Before the
Minnesota Pollution Control Agency
Request for Comments
Planned New Rules Governing Currently Unavoidable Use Determinations about Products Containing PFAS
Revisor's ID Number R-4837

Comments of the Chemical Users Coalition

The Chemical Users Coalition ("CUC") appreciates the opportunity to provide our comments on the Planned New Rules Governing Currently Unavoidable Use ("CUU") Determinations about Products Containing 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 5(c) ("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, is seeking comments on specific questions: The following are CUC's responses to those specific questions on which the MPCA requested input.

1. Should criteria be defined for "essential for health, safety, or the functioning of society"? If so, what should those criteria be?

Amara's Law 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." CUC suggests that greater clarity and detail from MPCA should be provided in the upcoming rulemaking to explain the criteria to determine when a PFAS use will qualify as "essential for health, safety or the functioning of society." MPCA should, in a rule, define these terms so that the regulated community clearly understands the criteria MPCA will use to judge essentiality.

CUC recommends that products or product components that are "essential for health, safety or the functioning of society" are those that, if unavailable, would result in a significant increase in negative healthcare outcomes, an inability to mitigate significant risks to human health or the

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

environment, or significantly interrupting the daily functions on which society relies. CUC also recommends that there should be an opportunity under the rules developed for applicants seeking a CUU determination may demonstrate PFAS or a PFAS use is "essential for health" without the need to also show that without the PFAS or its use there would be a "significant increase" in "negative health outcomes". This would allow room for the development of (and the Agency's ability to exempt) uses that are innovative and (at present) unforeseen, and which would otherwise become subject to the 2030 ban. Furthermore, products or product components that are "essential for health, safety or the functioning of society" also include those that are required by federal or state laws and regulations or are necessary for the purposes of national security, defense or space exploration. Products or product components that are "essential for the functioning of society" are those that are used in or to address climate mitigation, critical infrastructure, delivery of medicine, lifesaving equipment, public transport, aerospace, aeronautics, public safety and defense, and construction.

The interpretation of the phrase "alternatives are not reasonably available" must also be defined clearly by MPCA. CUC recommends that MPCA should take into account, when defining the term, that certain products, including but certainly not limited to products and components in the aerospace and defense sector, are often subject to batteries of qualifications tests, customer approvals, and "Type Certifications" with various regulatory bodies such as the Department of Defense and Federal Aviation Administration. Therefore, alternatives that appear initially to be available may not be reasonably available because they must be subjected to these processes that may take years to qualify and complete.

Furthermore, in many sectors there are often no readily available substitutes due to safety concerns. While a substitute (including a non-PFAS alternative) may exist on the market, it may be the case that such a substitute is more flammable, toxic, or otherwise unsafe—leading to an unwanted regulatory outcome (and possibly regrettable substitutions). MPCA must carefully factor in regrettable substitution when defining the "reasonable availability of alternatives."

To better understand what products are "essential," MPCA should consider conducting analyses to project the impact to the State if/when products from various sectors can no longer be sold due to the sales restriction under Amara's Law. The findings from such analyses should be made public and provided to the state legislature.

Additionally, MPCA should consider the possibility of making CUU determinations based on the specific use of PFAS, and not solely on a finished-products level. This categorical approach could ease the regulatory burden both on industry and on the agency, as industry would not need to have each specific product "evaluated" for essentiality, and MPCA would not need to consider myriads of individual products.

2. Should costs of PFAS alternatives be considered in the definition of "reasonably available"? What is a "reasonable" cost threshold?

CUC recommends that cost be taken into consideration, and economic analyses should be conducted to determine whether alternatives are "reasonably available." CUC believes that anytime use of alternative substances is mandated, a significant increase in cost to manufacturers

and in generation of waste is anticipated. Due to the research and development required to manufacture products using alternatives, the trial and error will lead to increased production costs and generation of products that do not function as needed and that will need to be discarded. The research and development activity also could lead to a diversion of resources from production of the product and consequently product shortages resulting in harm to the larger economy.

Furthermore, despite undertaking research activities, there is no guarantee that a manufacturer will identify alternatives that are available. The goal of the research and development process is to determine if, using alternative substances, products that perform just as well as the original products can be manufactured. Similar to what was done when developing the original products, the alternative products would also be required to obtain the same quality certifications, satisfy the same customer standards, and meet required safety evaluations. This is estimated to take a significant amount of time and money, which is another "cost" factor involved in the regulatory structure imposed by the statute.

In addition, costs must also be considered for replacement and spare parts for products that have long useful lives, such as those used by the aerospace and defense sector, among others. The inability to procure and sustain such products over the entire life cycle undermines the intended functionality of the products and may lead to early obsolescence, a costly and potentially dangerous situation that must be avoided, particularly in the case of replacement and spare parts found in products utilized for national security.

If these costs associated with the use of alternatives have significant negative impact upon business and society, such alternatives are not "reasonably" available.

3. Should unique considerations be made for small businesses with regards to economic feasibility?

CUC believes that MPCA must consider the magnitude of the economic impact that may be experienced by regulated small businesses, the total number of regulated small businesses that may experience the economic impact, and the percentage of regulated small businesses that may experience the economic impact. A small business may not be able to conduct research and development, redesign production methods, or purchase alternative substances due to prohibitive costs. Once MPCA has quantified and qualified the impact, it should develop criteria to establish what is indeed "economically feasible" for a small business.

4. What criteria should be used to determine the safety of potential PFAS alternatives?

CUC suggests that MPCA consider the following factors:

- Whether the alternative substance is subject to any restrictions on its use, concentration, or specific properties.
- Considering the toxicological data on the alternative substance, including studies on acute and chronic toxicity, carcinogenicity, and reproductive effects (or the potential lack of such data for new alternatives that have not been adequately studied).

- Assessing the likely exposure levels and potential risks to workers during product manufacturing, or to consumers during the other phases of the product's lifecycle, considering use patterns, frequency, and duration as well as disposal.
- Whether the alternative substance interacts negatively with other materials in the product or packaging, potentially leading to safety concerns.
- Assessing if that use of the alternative substance could compromise the integrity, durability, or safety of the overall product.
- The environmental impact of the alternative substance, including its biodegradability and potential harm to ecosystems.
- Reported adverse events related to use of the alternative substance.

All of these factors should be assessed by comparing the current (PFAS-containing) product in contrast to the "alternative" under consideration. Furthermore, the "safety" assessment might need to involve a "comparative-risk" determination that includes whether an alternative may be available and should be considered for use which may contain PFAS, but a variety of PFAS for which there are fewer health or environmental concerns, in which case, its use as a phased-in alternative should be considered and encouraged over time.

5. How long should PFAS currently unavoidable use determinations be good for? How should the length of the currently unavoidable use determination be decided. Should significant changes in available information about alternatives trigger a re-evaluation?

CUC recommends that "currently unavoidable use determinations" should be effective for at least five years, as, under Amara's Law, PFAS is a group of substance that may potentially encompass thousands of chemicals. A significant amount of time will be needed for research and development and for adequate supply to be made available for alternatives. However, CUC also suggests that MPCA consider indefinite exemptions, until further information is available, for products/sectors where it is clear that alternatives do not exist and are not reasonably anticipated to be identified in the foreseeable future. The CUC also supports the indefinite renewal of currently unavoidable use determinations.

CUC also strongly recommends that MPCA adopt a review and resolution process for newly identified PFAS in products. The statutory and impending regulatory definitions of PFAS are extremely broad and the supply chains complex, creating an inevitable situation of discovering PFAS post implementation of the program. A review and resolution process would enable business entities to present rationale or justification for newly identified currently unavoidable use(s) as well as time for MPCA to make determinations and/or grant exemptions based on criticality and unavoidable use.

6. How should stakeholders request to have a PFAS use be considered for currently unavoidable use determination by the MPCA? Conversely, could stakeholders request a PFAS use not be determined to be currently unavoidable? What information should be submitted in support of such requests?

Relying on agency rulemaking for individual product determinations will result in a significant burden being placed on MPCA, and MPCA simply will not be able to manage determination requests in a timely fashion. In order to ensure that exemptions for currently unavoidable uses can be considered and responded to in a timely and efficient manner, CUC recommends that MPCA establish an administrative process by which commercial entities may seek a determination that a use is currently unavoidable. MPCA should identify the kinds of evidence it would consider credible and sufficient to support a timely determination. MPCA should be required to make that determination administratively and in accordance with a deadline (e.g., 60 days).

MCP should consider at least the following factors in determinations:

- The cost of acquiring and processing the alterative substance compared to the existing ones.
- Changes in manufacturing processes that may affect overall production costs.
- Whether an underlying federal or state requirement necessitates use of the PFAS for the purposes of national security, defense, aviation, or space exploration.
- Whether products or product components are "essential for the functioning of society" including those that are used in or to address climate mitigation, critical infrastructure, delivery of medicine, lifesaving equipment, public transport, aerospace, aeronautics, public safety and defense, and construction.
- The likely exposure potential and levels for consumers during the product's lifecycle, considering usage patterns, frequency, and duration.
- Whether any potential alternative materials can meet the required specifications, performance standards, and quality benchmarks for the product.
- The impact of an alternative on the longevity and reliability of the final product.
- The availability of a consistent and reliable supply of the alternative materials.
- The reliability and stability of the suppliers providing the new materials.
- Safety standards and regulations applicable to the use of the alternative materials.
- Whether an alternative material will be compatible with existing manufacturing equipment and processes.
- The environmental impact of the new substance in products throughout their lifecycle, from extraction to disposal.
- Needed testing, prototyping, and (re)qualification for any alternative substance to identify any issues or improvements needed.

MPCA should be cognizant of the fact that product manufacturers may face some challenges providing information about PFAS present in products. Upstream suppliers may be reluctant to provide manufacturers with specific information about the type of PFAS used. Upstream suppliers may claim that the use of PFAS is essential but may not provide details due to confidentiality

concerns. MPCA should allow the use of supplier statements to substantiate a manufacturer's request. To facilitate this, MPCA should set up a system that would allow upstream suppliers to provide confidential information directly to MPCA. Furthermore, MPCA should develop and implement a review and resolution process to allow for newly discovered currently unavoidable uses that are identified post implementation of the program.

CUC suggests that MPCA should consider coordination with other jurisdictions, such as Maine, to create an approach that allows manufacturers to submit currently unavoidable use requests that can apply to multiple jurisdictions.

7. In order to get a sense of what type of and how many products may seek a currently unavoidable uses determination, please share what uses and products you may submit a request for in the future and briefly why. There will be a future opportunity to present your full argument and supporting information for a possible currently unavoidable uses determination.

CUC Member companies, rather than CUC itself, we be submitting such product and company-specific requests. However, see CUC's further input in our response to item 9, below.

8. Should MPCA make some initial currently unavoidable use determinations as part of this rulemaking using the proposed criteria?

We highly suggest MPCA make some initial determinations as to what uses of PFAS constitute "currently unavoidable use." The investigation of the use of PFAS is anticipated to take a significant amount of time and resources. If initial determinations can be made (for example for categories of product uses), that would alleviate some of the burden on the industry to find alternatives that may not exist and would allow the industry to focus on complying with the regulatory requirements where there are feasible alternatives.

Initially, CUC recommends that any PFAS containing products or product components that are "essential for health, safety or the functioning of society" as well as those that are required by federal or state laws and regulations or are necessary for the purposes of national security, defense or space exploration be granted a categorical exemption or considered a currently unavoidable use. Products or product components that are "essential for the functioning of society" are those that are used in or to address climate mitigation, critical infrastructure, delivery of medicine, lifesaving equipment, public transport, aerospace, aeronautics, public safety and defense, and construction.

9. Other questions or comments relating to defining currently unavoidable use criteria and the process MPCA uses to make currently unavoidable use determination.

CUC suggests that MPCA consider Interstate Chemicals Clearinghouse Alternatives Assessment Guide as a resource to be used in developing the criteria and process for alternative assessment.

CUC also considers (in addition to the suggestions above) the following categories of PFAS uses that would be suitable starting points for MPCA to propose as CUUs when seeking further public comment. The categories listed below are ones which CUC Members consider to be "essential" due to their criticality to health, safety, and the public welfare and for which CUC Members

understand there are no current "drop in" chemical alternatives that meet the technical and performance standards required for such products and uses.

- Certain medical devices and appliances (such as MRI and other imaging equipment) with PFAS-containing components (and their replacement parts) that are not specifically subject to an authorization which would qualify as a "federal preemption" determination.
- Products, supplies and spare (replacement) parts that are necessary for the purposes of national security, defense or space exploration, including but not limited to aircraft, naval vessels, communication/radar systems, satellites, and space vehicles.
- Gear, apparel, and personal protection equipment used by first responders such as fire fighters, EMTs, and rescue workers.
- Transportation equipment containing PFAS-containing parts and components such as aircraft, rail cars and train engines (including service equipment and replacement parts),
- PFAS containing waste disposal and waste movement equipment and storage devices for such materials.
- Appliances and equipment used in harnessing "clean" energy (e.g., windmills, solar panels).
- Energy storage equipment, such as batteries and other components in electric vehicles and stationary devices.
- PFAS used in the production of semiconductors, circuit boards, and related electronic products and their components. This should include PFAS used in the semiconductor manufacturing process; PFAS used in the production of semiconductor manufacturing equipment (and in replacement parts for such equipment); as well as PFAS that may remain present in semiconductors and the final packaged semiconductor devices that are produced. This CUU determination should extend to PFAS contained within electronic equipment and related devices which include semiconductors among their component parts or contain transistors, wiring, insulation, connections, housings, and electronic component parts that may include PFAS for purposes of ensuring reliability, limiting electronic interference, providing for safety, and other critical performance attributes.
- To the extent not included among those items CUC has identified above, our Members also support MPCA providing CUU determinations for PFAS uses in electrical equipment that contribute to meeting the nation's goals relating to climate preservation, electrification, energy security, human health and safety, and product reliability, durability, and sustainability. These products should include electronic components found in medical devices (e.g., imaging equipment and pacemakers), electronic sensors, industrial automation relays and soft starters, gas-insulated power grid equipment, insultation for wiring, and PFAS uses critical for the safe operation of essential and emergency lighting equipment,
- All uses of PFAS and PFAS-containing products and materials necessary to manufacture the products described above.

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.