo a strict approval process.
- Flea and tick preventatives administered topically (including via collars) at EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. §§ 136 *et seq.*). Through a robust federal regulatory framework, EPA focuses on the sale, distribution, storage, and use of such products, including the regulation of product labeling and disposal. Further, manufacturers of certain flea and tick preventatives must register their products with EPA (and the states) before such products may be sold or distributed in the United States.

While regulatory responsibility is divided among the above three agencies, animal health products are all subject to intense federal oversight and regulatory frameworks focusing on product safety and impact to the animal, humans, and the environment.

Are there definitions in subdivision 1 for which clarification would be useful to understanding reporting responsibilities?

"Product" and "Product Component"
The definitions of "product" and "product component," as well as the rest of the Products Containing PFAS law, are silent on whether a product's packaging itself, if it contains a PFAS chemistry, subjects the product to reporting requirements and the eventual product ban:

"Product" means "an item manufactured, assembled, packaged, or otherwise prepared for sale to consumers, including but not limited to its product components, sold or distributed for personal, residential, commercial, or industrial use, including for use in making other products."

"Product component" means "an identifiable component of a product, regardless of whether the manufacturer of the product is the manufacturer of the component."

It appears that the Minnesota legislature has given the Minnesota Pollution Control Agency (MPCA or the Agency) discretion in determining whether packaging itself is included or not under these definitions. Maine, the only other state with a PFAS statute like Minnesota's, uses the following definition in its list of exemptions, to make it clear that product packaging itself does not bring the product into the PFAS statute: "A package, as defined in Title 32, section 1732, subsection 4, for a product, except when the package is the product of the manufacturer . . ."

This carveout for a product's packaging is important. For example, while biologics (including vaccines) and medical devices do not contain active PFAS ingredients, their packaging can include PFAS chemistries in stoppers for injectables, bottles, and syringe barrels and caps. The PFAS coating provides an effective barrier against organic and inorganic extractables and minimizes interaction between the biologic and the primary packaging component. The tiny amounts of PFAS in biologics and medical

device packaging, compared to the difficulty and cost of complying with the reporting requirement, and the legislature's silence on the issue, point to using a common-sense approach: the Agency should clarify that "product" and "product component" do *not* include product packaging and that product packaging is excluded from the Products Containing PFAS law. Again, this would align Minnesota with Maine's PFAS law.

"Manufacturer"
AHI supports the clarification in the Official Notices (Revisor's ID Numbers R-4828 and R-4827) that the term, "manufacturer," does *not* include any person who sells, offers for sale, or distributes in Minnesota products which contain a pesticide ingredient regulated by and reported to the Minnesota Department of Agriculture. We recommend that the Agency include such clarification in any rulemaking, including, for example, in any definition of "manufacturer."

"Drug"
AHI requests that the Agency define in the rulemaking the term, "drug," as used in Subd. 8(b). We strongly recommend the following definition –

"Drug" has the meaning given: (1) "drug" under United States Code, title 21, section 321, subsection (g)(1), and (2) "biological products" under Code of Federal Regulations, title 9, section 101.2.

"Medical Device"
AHI requests that the Agency clarify the definition of "medical device" in the rulemaking. We note that the statute incorrectly cites the federal definition of "device" under the FFDCA. The correct citation should be United States Code, title 21, section 321, subsection (h)(1).

Are there terms or processes in subdivision 2 for which clarifications will help reporting entities determine reporting status or data-gathering process?

AHI requests clarification regarding the following terms used in Subd. 2: "commercially available analytical methods" at 2(a)(3), "additional information" at 2(a)(5), and "significant change" at 2(c).

Are there any terms used in subdivision 3 that should be further defined or where examples would be helpful?

"Subd. 3. Information requirement waivers; extensions. (a) The 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 grant a waiver under this paragraph to a manufacturer or a group of manufacturers for multiple products or a product category."

For animal health products regulated as small molecule drugs that contain a PFAS chemistry, the chemistry is the actual active ingredient. Active ingredients are required to be on the product label, along with their concentration in the product. A consumer can pick up any flea or tick product and read the ingredients list. The legislature has given the Agency authority here to determine that if a product label already includes the PFAS chemistry as publicly-available information, then the Agency should grant the manufacturer a waiver.

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Are there specific portions of the reporting process that should not be defined through guidance or the development of an application form?

AHI requests that all portions of the reporting process, including any of those defined through guidance or the development of application form(s), be subject to a period of public comment and review before implementation.

Should the Agency consider a per-PFAS or PFAS amount fee?

The Agency should consider whether amounts below a certain threshold need to pay a fee at all. The PFAS active ingredient in oral flea and tick medications is measured in milligrams. This demonstrates the questionable logic of regulating these products under the PFAS law.

Other questions or comments relating to reporting or the process of reporting.

"Subd. 8. 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."

Subd. 8(a)(1) specifically exempts animal health products from Minnesota's Products Containing PFAS law. Federal law governs the presence of PFAS in animal products in a manner that preempts state law. Animal health products and the overall safety of such products are tightly regulated under the FFDCA and VSTA. Animal drugs, biologics, and medical devices must be safe, effective, and suitable for their intended use(s). FDA and USDA can take appropriate regulatory actions if such products are unsafe, adulterated, or misbranded.

For example, the FFDCA provides FDA sole authority to review applications, approve new animal drugs, deem unapproved new animal drugs to be unsafe and adulterated or misbranded, and regulate animal drug facility registration and drug listing. Similarly, FDA regulations at 21 CFR Parts 510–530 prescribe extensive requirements for new animal drug applications and allowable uses for specific types of drugs. The FFDCA also provides FDA regulatory oversight of medical devices (including diagnostics) intended for animal use. Animal device manufacturers must assure that devices are safe, effective, and properly labeled. Medical device labeling may not be false or misleading and must be adequately labeled for the intended use(s). An animal device that is also a radiation emitting electronic product must comply with all requirements for animal devices in addition to the FDA's extensive requirements for radiation-emitting electronic products at 21 CFR Parts 1000–1050.

Similarly, the VSTA authorizes USDA to review, license, and regulate animal biologics manufacturers and their products and ensure animal biologics are pure, safe, potent, and effective. USDA holds sole responsibility for issuing licenses and determining allowable uses for biologics, the extensive regulations for which are detailed at 9 CFR Parts 101–124. Importantly, the VSTA makes it unlawful to prepare, sell, barter, or exchange dangerous or harmful biologics intended for use in the treatment of animals.

In conclusion, the Products Containing PFAS law authorizes the Agency to exempt all animal health products from the reporting requirements: small molecule drugs either through federal preemption or the publicly-available information waiver based on product labeling; biologics and medical devices through federal preemption or clarifying that their packaging alone does not make them a PFAS product; and

pesticides (such as topical flea and tick products) through the existing statutory provisions giving authority over reporting and banning PFAS pesticides to the Minnesota Department of Agriculture. Based on the above, we ask that any rulemaking clarify that manufacturers of animal health products are not subject to the Products Containing PFAS reporting requirements.

Sincerely,

Mandy Hagan
Director, State Government Affairs

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11/28/2023

RE: Request for Comment on PFAS Reporting Requirement

Dear Commissioner Kessler:

Thank you for the opportunity to comment on the proposed regulations implementing Minnesota Session Law - 2023, Chapter 60, H.F. No. 2310, An Act to establish reporting requirements and rulemaking for products containing PFAS. The National Marine Manufacturers Association (NMMA), the Marine Retailers Association of the Americas (MRAA) and the Water Sports Industry Association (WSIA) are deeply concerned about several mandates in this statute.

Our members, who are retailers and manufacturers of recreational boats, engines, trailers, and accessories, face substantial challenges in meeting the requirements of this statute and proposed implementing regulations. The EPA PFAS Master List,[1] encompassing over 12,000 potential chemicals falling within the reporting requirements, has added complexity to an already daunting task.

Our small marine businesses, many of whom are Minnesota-based businesses that assemble complex components (e.g., recreational marine engines, boats, trailers, and accessories) have determined that it will be exceedingly difficult to meet the demands for precise identification of the PFAS compounds used, the exact quantity, and other information required by Session Law - 2023, Chapter 60.

Obtaining the required information at this scale and specificity demands an unprecedented amount of cooperation from international importers and distributors, for whom Minnesota constitutes a minor fraction of their business. Moreover, these international businesses are often unaware of the ultimate destination of their products. In addition, the mandate that a product cannot be sold in the state if it falls even slightly short of universal reporting thresholds will establish a standard with which few manufacturers of complex products will be able to comply. Ultimately, marine businesses manufacture very few of the components used to assemble the products they make and will be hard-pressed to acquire the information demanded by this statute.

Given the technical nature of the reporting requirements, many of our members are ill-equipped to identify PFAS in the thousands of parts and accessories found in boats. For example, a typical 20-foot boat can contain over a thousand distinct stock keeping units (SKUs), making it impractical to identify the chemicals within each component. Larger boats with additional accessories pose even greater challenges, as many thousand individual SKUs will be used to build these products. In addition, boats use complete components such as steering systems, electronics, generators, and kitchen and bathroom facilities that themselves have many hundred more SKUs that are purchased and installed as a single SKU.

We urge the Minnesota Pollution Control Agency (MPCA) to consider several recommendations supported by Minnesota's small marine businesses:

[1] https://comptox.epa.gov/dashboard/chemical-lists/pfasmaster

Exempt assemblers, such as boat, engine and accessory manufacturers from reporting and shift the burden to manufacturers who directly use PFAS chemicals in their products. The US EPA exempts boats defined as motor vehicles in the PIP 3:1 regulation, and this approach aligns with industry capabilities.

Regulations should apply a risk-based approach to consider both hazard and exposure. To best protect human health and the environment, a risk-based approach focuses limited agency resources on the highest priorities based on actual environmental, health, and safety risk of chemistries, not just the mere presence of a substance.

Regulations should provide clear and reasonable timelines and abundant notice to stakeholders. Clear timelines will ensure policy decisions and regulatory outcomes are completed and implemented in a timely fashion. Reasonable timelines must be provided; even simple, singular chemical phaseouts for complex durable goods require a minimum of three to seven years if a feasible alternative has already been identified. If alternative analyses must be performed, additional time is necessary. Due to the difficulties associated with the chemical substitution process, which includes the high socio-economic cost of identifying chemicals in a complex, global, multitiered supply chain, trying to find an alternative (if one is available), and then launching the complicated process of product redesign (which includes, research, development, testing, and implementation), there is a great risk of unforeseen disruptions to supply chains and business continuity with all the associated economic impacts.

Regulations should provide reasonable and appropriate exemptions, including immunities for: complex articles; large-scale manufacturing equipment; replacement and spare parts; *de minimis* or trace amounts; and critical uses. There is precedent among controlling agencies at the international and federal level for these types of exemptions as these entities recognize the challenges associated with the chemical substitution process. This process includes the high socio-economic cost of identifying chemicals in a complex, global, multi-tiered supply chain, trying to find an alternative (if one is available), and then launching the complicated process of product redesign which includes, research, development, testing, and implementation. Regulatory bodies should take care to avoid hindering industry sustainability and innovative capacity, product diversity, and already-existing safe, durable, and essential products.

PFAS should be regulated independently, not as a single group. PFAS chemicals have a wide variety of different properties and uses. Due to this variation, it is inappropriate to regulate all PFAS as a single group. Instead, each individual chemistry should be regulated based on the specific risks it poses; risks associated with one member of the class should not be attributed to other members of the PFAS class without clear scientific justification. Furthermore, the grouping of thousands of PFAS chemicals creates regulations that are too complex to comply with or to enforce and thus not reasonable, practical, or achievable.

Targeted PFAS should be identified by its unique CASRN. Chemical Abstract Service Registry Numbers (CASRN) are unique numerical identifiers assigned by the Chemical Abstracts Service (CAS)

to every chemical substance described in the open scientific literature from 1957 through the present. Currently, the EPA has compiled a list of over 12,000 PFAS.[2] Without the CASRN to pinpoint the chemical in question, it would be difficult (if not impossible) to accurately assess the impact of, or comply with, any impending regulatory action.

Providing Industry Specific Training. We kindly request the MPCA provide industry-specific training using real examples. While the legislation allows for cross-referencing to reports from other manufacturers, there is no defined structure to ensure major manufacturers report first. This raises concerns about compliance and delays, particularly if foreign-made components are involved in boat manufacturing.

Regulations should be consistent and coordinated among agencies. The appropriate interagency processes should be used to coordinate regulatory actions among all interested agencies across jurisdictions from global to local, so that government regulations, actions, and communications are harmonized and coordinated for maximum effectiveness and minimum burden to regulated parties. Multiple and conflicting laws and regulations must be avoided.

Proactively Identify products above contamination thresholds. With sufficient time and collaboration between the MPCA and industry associations, we could identify certain marine products containing PFAS above a threshold limit, simplifying the reporting process.

Regulatory bodies should provide risk communication and regulatory transparency. Regulators and legislators should ensure that the public can easily understand the actual risks associated with specific PFAS. This includes transparent communication regarding the processes associated with evaluating those chemicals as well as any scientific uncertainties in those analyses.

Regulations should be based on sound science. Any regulatory action addressing PFAS should be based on sound, peer-reviewed science, and a transparent and well-informed record. Agencies should identify sources of uncertainty and the research needed to reduce those uncertainties, and regulations should remain flexible to accommodate emerging science.

In conclusion, we emphasize that while the statute appears straightforward, its implementation will be profoundly complex, expensive, and difficult to attain, even with an unlimited budget and staff. Even environmentally focused states like California, that has decades of significant experience regulating chemical classes, have minimized its PFAS reporting mandates due to the massive scale and cost associated with mandates such as those found in the Minnesota statutes. To mitigate the significant hardships associated with this statute, we implore the MCPA to collaborate with Minnesota's marine businesses and the critical users who rely on them to streamline the compliance process, to establish reasonable deadlines, and to reduce reporting requirements to the minimum information needed to achieve the intent of PFAS regulation.

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[2] https://comptox.epa.gov/dashboard/chemical_lists/pfasmaster.
[3] https://www.atsdr.cdc.gov/pfas/overview.html

Please reach out to the National Marine Manufacturers Association's Midwest Policy and Engagement Manager Jesse McArdell (Jmcardell@nmma.org) with any questions.

Respectfully submitted,

Jesse McArdell

Midwest and Northeast Policy and Engagement Manager, National Marine Manufacturers Association (NMMA)

Chad Tokowicz

Government Relations Manager, Marine Retailers Association of the Americas (MRAA)

Ethan Hellier

Government Affairs Manager, Water Sports Industry Association (WSIA)

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November 28, 2023

Email: maryl.ynn@state.mn.us

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

Re: Comments on Minnesota's Planned PFAS in Products Reporting Rule

Dear Mary Lynn,

On behalf of the Consumer Technology Association (CTA), we respectfully submit these comments on the planned new rules governing reporting by manufacturers upon submission of required information about products containing per-and polyfluoroalkyl substances (PFAS). 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. Our member companies have long been recognized for their commitment and leadership in innovation and sustainability, often taking measures to exceed regulatory requirements on environmental design and product stewardship.

We appreciate the opportunity to provide comments on the upcoming PFAS in Products Reporting Rule (Rule) implementing the 2023 PFAS in Products Law (the Act)[1], and welcome continued dialogue with the Minnesota Pollution Control Agency throughout the rulemaking process.

In our comments, first we address MPCA's proposed timeline and the need for an extension for the electronics sector to comply with the information requirements of the Act. Then, we organize the rest of our comments around the six questions contained in MPCA's request for comment.

Information Requirement Extension for Electronics Sector

Subdivision 3(d) of the Act grants the commissioner the authority to extend the deadline for submission by a manufacturer if the commissioner determines that more time is needed to comply. We respectfully ask that the MPCA issue an extension for complex articles, including electronic and electrical products, for compliance with the notification requirements of the Act. The MPCA's current rulemaking process schedule anticipates the final adoption of rules by January 1, 2026. This is the same date when manufacturers have to report the presence of PFAS in their products. Without the clarity and information provided by a rulemaking conducted well in advance of the reporting requirement deadline, it will be

[1] Minnesota Session Law – 2023, chapter 60, article 3, section 21 (Minnesota Statutes 116.943)

difficult for many electronics manufacturers to provide the data necessary to comply. Manufacturers do not know exactly what information will be required or how to provide that information to the Agency. Therefore, we encourage MPCA to issue a blanket extension for all manufacturers of electronic products (including their component) and products with electronic components.

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.

Until the MPCA completes its rulemaking, manufacturers cannot know exactly what information they will need to compile across their supply chain. Our comments below on the MPCA questions underscore the need for precise guidance on numerous technical points that we request b 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. For example, electronics manufacturers cannot say with certainty exactly how long it will take to gather this information present without knowing threshold limits and reporting ranges – issues which we address later in these comments. Given the complexity of the issue and the extensive reporting the law requires, we respectfully ask that the Agency grant an extension to the electronics sector for 48 months after the final adoption of their rulemaking.

MPCA Question 1) Are there definitions in subdivision 1 for which clarification would be useful to understanding reporting responsibilities?

There are several definitions for which clarification would be useful for manufacturers to understand their reporting responsibilities:

- **Currently Unavoidable Use:** The statute indicates that the commissioner will determine by rule which uses of PFAS will fall under this definition. It would be useful to the regulated community if MPCA could make "currently unavoidable use" determinations as soon as possible. MPCA should create clear guidelines and procedures for these determinations and include them in future rulemakings.
- **Fabric Treatment:** The Rule should be explicit that the definition of "fabric treatment" refers to treatment products which are applied to fabrics and does not include products with fabrics that have been treated. In a public hearing regarding their interpretation of Maine's comprehensive PFAS in products law, Maine's Department of Environmental Protection said that products treated with fabric treatment are not in scope of their definition of "fabric treatment." We ask that Minnesota and Maine align on this issue.
- **Product and Product Component:** These two definitions should clarify if spare parts are included in the scope of the Act. The statute says that goods are considered products if they are "for sale" to consumers. However, spare parts when provided under warranty to customers are not "sold" to consumers but they are sold when out

of warranty. These definitions should explicitly exclude spare parts to allow for the continued repair and maintenance of existing products.

- **Product:** The definition does not state whether or not packaging is included within the definition of "product." We support the Rule clearly excluding product packaging from the scope of the notification requirements. Product packaging should be out of the scope of the Act except for when packaging is sold separately/individually. In Maine's comprehensive PFAS in products law, they have excluded packaging and treat it separately.[2]
- **Textile Furnishings**: We ask that MPCA clarify that "textile furnishings" do not include electronic articles with textile elements. For example, home speakers, microphones, wearable technology, and other electronic products contain components like batteries and printed circuit boards which have currently unavoidable uses of PFAS. Since these products also happen to have textile elements, they may be unintentionally caught in this definition, so we ask that they be explicitly excluded.
- **Upholstered Furniture:** We ask that MPCA exempt internal electronic and electrical components from the definition of upholstered furniture. Products such as massage chairs, gaming chairs, and motorized swings contain electronic components (motors, wires, batteries, circuit boards) which have currently unavoidable uses of PFAS. These internal electronic components have unique requirements and should be treated separately from the upholstery components of furniture.

MPCA Question 2) Are there terms or processes in subdivision 2 for which clarifications will help reporting entities determine reporting status or data-gathering process?

- **MPCA should provide CASRNs for all regulated PFAS substances:** Subdivision 2 requires manufacturers to report the amount of each PFAS in a product and identify it by its chemical abstracts service registry number (CASRN). We strongly encourage the Agency to issue a full list of PFAS substances covered by the Act and their CASRNs. Without a specified list of chemical names and CASRNs, tracking a class of thousands of chemicals across a complex global supply chain is incredibly difficult especially for complex article manufacturers that are far down the supply chain.

  MPCA should consider limiting reporting requirements under the Rule to those PFAS with CASRNs. These registry numbers exist for many PFAS, but the definition of PFAS in the Act is so broad that there may be substances which fall under scope that do not have CASRNs. We also recommend that reporting be allowed by PFAS group instead of only by discrete PFAS substance.

- **The MPCA should clarify that manufacturers can report products by category:** The MPCA should provide guidance on what level of product will require notification. If manufacturers are required to report on the smallest individual product and component level, there could be tens of thousands of reports per manufacturer for complex products like electronics. Electronic products can be modular with many component parts. For example, if a consumer purchases a computer, they often

[2] https://legislature.maine.gov/ros/LawsOfMaine/breeze/Law/getDocById/?docId=101620

custom order various components like hard drives, batteries, and even the color of the plastic casing. This can lead to thousands of possible permutations for a single "product" and therefore thousands of notifications.

Subdivision 2(b) authorizes MPCA to allow manufacturers to provide information by product category, and we support the Agency allowing flexibility in reporting by category. We encourage the Agency to allow manufacturers the option to report by Global Product Classification (GPC) brick code or Harmonized Tariff Schedule (HTS) code. Different industries utilize different codes for reporting, and allowing flexibility in reporting will enable manufacturers of articles to comply more easily. Reporting by product category will also prevent the Agency from being inundated with unnecessary superfluous reporting.

- **Testing and "Commercially Available Analytical Methods:"** We ask that the MPCA define this term and provide a list of approved test methodologies for PFAS. The EPA's website on testing perfluorinated compounds confirms that "nationally approved methods for measuring [perfluorinated compounds] in non-drinking water samples are not yet available."[3] Manufacturers of electronic products will find it difficult to test their products to determine exact quantity of PFAS as described in Subdivision 2. Currently, there is a notable absence of approved analytical methods tailored for media specifically pertinent to consumer electronics. Regulatory agencies in the US, including the EPA, CDC, FDA, DoD, and USGS, only have validated analytical methodologies for PFAS pertaining to environmental media, biological tissues, food, and firefighting foam. There are limited opportunities for testing complex articles, not all PFAS can be accurately tested for, and there are no internationally-recognized test methods for complex articles for "PFAS" as defined within the Act. MPCA should provide clear information on what test methods it would accept for complex articles.

  Additionally, we respectfully ask that the MPCA allow for supplier declarations as an appropriate proxy for a manufacturer in lieu of testing data. It is unrealistic to expect individual testing of the thousands of components within electronic products. Allowing manufacturers to rely on declarations of suppliers will help mitigate this issue. Supply chain restricted substance information has been used for decades to demonstrate compliance with restricted substance laws such as the EU Restriction of Hazardous Substances Directive.

- **MPCA should clarify the meaning of "Significant Change" used in Subdivision 2:** The Act requires that manufacturers update and revise information provided to MPCA "whenever there is significant change in the information." We ask that the Agency provide information on how it interprets "significant change." We suggest that it should be limited to the addition of an intentionally-added PFAS above reasonable minimum threshold levels and should not include the reduction or removal of PFAS. Reporting on the reduction or removal of PFAS should be voluntary.

[3] https://www.epa.gov/measurements-modeling/challenges-measuring-perfluorinated-compounds-pfcs

- **The Rule should establish a minimum reporting threshold:** MPCA must establish a de minimis reporting threshold for the information required in Subdivision 2. Such a threshold is necessary for effective and efficient application of any chemical reporting regime. A lack of a minimum threshold for PFAS in products would make it difficult for manufacturers to properly comply with the Act. The Act is focused on the notification and prohibition of intentionally added PFAS chemicals, and adding a minimum threshold will avoid unnecessary reporting of byproducts and impurities in products.

  We respectfully ask that the MPCA include in their rulemaking a threshold consistent with other jurisdictions' chemical reporting and restriction requirements. EU REACH provides a 0.1% by weight threshold for substances of very high concern and Candidate List substances, above which suppliers of articles must provide to their customers relevant information on the substances in the products they sell. This threshold provides a rational, reasonable level that promotes 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. A threshold would also help ease the burden on the Agency by preventing many notifications related to parts and components that contain only trace amounts of PFAS.

- **The Rule should provide concentration ranges for reporting:** MPCA should provide reporting concentration ranges in its rulemaking for the information required in Subdivision 2. Compliance with the notification requirement for many PFAS substances will be impossible without ranges promulgated by the MPCA because there is no commercially available methodology for identifying an exact quantity of PFAS. The Act specifically authorizes MPCA to approve reporting ranges. However, without knowing those ranges in advance, manufacturers have no way to plan for using them. We ask that the MPCA provide these ranges well in advance of the notification deadline. As part of the rulemaking, the Agency should specify concentration ranges for all PFAS or groups of PFAS subject to notification. Disclosing chemical concentration in ranges has been a long-established practice in other regulatory regimes such as the Globally Harmonized System of Classification and Labeling of Chemicals for Composition and Information on Ingredients[4], EUSCIP reporting, and EU REACH.

  We strongly encourage the MPCA to consider using the reporting ranges already used under the federal Toxic Substances Control Act (TSCA)[5].

- **Notifications should be submitted on a "reasonably ascertainable information" standard:** We ask that the reporting requirements be based on a "reasonably ascertainable information" standard. Due to the complexity of the supply chain for the electronics sector, a significant amount of time would be required to determine

[4] https://unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev08/ST-SG-AC10-30-Rev8e.pdf
[5] TSCA 8a7 Reporting Instructions: https://www.epa.gov/system/files/documents/2023-11/tsca-8a7-reporting-instructions-10-11-23.pdf

the use/non-use of unregulated PFAS chemicals. Therefore, the notification requirements should be based on information that is "reasonably ascertainable." For chemical reporting rules, EPA typically requires reporting information that is known or reasonably ascertainable. This is the standard EPA uses for its quadrennial Chemical Data Reporting rule [6] requirements as well as the standard EPA is using for its new PFAS reporting rule.[7]

MPCA Question 3) How should the MPCA balance public availability of data and trade secrecy as part of the reporting requirements?

- **MPCA should adopt clear, highly protective, and enforceable confidential business information protections:** We respectfully ask that the MPCA make clear how, practically, a manufacturer could assert a confidential business information (CBI) claim or trade secret under this law. A well-defined framework for all notification and future rulemaking will be essential for the protection of valuable intellectual property that might otherwise be jeopardized. We urge the Agency to adopt highly protective and enforceable CBI protections in its rulemakings for this law.

  The technology sector treats the chemical composition of materials as proprietary information that is carefully protected and of significant commercial value. The MPCA's regulations should contain explicit language explaining how manufacturers would provide reporting information to the Agency, how the MPCA will determine what CBI data may be withheld or provided in a generic/sanitized manner, and how that information will be stored and ultimately protected from unlawful disclosure to third parties.

MPCA Question 4) Are there any terms used in subdivision 3 that should be further defined or where examples would be helpful?

- **Waiver:** Subdivision 3(a) permits the commissioner to waive the information requirement if the commissioner determines that substantially equivalent information is already publicly available. MPCA should clarify whether and how waivers are established in advance of an applicable reporting deadline.
- **Coordination with other jurisdictions:** Subdivision 3(b) allows the commissioner to enter into an agreement with other states to collect information and accept information to a shared system to meet the requirements of the Act. We encourage the MPCA to engage with the U.S. EPA, Maine, and any other states which may pass similar laws regarding notification of PFAS in consumer products. We encourage MPCA to align with other jurisdictions wherever possible. Manufacturers and state agencies implementing these laws will benefit from avoiding the unnecessary burdens of an uneven patchwork of requirements. It would be ideal if Minnesota and Maine could coordinate and use a single reporting database with aligned criteria. MPCA should also coordinate with the EPA in obtaining information related to PFAS.

[6] 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

MPCA Question 5) Are there specific portions of the reporting process that should not be defined through guidance or the development of an application form?
CTA generally supports MPCA providing guidance wherever possible. Predictability and clarity are important for manufacturers to comply with the Act.

MPCA Question 6) Other questions or comments relating to reporting or the process of reporting.

- **Subdivision 4 and testing:** As we commented above regarding testing standards in Subdivision 2, MPCA should be clear about how exactly manufacturers are to comply with testing that may be required by the commissioner. There are no internationally-recognized test methods for "PFAS" as defined in this law. Subdivision 4 authorizes the commissioner to require testing if the commissioner has "reason to believe" a product contains PFAS. "Reason to believe" should be defined and outlined with specific principles and guidelines. MPCA should create clear standards and issue justifications for when it requires manufacturers to conduct testing.
- **"Used Products:"** Subdivision 8(a)(3) exempts the sale or resale of used products. We ask that the term "used product" be defined in the Rule. We also suggest that the definition for "used product" include remanufactured, refurbished, or repaired products.

Conclusion
Thank you again for the opportunity to provide these comments on the upcoming PFAS in Products Reporting Rule. We welcome further engagement with MPCA in this process, and if you have any questions about our comments, please do not hesitate to contact me at dmoyer@cta.tech.

Sincerely,

Dan Moyer
Sr. Manager, Environmental Law & Policy
Consumer Technology Association

November 28, 2023

Mary H. Lynn
Minnesota Pollution Control Agency
520 Lafayette Road
North St. Paul, MN 55155-4194

RE: Minnesota Pollution Control Agency Request for Comments on PFAS in Products Reporting; OAH Docket No. 65-9003-39507

Dear Ms. Lynn:

The American Chemistry Council (ACC) represents over 190 companies engaged in the business of chemistry—an innovative, $639 billion enterprise that is helping solve the biggest challenges facing our nation and the world. The business of chemistry drives innovations that enable a more sustainable future, creates 555,000 manufacturing and high-tech jobs—plus over four million related jobs—that support families and communities, and enhances safety through the products of chemistry and investment in research.

ACC respectfully submits the following comments from three groups within our association: The Performance Fluoropolymer Partnership, the Alliance for Telomer Chemistry Stewardship, and the Center for the Polyurethanes Industry. All three groups have extensive expertise as it relates to the rulemakings the Minnesota Pollution Control Agency (MPCA) is going to undertake and were all engaged during the legislative process.

Per- and polyfluoroalkyl substances (PFAS), or Fluorotechnology, are a diverse universe of chemistries that makes possible the products that power our lives – the cellphones, tablets and telecommunications we use every day to connect with our friends and family; the aircraft that power the U.S. military; alternative energy sources critical to sustainability goals; and medical devices that help keep us healthy. However, all PFAS are not the same. Individual chemistries have their own unique properties and uses, as well as environmental and health profiles.

ACC strongly supports the use of sound scientific principles during any rulemaking that impacts chemistry in commerce, and we stand ready to work with the MPCA during this process.

Thank you for the opportunity to provide comments during this pre-rulemaking comment period. Should you have any questions or concerns, please do not hesitate to contact me at (515) 471-1960 or by email at Marcus_Branstad@americanchemistry.com.

Sincerely,

Marcus Branstad
Senior Director, State Affairs

Alliance for Telomer Chemistry Stewardship

Re: 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[1]

Submitted via: https://minnesotaoah.granicusideas.com/

The Alliance for Telomer Chemistry Stewardship (ATCS) would like to submit the below general comments, specific comments to the Maine Department of Environmental Protection (DEP) Second Concept Draft (Draft) on PFAS in Products.

ATCS is a global organization that advocates on behalf of C6 fluorotelomer-based products. Our members are leading manufacturers of fluorotelomer based products in North America, Europe, and Japan. Our mission is to promote the responsible production, use, and management of fluorotelomer based products, while also advocating for a sound science and risk-based approach to regulation. Fluorotelomer-based products are versatile chemistries with wetting and spreading features, as well as unique properties that repel water, oil, and stains. These unique characteristics make fluorotelomers a critical component of first responder gear, medical garments, paints and coatings, upholstery, class B firefighting foam, among other uses that families and businesses across the world rely on.

ATCS has added responses to the following questions to best respond with the MCPA (Agency) requested information.

Are there definitions in subdivision 1 for which clarification would be useful to understanding reporting responsibilities?

Yes, there are several definitions in subdivision 1 for which clarification would be useful to understand reporting responsibilities. We address those definitions below in the order in which they appear in subdivision 1.

> **"Carpet or rug"** The Agency should **clarity** in regulation that "carpet or rug" means "intended for use in a building." Carpeting used in automobiles, airplanes, and non-building applications should not be included.
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> **"Currently unavoidable use"** We recommend clarification of several concepts within the definition of "currently unavoidable use" as described below.
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> **"Essential for health, safety, or the functioning of society"** An essential use assessment should only be initiated when there is deemed to be a risk to human health or the environment from the use of an intentionally added PFAS in a product. If there is no concern about risk during the use of an intentionally added PFAS in a product, valuable Agency time should not be wasted on an essentiality analysis. Similarly, other PFAS for which exposure will be minimal to non-existent

[1] https://www.pca.state.mn.us/sites/default/files/c-pfas-rule1-01.pdf

due to the nature of their use should not be subject to an essentiality analysis in the absence of a concern about human or environmental impact.

"Alternatives" The Agency should provide a detailed definition of "alternatives." The definition should include concepts of functional equivalency and reducing potential risk to human health or the environment. The basis for those concepts must be consistent, fair, transparent, and well-defined.

"Reasonably available" We request that the Agency provide a detailed definition of "reasonably available." How the Agency will determine when alternatives are not reasonably available should also be explained in regulation and should include the concepts of performance, safety, cost, and supply chain considerations.**"**

"Manufacturer" We are concerned that the definition of "Manufacturer" does not account for the way goods are bought, sold, and distributed, either through traditional or on-line markets. We predict significant confusion and a high likelihood of duplicative 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. 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.

For example, consider a scenario in which Company A contract**s with** Company B to manufacture a private label product carrying Company B's logo. Both Company A and Company B would be "manufacturers" with reporting obligations for the same product. The same potential for confusion and duplication would occur in a situation where a manufacturer, Company C, allows a licensee, Company D, to sell Company C's products under a brand name owned by Company D. Although both would be considered "manufacturers" according to the statute, Company C may not have perfect information about exactly where Company D sells Company C's products.

The definition in the statute does not allow the regulated community to identify the precise entity with the reporting obligation. The Agency should offer more clarity in proposed regulations concerning the entities that will and will not be considered the responsible manufacturer and attempt to make determinations that are more precise and not overlapping or conflicting.

We suggest that "manufacturer" should be limited to the entity whose brand name appears on the product and has potentially replaced the name of the actual manufacturer. Such an approach would mirror existing hazard communication instructions from the Occupational Health and Safety Administration (OSHA) concerning responsibility for the information on safety data sheets (SDS). Specifically, OSHA says, "Distributors who substitute their names on the SDS in place of the

manufacturer's or importer's information become responsible for the accuracy and completeness of the SDS."[2] OSHA's instructions make it clear who is responsible for the SDS.

> **"Product"** The Agency must clarify its intent regarding the word "item." Is a chemical an "item"? Does "item" refer to what is commonly understood as an "article"? Also, the Agency should substitute "purchasers" for "consumers" and clarify that the definition applies to "items . . . to consumers **in Minnesota.**"

Are there terms or processes in subdivision 2 for which clarifications will help reporting entities determine reporting status or data-gathering process?

Yes, there are terms or processes in subdivision 2 for which clarification will help reporting entities determine reporting status or the data-gathering process. We address those terms and processes below in the order in which they appear in subdivision 2.

> **"Amount of each PFAS"** Section 2 calls for reporting of "the amount of each PFAS, identified by its chemical abstracts service registry number." The Agency should allow for alternatives to CAS numbers, such as EPA-assigned Accession numbers, for proprietary chemicals with CAS numbers that are federally protected as confidential and for which the manufacture can substantiate both the need for ongoing protection to sustain a commercial advantage and steps the manufacturer takes to maintain confidentiality.

> **"Commercially available analytical method"** Analytical methods must be appropriate for the PFAS that are the target of the analysis and for the physical form of the product**;** e.g., gas, liquid, or solid. Analytical methods differ in which PFAS they are capable of detecting. For example, the analytical method EPA uses to identify PFAS in food contact materials targets 17 PFAS. In contrast, EPA's Draft Method 1633 is designed to identify 40 different PFAS in aqueous media (i.e., water, wastewater, landfill leachate), soil, biosolids, sediment, and biological tissues.

To create an even playing field, the Agency should elaborate in proposed regulations its intention regarding baseline criteria or performance standards for "any test methodology." It would be inappropriate in our view for the Agency to allow the use of any method that any commercial lab says it can perform on any product matrix with no consideration of whether the method is fit for purpose or has undergone any multi-laboratory validation or otherwise assessed for the purpose for which they are being used (i.e., accuracy, precision, specificity, detection limit, and quantification limit). Doing so would be well outside the realm of good regulatory science. We also recommend that the Agency incorporate the concept of validation into its regulatory explanation of what "commercially available analytical methods" will be acceptable.

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[2] U.S. Department of Labor, Occupational Safety and Health Administration (OSHA). OSHA Directive. Directive Number: CPL 02-02-079. Effective Date: July 9, 2015. Page 66. https://www.osha.gov/sites/default/files/enforcement/directives/CPL_02-02-079.pdf.

It is imperative for the Agency to recognize that many commercial PFAS compounds are proprietary chemicals for which there are no commercially available analytical methods. Without analytical standards for these proprietary chemicals, commercial laboratories will not be able to develop analytical methods. As a result, it will be impossible for manufacturers of products containing these PFAS chemistries to comply with the requirements of subdivision 2 of the statute unless the department establishes approved reporting ranges.

> **"Range approved for reporting purposes"** The ranges approved for reporting purposes should be codified in regulation well in advance of the first reporting deadline so that manufacturers with reporting obligations can prepare accordingly. We recommend that the Agency not develop ranges for different types of products. Doing so would create unnecessary confusion about the definition of products falling within each range and further complicate the ability of manufacturers with reporting obligations to report accurately and in a timely manner.
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> **"Significant Change"** The phrase "significant change" needs to be defined in regulation so that a manufacturer might **not** unknowingly violat**e**~~ing~~ the Agency's expectation when, in the manufacturer's legitimate view, only minor changes have been made to a product.
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> **"Standard for Reporting"** The U.S. EPA has finalized a reporting and record keeping rule for PFAS under Section 8(a)(7) of the Toxic Substances Control Act. Like other Section 8(a) reporting rules, the reporting standard for the forthcoming rule is "known or reasonably ascertainable by", and we strongly urge the Agency to adopt such a standard.[3] Notably, the federal standard does not require extensive new customer or supplier surveys or create an obligation for novel testing, which would significantly reduce the burden for reporting.

How should the MPCA balance public availability of data and trade secrecy as part of the reporting requirements?

Minnesota's program would require manufacturers to disclose sensitive proprietary information about the specific chemical identities, functions, and amounts of PFAS in their products. Manufacturers derive independent economic value from this information and take the necessary steps at to protect such information since, without such protection, manufacturers would be placed at a competitive disadvantage and their investments in innovation would be undermined. Given that fluoropolymers are essential to products in vital economic sectors such as electronics, energy, transportation, and construction, inadequate protection could compromise national security and infrastructure. In addition, manufacturers that are unable to assure the protection of their intellectual property in the State of Minnesota may choose to avoid the Minnesota market, which would inevitably result in Minnesota residents and businesses being deprived access to innovative products and technologies.

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[3] 40 CFR 710.23 "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." *See* 76 FR 50829 (August 16, 2011) for EPA's detailed explanation of the standard in the context of the TSCA Chemical Data Reporting Rule.

The concept of a "trade secret" is well established in Minnesota law and is defined in the Minnesota Uniform Trade Secrets Act as follows:

"Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process, that:
(i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and
(ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.[4]

This definition of "trade secrets" is recapitulated in the Minnesota Government Data Practices Act,[5] which requires that trade secrets be treated as general nonpublic data by Minnesota agencies. "Nonpublic data" is defined as "any government data classified by statute, federal law, or temporary classification as confidential, private, nonpublic, or protected nonpublic."[6] Furthermore, Minnesota Statutes § 115.A.06 states that:

(a) Any data held by the commissioner which consists of trade secret information as defined by section 13.37, subdivision 1, clause (b), or sales information, shall be classified as private or nonpublic data as defined in section 13.02, subdivisions 9 and 12. 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.

Some types of proprietary information the Agency will request derive independent economic value and are the subject of efforts to maintain its secrecy. Such information may also be recognized as confidential by federal or other state agencies. Therefore, in the proposed rule, the Agency must provide clear instructions regarding the specific steps that must be taken to officially assert and/or substantiate a trade secret claims for information submitted that qualifies as a trade secret under Minnesota law, including the timeline by which such claims must be made relative to the reporting deadlines.

The Agency also should define in regulation a process whereby a manufacturer is to be notified if its trade secret is subject to a public records request or is inadvertently disclosed by the Agency or any organization with which the Agency collaborates or contracts in the administration of the reporting

[4] Minnesota Statutes § 325C.01, subdivision 5
[5] Minnesota Statutes § 13.37 (General Nonpublic Data)
[6] Minnesota Statutes § 13.02, subdivision 8a

program, including other states and the organization that designs, operates, or otherwise administers the reporting platform.
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The Agency should not enter into data sharing agreements with other states if it cannot assure that those states possess equivalently protective policies for trade secrets submitted to Minnesota, and, as we have previously noted in comments to the State of Maine, we are particularly concerned about how commercially valuable trade secret information will be managed by the Interstate Chemicals Clearinghouse (IC2) of which the Agency is a member.

Are there any terms used in subdivision 3 that should be further defined or where examples would be helpful?

The following term subdivision 3 needs to be further defined or where examples would be helpful.

> **"Substantially equivalent information"** The authorizing statute clearly gives the Agency authority to "waive all or part of the notification requirement under subdivision 2 if the commissioner determines that substantially equivalent information is already publicly available." The Agency should define in proposed regulations what it will consider "substantially equivalent information."

Are there specific portions of the reporting process that should not be defined through guidance or the development of an application form?

No part of the reporting process should be defined through guidance. Guidance may be a useful tool for providing illustrative examples, but its value is otherwise limited. PCA should provide manufacturers with reporting obligations clear and concise explanation of expectations and procedures in regulation. No regulatory obligation dictated by a "shall" statement in the statute or that concerns the protection of trade secrets should be left to guidance. Such requirements must be articulated in regulation.

We do not understand the part of the question about an application form. We do not know what an application form is or what the Agency intends a manufacturer **to be** potentially applying for. We would appreciate additional clarity from the Agency.

Other questions or comments relating to reporting or the process of reporting.

Reporting Database: As the Agency is certainly aware, it will receive notifications for hundreds of thousands of products from all sectors of the economy. We are concerned about the ability of the reporting tool being developed and administered by the IC2 to manage this task since, as far as we are aware, IC2 has not previously developed a reporting system of this scope and magnitude. Consequently, it will be essential that the Agency take whatever measures are necessary to build in a beta testing phase to ensure that the IC2 system is sufficiently robust to manage the number of users and volume of

information anticipated and sufficiently flexible to allow for reporting of information that may not conform to a particular format contemplated by the Agency.

PERFORMANCE FLUOROPOLYMER PARTNERSHIP

November 28, 2023

Re: 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[1]

Submitted via https://minnesotaoah.granicusideas.com/

On behalf of the American Chemistry Council's Performance Fluoropolymer Partnership,[2] thank you for the opportunity to submit comments on planned new rules for the reporting of the intentional use of per- and polyfluoroalkyl substances (PFAS) in products. The Partnership's members are some of the world's leading manufacturers, processors, and users of fluoropolymers, including fluoroelastomers, and polymeric perfluoropolyethers. 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 regulation. We hope the Minnesota Pollution Control Agency (hereafter "Agency") will find our comments useful in crafting proposed regulations. First, we provide general comments on the proposed regulation, followed by responses to the specific questions raised by the Agency.

General Comments

We request that the Agency exclude fluoropolymers and fluoropolymer-based products from the scope of the proposed regulations. Fluoropolymers are large, stable molecules that have been demonstrated to meet criteria developed by governmental and intergovernmental regulators to identify "polymers of low concern" for potential impacts on humans and the environment.[3,4] As demonstrated in our references provided here, fluoropolymers are insoluble substances and therefore do not present concerns about mobility in the environment, in contrast to certain highly water soluble PFAS substances. In addition, fluoropolymers are neither bioavailable nor bioaccumulative, are not long-chain non-polymer PFAS, such as PFOA and PFOS, and do not transform into non-polymer PFAS in the environment. Furthermore, because of their chemical and heat resistance as well as their dielectric properties, fluoropolymers are often used in components such as gaskets, tubing, electrical wiring, and printed circuit boards, that are found in tens of thousands of different products, ranging from Heating, Ventilation and Air Conditioning (HVAC) systems to aerospace equipment. Compliance with the notification requirement will be

[1] https://www.pca.state.mn.us/sites/default/files/c-pfas-rule1-01.pdf
[2] https://fluoropolymerpartnership.com/
[3] 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, https://doi.org/10.1002/ieam.4035.
[4] 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, https://doi.org/10.1002/ieam.4646.

exponentially more complex and burdensome if fluoropolymers are not excluded and, because of the benign nature of fluoropolymers, little useful information will be gained from their inclusion in the rule.

To avoid unnecessary and duplicative reporting, we urge the Agency to delay development and implementation of the reporting regulations until the data reported pursuant to the United States Environmental Protection Agency's (EPA) recently finalized reporting and record keeping regulation become available.[5] The rule requires comprehensive reporting on all PFAS substances manufactured or imported into the United States since 2011, including PFAS substances imported as part of articles. Reporting under this regulation will be completed in 2025, and much of the information reported is expected to be made available to the public. Even if the data collected by EPA do not completely address all of Minnesota's information needs, the EPA data should allow the Agency to more carefully tailor the reporting requirements that will apply to manufacturers in Minnesota so that manufacturers in the state are not saddled with unnecessarily burdensome reporting obligations.

Finally, the overly broad definition of PFAS in the authorizing legislation creates an overwhelming task for the Agency. We suggest that the Agency reconsider the working definition of the program to focus on non-polymeric perfluoroalkyl and polyfluoroalkyl substances that contain at least two fully fluorinated sequential carbon atoms, excluding gasses and volatile liquids. This definition of PFAS would focus on smaller, lower molecular weight, soluble PFAS that may move between environmental media, may be more bioavailable and bioaccumulative, and should be of higher regulatory priority. It would allow the Agency to focus its limited resources and more quickly identify sources of PFAS that may be potentially of concern to human or environmental health.

Responses to Specific Questions Raised by MPCA

1. Are there definitions in subdivision 1 for which clarification would be useful to understanding reporting responsibilities?

There are several definitions in subdivision 1 for which clarification would be necessary or useful to understand reporting responsibilities. We address those definitions below in the order in which they appear in subdivision 1.

Air care product. The regulations should clarify that the term "air care product" is limited to formulated chemical products and does not include air filters, air purifying devices, or similar articles.

Durable houseware items. The Agency should provide a definition for "durable houseware items" or otherwise clarify the definition of "cookware." In particular, the regulations should clarify that the term "cookware" does not include household appliances such as refrigerators, ranges, microwaves, air fryers, and other types of countertop electrical appliances. More

[5] *See* 88 Fed. Reg. 70516 (October 11, 2023).

generally, the regulations should include a complete list of articles that are "cookware" rather than providing only an illustrative list of covered products. These clarifications are necessary to help ensure that the scope of the prohibition is clear and unambiguous.

Carpet or rug. The Agency should clarify in regulation that "carpet or rug" means a fabric floor covering "intended for use in a building." Carpeting used in automobiles, airplanes, and non-building applications should not be included.

Currently unavoidable use. Clarification is needed for several of the concepts embedded within the definition of "currently unavoidable use" as described below.

> **Essential for health, safety, or the functioning of society.** An "essentiality" assessment should only be initiated when there is deemed to be a risk to human health or the environment from the use of an intentionally added PFAS in a product. On this point, we reiterate that fluoropolymers have been demonstrated to satisfy internationally accepted criteria for being polymers of low concern.[6] If there is no concern about risk during the use of an intentionally added PFAS in a product, such as a fluoropolymer, valuable Agency time and resources should not be wasted on an essentiality analysis. Neither should residents of Minnesota be denied access to a myriad of products important to their daily lives simply because those products contain polymers of low concern.
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> More generally, as illustrated by the following examples, the concept of essentiality must be interpreted broadly in order to be workable. For example, under a narrow interpretation of "essentiality" it may be argued that products such as cell phones, laptop computers, or automobiles are not "essential to the functioning of society" since society can continue to function without these conveniences. But this narrow, and in our view inappropriate, interpretation fails to properly account for the fact that these types of products are highly beneficial and are an ***essential feature*** of our society. Similarly, under a narrow interpretation of "essentiality" it could be argued that products such as refrigeration units are not "essential to health" since people can live healthy lives without refrigeration. However, this narrow interpretation ignores the critical role that refrigeration plays in supporting good health by preventing food spoilage and preserving pharmaceuticals. These are a few examples of the types of products that, if they became unavailable, would cause massive social and economic dislocation. To avoid this type of disruption we strongly urge the Agency to adopt a broader interpretation of essentiality.
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> Finally, we urge the Agency to take notice of a report recently issued by the Department of Defense (DOD), highlighting the criticality of certain PFAS chemistries across a broad

[6] Henry, B.J., *et al.* 2018. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integr Environ Assess Manag, 14: 316-334. https://doi.org/10.1002/ieam.4035. Open access; Korzeniowski, S.H., *et al.* 2022. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. Integr Environ Assess Manag, 19: 326-354. https://doi.org/10.1002/ieam.4646. Open access.

swath of applications of strategic and national importance.[7] Based on an extensive survey of known uses of PFAS chemistries, DOD concluded as follows (emphases added):

> ***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**. DoD relies on an innovative, diverse U.S. industrial economy. **Most of the structurally defined PFAS are critical to the national security of the United States, not because they are used exclusively in military applications (although a few are) but because of the civil-military commonality and the potentially broad civilian impact**.[8]*

DOD went on to warn that:

> *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.[9]*

In developing regulations interpreting the concept of "currently unavoidable use" the Agency should heed DOD's warning and ensure that the term is interpreted broadly enough to encompass uses of PFAS that are critical to national infrastructure and supply chains.

Alternatives. The Agency should clarify that an "alternative" to PFAS means a chemical or non-chemical substitute that: (i) provides performance at least equivalent to the performance of the PFAS to be substituted; (ii) has been demonstrated to present lower risks to health and the environment than the product manufactured with PFAS; and is both technologically and commercially feasible.

Reasonably available. The Agency should provide a detailed definition of "reasonably available" that specifies the types of criteria that will be assessed to determine reasonable availability. In particular, the definition should help ensure that alternatives

[7] US Department of Defense. Report on Critical Per- and Polyfluoroalkyl Substance Uses. August 2023. *Available at* https://www.acq.osd.mil/eie/eer/ecc/pfas/docs/reports/Report-on-Critical-PFAS-Substance-Uses.pdf
[8] Id. at 15.
[9] Id.

are considered to be "reasonably available" only if they can be implemented at scale, at a cost that is comparable to the substance or product being replaced. The definition should also account for performance, safety, and supply chain considerations as well as regulatory restrictions or requirements that may otherwise impede availability.

Manufacturer. We are concerned that the definition of "Manufacturer" does not account for the way goods are bought, sold, and distributed, either through traditional or on-line markets. 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. 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.

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 statutory definition, both Company A (the brand owner) and Company B (the manufacturer) would be "manufacturers" with reporting obligations for the same product.

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 the State of Minnesota. Company A may not sell its product to purchasers in Minnesota, but, unbeknownst to Company A, the out-of-state distributor may sell 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 statutory definition, even though Company A has no idea that its product is being sold in the State. This is not an uncommon scenario. The same is true for sales made through on-line platforms where the original manufacturer is not the entity fulfilling the sale of the product into Minnesota. Products sold to members of the public through on-line platforms can come from anywhere, and the original manufacturer has little to no control over that sale or the ability to get sales information through such channels.

As these examples illustrate, the definition in the statute 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 a manufacturer that does not know its product is being sold in Minnesota. To address this concern, the regulations 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 ensure that there will be no "double counting" of products sold or offered for sale. To further improve the accuracy of the information reported, the Agency should

consider allowing joint submissions by the entity that first sells a product (or offers to sell a product) in Minnesota (i.e., the entity that knows the product is sold or offered for sale in Minnesota) and the entity that produces the product (i.e., the entity that may be more familiar with the chemical composition of the product).

Product. The Agency should clarify that the scope of products covered by the reporting requirement is limited to items intended for use by consumers and does not extend to products intended solely for industrial or commercial use. Also, the Agency should clarify that the definition applies to "items . . . for sale to consumers **in Minnesota.**"

2. Are there terms or processes in subdivision 2 for which clarifications will help reporting entities determine reporting status or data-gathering process?

There are terms or processes in subdivision 2 for which clarification will help reporting entities determine reporting status or the data-gathering process. We address those terms and processes below in the order in which they appear in subdivision 2.

Amount of each PFAS. Section 2 calls for reporting of "the amount of each PFAS, identified by its chemical abstracts service registry number." Substances listed on the TSCA Inventory should be reported using the same identifier listed on the non-confidential Inventory. The Agency should allow the use of EPA-assigned Accession numbers, which are used for proprietary chemicals with CAS numbers that are federally protected as confidential business information and for which the manufacture can substantiate both the need for ongoing protection to sustain a commercial advantage and steps the manufacturer takes to maintain confidentiality. Pre-manufacture notice (PMN) numbers should also be an option. Also, some fluoropolymers do not have CAS numbers, and the Agency should clarify how manufacturers should report PFAS that do not have a CAS number, if at all.

Commercially available analytical method. Analytical methods must be appropriate for the specific PFAS compounds that are the target of the analysis and for the physical form of the product, e.g., gas, liquid, or solid. To create an even playing field, the Agency should elaborate in proposed regulations its intention regarding baseline criteria or performance standards for acceptable analytical methods. It would be inappropriate in our view for the Agency to allow the use of any method that any commercial lab says it can perform on any product matrix with no consideration of whether the method is fit for purpose or has undergone standard multi-laboratory validation or otherwise assessed for the purpose for which it is being used (i.e., accuracy, precision, specificity, detection limit, and quantification limit). Doing so would be well outside the realm of good regulatory science. To help assure the validity and reliability of information reported under the regulations, it is essential that the Agency incorporate the concept of validation into its regulatory explanation of what "commercially available analytical methods" will be acceptable.

Finally, it is critically important for the Agency to recognize that the vast majority of commercial PFAS compounds are proprietary chemicals for which there are no commercially available analytical methods. Moreover, without analytical standards for these proprietary

chemicals, commercial laboratories will not be able to develop analytical methods. As a result, it will be impossible for manufacturers of products containing these PFAS chemistries to comply with the requirements of subdivision 2 of the statute unless the Agency permits product manufacturers to report on the quantity and identity of PFAS in their products based on information provided by their suppliers of PFAS-containing components, rather than requiring testing which, in the vast majority of cases, product manufacturers will be unable to perform. For example, consider the following scenario. Company A manufactures a PFAS-containing component such as a gasket, which is sold to the manufacturer of an engine sub-assembly (Company B) located outside the State of Minnesota. The sub-assembly may be sold to another company located outside of Minnesota (Company C), which incorporates the sub-assembly into a finished complex article such as a tractor. As the manufacturer of the tractor and the company that offers the tractor for sale in Minnesota, Company C bears responsibility for reporting on the PFAS content of the tractor. Rather than requiring Company C to test all of the gaskets, hoses, and electrical wiring in the tractor to determine their PFAS content, Company C should be allowed to rely on PFAS content information provided by their supplier, Company B. For similar reasons it is essential for the Agency to establish approved reporting ranges. See also our comment immediately below concerning the phrase " information required."

Information required. Regarding the amount of each PFAS in a product sold, offered for sale, or distributed in the state, that Agency should allow reporting entities to report based on documentable information obtained from suppliers. Doing so would significantly reduce the reporting burden.

Range approved for reporting purposes. The ranges approved for reporting purposes, including any de minimis thresholds, should be codified in regulation well in advance of the first reporting deadline so that manufacturers with reporting obligations can prepare accordingly. We recommend that the Agency not develop ranges for different types of products. Doing so would create unnecessary confusion about the definition of products falling within each range and further complicate the ability of manufacturers with reporting obligations to report accurately and in a timely manner.

Significant Change. The phrase "significant change" needs to be defined in regulation so that a manufacturer does not unknowingly violate the Agency's expectations when, in the manufacturer's legitimate view, only minor changes have been made to a product.

Standard for Reporting. As discussed earlier, EPA has finalized a comprehensive reporting and record keeping rule for all PFAS compounds manufactured in the United States under Section 8(a)(7) of the Toxic Substances Control Act. Under this regulation, manufacturers subject to the rule must report required information to the extent that information is "known or reasonably ascertainable by" the manufacturer.[10] We strongly urge the Agency to adopt such a standard for this rule, especially since manufacturers–particularly manufacturers of complex

[10] 40 CFR 710.23 "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." *See* 76 FR 50829 (August 16, 2011) for EPA's detailed explanation of the standard in the context of the TSCA Chemical Data Reporting Rule.

articles–will be responsible for reporting information on components that may be incorporated into their product through a multi-tiered global supply chain. Notably, the federal standard does not create an obligation for novel testing, which would significantly reduce the burden for reporting and bring it into the realm of what is feasible. Aligning with existing federal regulations avoids a patchwork of conflicting regulation and reduces the burden for those entities already subject to the federal reporting rules.

3. How should the MPCA balance public availability of data and trade secrecy as part of the reporting requirements?

Minnesota's program would require manufacturers to disclose sensitive proprietary information about the specific chemical identities, functions, and amounts of PFAS in their products. Manufacturers derive independent economic value from this information and take the necessary steps to protect such information since, without such protection, manufacturers would be placed at a competitive disadvantage and their investments in innovation would be undermined. Given that fluoropolymers are essential to products in vital economic sectors such as electronics, energy, transportation, construction, and healthcare, including medical devices, inadequate protection could compromise national competitiveness, security, and infrastructure. In addition, manufacturers that are unable to assure the protection of their intellectual property in the State of Minnesota may choose to avoid the Minnesota market, which would inevitably result in Minnesota residents and businesses being deprived access to innovative products and technologies.

The concept of a "trade secret" is well established in Minnesota law and is defined in the Minnesota Uniform Trade Secrets Act as follows:

> *"Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process, that:*
>
> *(i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and*
>
> *(ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.*[11]

This definition of "trade secret" appears in the definition of "trade secret information" in the Minnesota Government Data Practices Act,[12] which requires that trade secrets be treated as general nonpublic data by Minnesota agencies. "Nonpublic data" is defined as "any government data classified by statute, federal law, or temporary classification as confidential, private, nonpublic, or protected nonpublic."[13] Furthermore, Minnesota Statutes § 115.A.06 states that:

[11] Minnesota Statutes § 325C.01, subdivision 5
[12] Minnesota Statutes § 13.37 (General Nonpublic Data)
[13] Minnesota Statutes § 13.02, subdivision 8a

> *(a) Any data held by the commissioner which consists of trade secret information as defined by section 13.37, subdivision 1, clause (b), or sales information, shall be classified as private or nonpublic data as defined in section 13.02, subdivisions 9 and 12. 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.*

Some types of proprietary information the Agency will request derive independent economic value and are the subject of efforts to maintain its secrecy. Such information may also be recognized as confidential by federal or other state agencies, and trade secrets that are inadvertently disclosed may compromise national security and infrastructure. Therefore, in the proposed rule, the Agency must provide clear instructions regarding the specific steps that must be taken to officially assert and/or substantiate a trade secrets claim for information submitted that qualifies as a trade secret under Minnesota law, including the timeline by which such claims must be made relative to the reporting deadlines.

The Agency also should define in regulation a process whereby a manufacturer is to be notified if its trade secret is subject to a public records request or is inadvertently disclosed by the Agency or any organization with which the Agency collaborates or contracts in the administration of the reporting program, including other states and the organization that designs, operates, or otherwise administers the reporting platform. The Agency should not enter into data sharing agreements with any organization, including but not limited to other states, if the Agency cannot assure that those organizations possess equivalently protective policies for trade secrets submitted to Minnesota. As we have previously noted in comments to the State of Maine, we are particularly concerned about how commercially valuable trade secret information will be managed by the Interstate Chemicals Clearinghouse (IC2) of which the Agency is a member.

4. Are there any terms used in subdivision 3 that should be further defined or where examples would be helpful?

There is a term used in subdivision 3 that should be further defined and for which examples should be provided.

Substantially equivalent information. The authorizing statute clearly gives the Agency authority to "waive all or part of the notification requirement under subdivision 2 if the commissioner determines that substantially equivalent information is already publicly available." The Agency should define in proposed regulations what it will consider "substantially equivalent information."

In addition, with respect to paragraph (c) of subdivision 3, the Agency should make clear in its regulations that, prior to entering into any agreement to share reported information, the Agency will assure that confidential business information will be protected by all parties to the agreement to the same extent, or greater, that such information is protected in Minnesota.

5. Are there specific portions of the reporting process that should not be defined through guidance or the development of an application form?

No part of the reporting process should be defined through guidance. Guidance may be a useful tool for providing illustrative examples, but its value is otherwise limited. The Agency must establish a clear and concise explanation of expectations and procedures in regulations so that subject manufacturers have regulatory certainty and an ability to comply with the Agency's rules. No regulatory obligation dictated by a "shall" statement in the statute or that concerns the protection of trade secrets should be left to guidance. Such requirements must be articulated in regulation.

We do not understand the part of the question about an application form. We do not know what an application form is or what the Agency anticipates a manufacturer to be potentially applying for. We would appreciate additional clarity from the Agency; however, as a general principle, an application form should not be used to establish new definitions not otherwise specified in regulation unless the application form itself is developed and vetted through a notice and comment process.

6. Other questions or comments relating to reporting or the process of reporting.

Reporting Database. As the Agency is certainly aware, it will receive notifications for hundreds of thousands of products (if not more) from all sectors of the economy. We understand that the Agency may be considering utilizing a reporting tool and database being developed by the Interstate Chemicals Clearinghouse (IC2). However, we have serious concerns about the ability of the IC2 reporting tool to manage this task since, as far as we are aware, IC2 has not previously developed a reporting system of this scope and magnitude. Consequently, it will be essential that the Agency take whatever measures are necessary to build in a beta testing phase to help ensure that the IC2 system (or whatever system is utilized by the Agency) is sufficiently robust to manage the number of users and volume of information anticipated, sufficiently flexible to allow for reporting of information that may not conform to a particular format contemplated by the Agency, and sufficiently protective of trade secrets claims (see our response to question #3 above). The Agency's rules should not become effective until the IC2 system has successfully completed beta testing.

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Thank you for the opportunity to provide these comments. Please contact me if you have any questions.

Jay West
Executive Director
Performance Fluoropolymer Partnership

November 28, 2023

Mary H. Lynn
MPCA
520 Lafayette Road North
St. Paul, Minnesota, 55155-4194

RE: 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

Dear Ms. Lynn,

The American Chemistry Council's Center for the Polyurethanes Industry[1] (CPI) thanks the Minnesota Pollution Control Agency (MPCA) for engaging stakeholders during its rulemaking regarding reporting of products containing per-and polyfluoroalkyl substances (PFAS).

Polyurethanes manufacturers and chemical producers have been investing in the transition to low-global warming potential (GWP) foam blowing agents for decades. Since the early 2010s, polyurethanes manufacturers have had access to hydrofluoroolefin (HFO) foam blowing agents. HFO blowing agents provide a significant GWP reduction as compared to earlier generations of blowing agents and have a short atmospheric lifetime. The three primary HFO foam blowing agents used in the polyurethanes sector have GWPs < 7, which is approximately 200-1400 times lower than the substances previously used in the industry. In October, the U.S. Environmental Protection Agency (U.S. EPA) published a final rule outlining the federal phaseout of HFC blowing agents with a GWP of over 150 for polyurethane end uses by Jan 1. 2025.

CPI has the following comments on the request for information regarding 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:

1) Are there definitions in subdivision 1 for which clarification would be useful to understanding reporting responsibilities?

The most important definition to clarify in subdivision 1 is the definition of PFAS. While the definition used in the Request for Information is clear, there are several federal bodies that have proposed a different definition, and the Organisation for Economic Co-operation and Development (OECD), which serves as the basis for the definition used in the regulation, even cautions against using its definition to regulate PFAS as a class. The proposed PFAS class is unified only by a single chemical feature, which results in an overly broad group of substances with vastly different physico-chemical, toxicological and degradation properties, instead of a well-defined group of substances that have been demonstrated to have actual or potential hazardous effects on the environment or on human health. We believe that the scope of any

[1] The Center for the Polyurethanes Industry's (CPI) mission is to promote the growth of the North American polyurethanes industry through effective advocacy, delivery of compelling benefits messages demonstrating how polyurethanes deliver sustainable outcomes, and creation of robust safety education and product stewardship programs.

PFAS reporting requirement should be tailored to substances with recognized persistent and bioaccumulation characteristics. It is well established that persistent and bioaccumulation properties of PFAS depend on carbon chain length. For instance, smaller and larger molecules (< C4 or > C20) have been shown to not exhibit bioaccumulative properties.

An overly broad definition of PFAS will include chemicals that have been determined as non-toxic and non-bioaccumulative based on U.S. EPA criteria. Many are approved for their respective end-use applications by U.S. EPA under Section 612 of the Clean Air Act (CAA), as well as specific Toxic Substances Control Act (TSCA) significant new use rules and Section 5(e) Consent Orders, and these substances also are already subject to CAA and TSCA reporting requirements. U.S. EPA has taken several key federal actions to regulate PFAS, and MPCA should consider these approaches in more detail as it decides its policy options. Per U.S. EPA's approach, there are multiple definitions of PFAS, and the choice of definition determines which fluorinated chemicals are subject to regulation based on the Agency's goals of addressing and prioritizing those PFAS compounds that have demonstrated persistence, bioaccumulation potential, and toxicity. Most recently, U.S. EPA announced its planned framework for reviewing new PFAS and new uses of PFAS.[2] This latest framework proposes extensive review of PFAS before they enter the market. Further, the definition of PFAS that has been proposed under this approach is based on chemical structure and is narrower and more appropriate. The framework includes differing levels of PFAS classification based on the potential for exposure and environmental release.

HFO blowing agents fall into a broad class of fluorinated chemicals, but they do not possess the properties that have been associated with PFAS. HFO foam blowing agents are not classified as persistent, bioaccumulative, or toxic (PBT).[3] The HFOs used as foam blowing agents have atmospheric lifetimes measured in days and are designed to readily breakdown in the atmosphere if released, forming compounds that occur naturally in the environment.[4,5] Under Section 612 of the CAA, U.S. EPA's Significant New Alternatives Policy (SNAP) program reviewed environmental fate data on the HFO foam blowing agents for acceptability as approved alternatives to previous generation materials. By deeming HFO foam blowing agents "acceptable," U.S. EPA has determined that HFO foam blowing agents "reduce overall risk to human health and the environment compared to other substitutes for the particular end-use." Additionally, on April 28, 2023, U.S. EPA stated in the final rulemaking for SNAP Rule 25 regarding HFOs in refrigerant end uses:

> Regardless of what definition of PFAS is used, not all PFAS are the same in terms of toxicity or any other risk. Some PFAS have been shown to have extremely low toxicity, for example. If a chemical has been found to present lower overall risk to human health or the environment, it might be found acceptable under SNAP regardless of whether or not it falls under a particular definition of PFAS. Likewise, SNAP might not find a potential alternative acceptable if it presented greater overall risk, regardless of whether or not it falls under a particular definition of PFAS. As described in the risk screens for alternatives found in the docket for this rulemaking, potential risk to human health or the

[2] U.S. EPA Framework for TSCA New Chemicals Review of PFAS Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs), dated June 28, 2023.
[3] ECHA PBT Assessment List. Available at: https://echa.europa.eu/fi/pbt
[4] D.K. Papanastsiou, Atmospheric Chemistry of HFOs and HCFOs, DKV Annual Meeting, November 17-19, 2021, Dresden, Germany.
[5] EFCTC Position Paper: Published evidence supports very low yield of TFA from most HFOs and HCFOs (August 2021). Available at: https://www. fluorocarbons.org/wp-content/uploads/2021/08/2021_08_EFCTC_Position-Paper_Published-evidence-supports-very-lowyields-of-TFA-from-most-HFOs-and-HCFOs_F.pdf

> environment has been considered directly for each chemical, and the risks are not assumed to follow from a chemical falling into any particular category of substances.[6]

HFO foam blowing agents are not considered PFAS by U.S. EPA[7] and should not be classified or regulated as PFAS. It is inappropriate to regulate these chemicals in the same manner as PFAS. Unfortunately, the definition of PFAS used in the Request for Comments is broad enough to improperly include HFO blowing agents as PFAS. HFO blowing agents should be exempt from the reporting requirement and ban in any proposed rule.

Additionally, the definition used in the Request for Comments appears to be based on the OECD definition of PFAS. The OECD and U.S. Department of Defense (DOD) caution against the use of the OECD definition as a basis for regulating PFAS chemistries by family. The OECD stated:

> The term "PFAS" is a broad, general, non-specific term, which 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.[8]

The DOD, citing the OECD, provided the following caution in a recent report on PFAS:

> If future PFAS legal and regulatory frameworks ignore the OECD caution on the use of its PFAS definition and seek to broadly restrict the use of PFAS based on chemical structure, there could be extensive economic, industrial competitiveness, and quality-of-life impacts to U.S. society. The PFAS universe is structurally and physiochemically diverse and subgroups of PFAS may be more or less stable, persistent, and/or bioaccumulative compared to well-studied PFAS such as perfluorooctane sulfonate and perfluorooctanoic acid. Congress and the Federal regulatory agencies should avoid taking a broad, purely "structural" approach to restricting or banning PFAS. It is critical that future laws and regulations consider and balance the range of environmental and health risks associated with different individual PFAS, their essentiality to the U.S. economy and society, and the availability of viable alternatives.[9]

CPI strongly disagrees with the overly broad definition of PFAS in the Request for Comments. MPCA should recognize that HFO foam blowing agents, though structurally classified as PFAS under the OECD definition, do not have the same properties. EPA has listed HFO foam blowing agents as acceptable substitutes for the respective end-use applications under CAA Section 612. Additionally, HFO foam blowing agents are subject to CAA reporting requirements under SNAP Rule 21. The additional reporting of HFO blowing agents by MPCA creates a repetitive and unnecessary obligation for companies using these products.

A more appropriate definition of PFAS is:

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[6] Final Rule, Protection of Stratospheric Ozone: Listing of Substitutes Under the Significant New Alternatives Policy Program in Refrigeration, Air Conditioning, and Fire Suppression, 88 Fed. Reg. 26382, 26414 (Apr. 28, 2023).

[7] U.S. Environmental Protection Agency, National PFAS Testing Strategy: Identification of Candidate Per- and Polyfluoroalkyl Substances (PFAS) for Testing, US EPA, May 2, 2023

[8] Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance, OECD (July 9, 2021)

[9] Report on Critical Per- and Polyfluoroalkyl Substance Uses, United States Department of Defense (2023)

PFAS means non-polymeric perfluoroalkyl and polyfluoroalkyl substances that are a group of man-made chemicals that contain at least 2 fully fluorinated carbon atoms, excluding gasses and volatile liquids.

CPI recommends that products that contain chemistries that are non-persistent, non-bioaccumulative, and non-toxic be exempt from reporting, as they do not meet the characteristics of PFAS.

3) How should the MPCA balance public availability of data and trade secrecy as part of the reporting requirements?

Like the TSCA PFAS reporting rule, MPCA should clarify what information can be claimed as Confidential Business Information (CBI) and, therefore, not available to the public. See 40 CFR § 705.30. MPCA should also establish an efficient procedure for manufacturers to identify information as CBI or trade secret in its rulemaking. The program would require the disclosure of highly sensitive and proprietary information. MPCA should address questions about what information will be considered CB), how CBI will be protected by the entities managing the database, and how affected parties can make CBI claims. Moreover, MPCA should provide clarity on the overall management of CBI.

As a model, the TSCA PFAS reporting rule allows, with certain exceptions, reported information such as specific chemical identities that are not on the public inventory, company identifier information, and production volumes to be treated as CBI. See 40 CFR § 705.30(b)(2). Certain information likely to be CBI does not require additional substantiation, such as production or import volumes or specific chemical identity and molecular structures when the substance has not been introduced into commerce. MPCA should follow a similar approach for categories of requested information likely to be CBI or trade secret. Products subject to TSCA reporting requirements should be exempt from reporting obligations under this planned rule. MPCA should avoid unnecessary or duplicative reporting. Reporting obligations should only be imposed on those entities most likely to have relevant information not otherwise available to MPCA.

Regulated manufacturers of products containing PFAS will already be under a significant burden to comply with the TSCA PFAS reporting rule and such information, much of which will be publicly available, should meet MCPA's needs for this information.

4) Are there any terms used in subdivision 3 that should be further defined or where examples would be helpful?

CPI believes that clarification around subdivision 3, section d, would be helpful. Section d states: "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."

CPI recommends the duration of extension be one year. CPI also recommends that entities should be allowed to request an extension at least 60 days in advance of the reporting deadline and that MPCA provide a response within 30 days of whether the extension is granted and if not, why the extension was not granted. Failure of MPCA to respond within 30 days should grant the entity an automatic one-year extension. CPI also recommends that a web portal be established for extension requests, similar to the one established by the Maine Department of Environmental Protection for extension requests for PFAS reporting.

6) Other questions or comments relating to reporting or the process of reporting.

CPI requests clarification on the timeframe for registering and reporting new products that come to market. Additionally, CPI requests clarification on the frequency of reporting. CPI believes that increased frequency of reporting can be difficult due to a lag time in data.

Additionally, CPI requests clarification on the due date for fees. CPI recommends that MPCA follow the U.S. EPA reporting guidance.[10]

Other Issues

CPI recommends that the regulation provide accountability measures for the reporting program and collection and use of fees. MPCA should regularly review both the chemistry of PFAS, to account for changes in the chemistry, and the MPCA PFAS Reporting Program.

Conclusion

The fluorocarbons used in blowing agents break down quickly in the atmosphere, and are non-toxic, non-persistent and non-bioaccumulative, and thus not considered PFAS by U.S. EPA. Additionally, OECD and DOD both caution against broad use of the OECD definition as a basis for regulation of PFAS chemistries. CPI strongly believes that amending the definition of PFAS used in the Request for Comments to a more appropriate definition will alleviate many issues related to reporting. CPI opposes reporting related to fluorinated chemistries that are non-persistent, non-bioaccumulative, and non-toxic.

If you have any questions or need additional information, please contact me at Ian_Choiniere@americanchemistry.com or (202) 249-6424.

Sincerely,

Ian Choiniere
Director
Center for the Polyurethanes Industry

[10] TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, US EPA, October 11, 2023

RECEIVED
By: OAH on 11/28/2023

Best Technology Attachment

14040 23rd Ave N
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To: Minnesota Pollution Control Agency (MPCA)

Subject: Re: MPCA Request for Comments regarding PFAS in Products Reporting Rule (Revisor ID No. R-4828)

Best Technology offers the following comments on the PFAS regulations being developed by the Minnesota Pollution Control Agency (MPCA) as authorized in Chapter 60 of H.F. 2310. The MPCA has requested comments on planned new rules for the PFAS in Products Reporting Rule (Revisor ID No. R4828) and the PFAS in Products Fee Rule (Revisor ID No. R-4827). The MPCA also stated that it is interested in comments on the phaseout and ban of intentionally added PFAS in products in 2032.

Best Technology is a distributor of metal finishing equipment and chemicals to many vital industries in the U.S. As a small business, Best Technology has concerns regarding the costs to report and fees associated in reporting chemicals which it distributes. Since starting in the early 1990s, Best Technology has always strived to offer technologically advanced products for use in surface finish manufacturing processes. Our products are used by our customers as in-process manufacturing not as a final consumer product.

For certain manufacturing process applications, regulated industries such as medical device, aerospace, semiconductor, etc. do not have viable technological PFAS-free alternatives. Best Technology looks forward to helping customers transition as soon as alternatives are developed and proven safe and effective.

Please consider the following comments and responses to the questions raised in the request for comments document.

1) Are there definitions in subdivision 1 for which clarification would be useful to understanding reporting responsibilities?

"Subdivision 1. Definitions. (a) For purposes of this section, the following terms have the meanings given.

- *"(f) "Cleaning product" means a finished product used primarily for domestic, commercial, or institutional cleaning purposes, including but not limited to an air care product, an automotive maintenance product, a general cleaning product, or a polish or floor maintenance product."*

- Is this definition of "cleaning product" intended to be used for in-process cleaning during the manufacturing process and also as a final product?

- *"(j) "Currently unavoidable use" means 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."*
  - How, and when are applications going to be deemed "Currently unavoidable use" by the commissioner?
  - The use of the PFAS or PFAS-containing product is of great value to society because it contributes to the safety, efficacy, or accuracy of useful economic activities and societal advancing products, including those used in scientific research, medical equipment, aerospace, national defense, and in the manufacture of components in critical goods.
  - PFAS-containing materials change how different properties of substances behave, such as surface tension, thermal stability, flammability, and chemical compatibility. Many manufacturing processes are enormously dependent on PFAS, for which there are currently no viable PFAS-free alternatives.
  - Without established and clear exemptions for applications which truly have no current viable alternative, research and development innovation product alternatives which would take years given that regulated industries such as medical device, semiconductor, aerospace, etc. often must seek and receive approval from the appropriate regulatory authority for changes to their products. These alternatives may not be readily available without impacting the safety, quality, or efficacy of those products. Given this potential lengthy delay in the development and production of product alternatives, the elimination of medical and pharmaceutical products from the market would have devastating effects on millions of people, jeopardize our national security, and result in substantial economic consequences.
  - Any alternative to an existing use of a PFAS substance is to be considered a true replacement if it is both technologically innovative and commercially feasible (functionally equivalent/better and economically viable).

- *"(l) "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."*
  - What is considered a final product? It appears overall the ruling is to protect end consumers' health and environmental risk. Best Technology chemicals are not intended to be present in our customers final product (consumer or commercial).
  - Is this statement applicable if it is used in the manufacturing process but NOT in the final product?
  - While many final products may not contain intentionally added PFAS, fluorinated chemicals with PFAS components are used in the

manufacturing process and as such do not present a concern for human health or the environment.

- "(n) *"Manufacturer" means the person that creates or produces a product or whose brand name is affixed to the product. In the case of a product imported into the United States, manufacturer includes the importer or first domestic distributor of the product if the person that manufactured or assembled the product or whose brand name is affixed to the product does not have a presence in the United States."*
    - Does this mean the person with brand name affixed AND, if imported, must also include reporting from the importer and/or first domestic distributor?
    - In certain cases (namely trademark licenses to third parties), the definition may be interpreted to place the burden on two parties – the manufacturer/distributor and the brand owner.

- *"(p) "Perfluoroalkyl and polyfluoroalkyl substances" or "PFAS" means a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom."*
    - There is no single, globally-accepted definition for PFAS. The Act relies on the structure and atomic composition of PFAS and specifically the carbon-fluorine ("C-F") bond found in PFAS. The C-F bond-based definitions cover a broad group of over 10,000+ substances.
    - This overly broad grouping of substances with vastly different chemical, toxicological, degradation properties and treating the PFAS whole class as a "toxic substance" departs from the aim of targeting well-defined groups of substances that have been demonstrated to have actual or potential hazardous effects on the environment or on human health.
    - The presence of one (or more) C-F bonds in different chemicals has not been scientifically proven to be a risk to human health and the environment. Complex molecules with many C-F bonds are under higher consideration by the EPA for risk to human health and environment.
    - The PFAS reporting requirement should only include substances that have persistent and bioaccumulation characteristics. Molecules with smaller and larger carbon chain lengths (< C4 or > C20) have been systematically shown not to exhibit bioaccumulative properties. Certain PFAS compounds with short carbon chain lengths (shorter than 3-carbons) or alternative chemical structures are known to be non-persistent upon evaporation. These molecules were designed to have short lifetimes in the environment which have been deemed by multiple regulatory authorities not to have bioaccumulation or toxicity potential.
    - A defined list of CAS-identified PFAS chemistries that are subject to the reporting requirements seems essential. Without reasonable limits on the scope of the reporting requirements, manufacturers face an insurmountable administrative task which doesn't seem to have a verifiable impact on the goal.

- As such, reporting of every C-F bonded molecule will be extremely burdensome for companies and the MPCA without achieving the end goal of the original legislation to reduce risk to human health and the environment.

- *"(q) "Product" means an item manufactured, assembled, packaged, or otherwise prepared for sale to consumers, including but not limited to its product components, sold or distributed for personal, residential, commercial, or industrial use, including for use in making other products. "(r) "Product component" means an identifiable component of a product, regardless of whether the manufacturer of the product is the manufacturer of the component."*
  - The intent seems to describe products for sale ultimately to end consumers or components used in making other products for all applications. Best Technology chemicals are not intended to be present in our customers final product (consumer or commercial). Is this statement applicable if it is used in the manufacturing process but NOT in the final product?
  - If downstream supply chain repackage the product, who is responsible for reporting? If the customer repackages the product, or includes it with a package/combination of their other products are they responsible for reporting it as well? This seems ambiguous and could lead to lack of reporting or duplicated reporting.

2) Are there terms or processes in subdivision 2 for which clarifications will help reporting entities determine reporting status or data-gathering process?

"Subdivision 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: (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; (5) any additional information requested by the commissioner as necessary to implement the requirements of this section."

- This is really broad and could drastically change the resources required and costs incurred in reporting. This would make for a moving target and cost small companies, such as ours, a great deal of capital investment.
- Are there set schedules for the commissioner to review the information they are requesting?

3) How should the MPCA balance public availability of data and trade secrecy as part of the reporting requirements?

- Significant trade secrets exist in individual and compounded chemical substances, including fluorinated chemicals. Trade secrets are vital to a company's product value, incurred costs in R&D, production, future

protection of the company, and its profitability, and unauthorized acquisition or disclosure.

- The final rule should acknowledge that companies can assert claims of trade secrecy for any PFAS already approved by EPA for inclusion on the TSCA Confidential Inventory or protected under the Uniform Trade Secrets Act.
- The final rule should also clarify what information can be claimed as confidential and offer simplified substantiation procedures for trade secret claims to reduce the burden on submitters.

4) Are there any terms used in subdivision 3 that should be further defined or where examples would be helpful?

"Subdivision 3. Information requirement waivers; extensions. (a) The 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 grant a waiver under this paragraph to a manufacturer or a group of manufacturers for multiple products or a product category."

- What is "publicly available"? What will this process look like? What information will the commissioner use to make this determination? How will a company be made aware of this waiver if the commissioner determines that information is already publicly available?
- What would define a product category that would waive subdivision 2? How long would the waiver be in effect?
- EPA is currently working on a comprehensive process that requires manufacturers and importers of identified PFAS to report information. The EPA reporting requirements provide a chance to simplify reporting and utilize data collected by the respected federal environmental regulator that many states trust.

5) Are there specific portions of the reporting process that should not be defined through guidance or the development of an application form?

- The reporting process should be clearly defined through an application form and not through general guidance.

6) Other questions or comments relating to reporting or the process of reporting.

- Depending on the size of the company and type of manufacturer involved, compliance with the reporting requirements may be extremely cost prohibitive and negatively impact the company's ability to maintain financial viability, especially small businesses that do not have dedicated resources for these types of activities.
- Small businesses lack the established / dedicated resources and economies of scale necessary for such administrative and reporting tasks. The cost of hiring employees for this function would be extremely cost prohibitive.
- Incorporating EPA's "known to or reasonably ascertainable by" standard that allows notifying entities to rely on supplier declarations, and to limit

the scope of testing/investigation that manufacturers would be expected to undertake. The EPA has applied this standard for years in its TSCA Chemical Data Reporting Rule and recently extended its use to the agency's PFAS reporting rule. In order to prevent a reporting scheme unnecessary and broader than EPA PFAS could result in more expensive to implement than EPA's $843 million estimate for the associated rule compliance costs.

- If all proposed PFAS reporting are implemented at the same time in January 2026, the initial resource requirement jointly on companies and the MPCA would be significant and possibly crippling economically to both entities. The MCPA should consider imposing the reporting requirements incrementally based on different PFAS product categories risk to human health or the environment in Minnesota. A phased approach will allow both MCPA and the regulated community to adjust the new requirements and address any practical issues which invariably will arise. MCPA can then make any adjustments to reporting requirements if needed.
- This phased-in approach will also provide time for reporting under the EPA federal program to be compiled, understood and provide an opportunity for individual states to utilize the EPA federal reported information. Combining reported information from the EPA and initial state reporting could allow for better direction to prioritize products or use applications that may warrant future restrictions. This will ultimately reduce the burdens on both the entities subject to the final reporting regulations and MCPA. It will also allow for more orderly and responsive reporting compliance.

In summary, the goal of MPCA's ruling for PFAS reporting is to protect human health and the environment. It can be achieved by scientifically driven and consumer-minded implementation using a phased in approach for PFAS most likely to impact human health or the environment. With the above discussed recommendations, the PFAS in Products Reporting Rule would avoid unnecessary and adverse burdens upon the large number of manufacturers of products in industrial applications which do not create a risk to human health or the environment. Such proper drafting of the reporting requirement will support efforts and investment toward continued technological innovation in chemicals.

Best Technology appreciates the opportunity to provide these comments and looks forward to collaborating with MPCA and other stakeholders to ensure that the residents of Minnesota continue to have access to products that enhance their daily lives safely.