FCJ 日本フルオロケミカルプロダクト協議会
Conference of Fluoro-Chemical Product Japan

1. Who is commenting? (choose the best fit)

- **Member of the general public**
- **Representative of an environmental group**
- **Representative of a product manufacturer(s)**
- **Representative of another unit of government**
- **Representative of a public health group**
- **Academic or research organization**
- **Other (please specify)**

Representative of product manufacturers

2. If you are commenting as a representative, what is the name of the entity you are commenting on behalf of?

Conference of Fluorochemical Product Japan

3. If you represent a product manufacturer or industry group, what industry(ies) do you represent?

PFAS manufacturers including Fluoropolymers, Fluoroelastomers, Lubricant, Intermediate for Agrichemicals/Pharmaceuticals, F-gas, etc.

4. If you represent a product manufacturer, what types of components, products, or product categories do you manufacture that you will be requesting a CUU determination for?

- Flouropolymer (including fluoroelastomer) emulsions, granules, powders, films etc. sold directly to processors and users
- Perfluoropolyether oils sold directly to processors and users
- Fluoropolymer-based coatings
- Fluoropolymer -based products (tubes, hoses, o-rings, gasket seals, etc.) used in laboratory diagnostics, pharmaceutical research and development, cable and wire insulation, vehicles, aircraft, vessels, semiconductor manufacturing, electronics, and manufacturing generally.
- Pharmaceutical and agrochemical intermediates.
- F-gases for the use in refrigeration, air conditioning, heat pumps, foam blowing agents, aerosol propellants, fire suppression, dry etching, CVD chamber cleaning, etc.

5. Do you have any recommended changes or other considerations that you think the MPCA should take into account when defining the term "essential for health, safety, or the functioning of society" (Please review the proposed definitions prior to answering)

As drafted, MPCA creates a high and perhaps impossible bar for demonstrating "essential for health, safety, or the functioning of society." Under the definition proposed by MPCA, Minnesotans could be deprived of ordinary fixtures of daily life, such as televisions, air conditioning, household appliances, musical instruments and equipment, etc., since none of those societal fixtures are otherwise covered under Items A through C of the definition in the Draft Rule Concept Summary.

We propose the following alternate definition:

"Essential for health, safety, or the functioning of society" means a use of a PFAS in a product or component when the function provided by the PFAS is, at the time of a determination by the commissioner, necessary for the product, component, or spare or replacement component to perform as intended, such that the unavailability of the PFAS for use in the product would ***result in a substantial loss of product reliability, durability or functionality*** ~~*cause the product's services to be unavailable*~~*, which would result in:*

A. *A significant increase in negative health outcomes;*
B. *An inability to mitigate significant risks to human health or the environment; or,*
C. *A significant disruption of commercial, public, or ecosystem services on which society relies* ***or ordinary functions of daily living****, including:*
   (1) *Provision of food, water, shelter, health, hygiene, or bare necessities for human survival;*
   (2) *Provision of transportation and utilities such as gas, electricity, data, communications, and sewer;*
   (3) *Provision of personal, occupational, or public safety* ~~*particularly for extreme conditions of use*~~*; and,*
   (4) *Other services not covered under subitems (1) through (3)* ***that are necessary for the ordinary functions of daily living for residents of the state*** ~~*serve the basic needs of human beings*~~**.**

6. Do you have any recommended changes or other considerations that you think the MPCA should take into account when defining the term "alternative"? (Please review the proposed definitions prior to answering)

The phrase “functionally equivalent” must be defined to include no meaningful loss of performance or functionality. Otherwise, one could argue that rooftop antennae and ethernet cables are functionally equivalent alternatives because their purpose is to transmit signals.

We recommend that MPCA propose the definition codified in regulation in Maine (06-096 C.M.R. ch. 90, § 2 – Definitions):

"Functionally Equivalent" means a product or product component that functions in the same basic manner as the product it is being compared against to perform the same purpose to the same standard as the original PFAS containing product or product component it is being compared against.

7. Do you have any recommended changes or other considerations that you think the MPCA should take into account when defining the term "reasonably available"? (Please review the proposed definitions prior to answering)

The proposed definition includes the concept of performance. We strongly recommend that it is more appropriate to address performance is already addressed in the definitions of “alternative” and “functionally equivalent.” The alternative is the thing that will be assessed for performance. Performance should not be addressed also in the definition of “reasonably available.” “Reasonably available” should be about access and must therefore include a cost element.

The regulations must define "reasonably available" in a manner that includes consideration of costs. If the cost of utilizing an alternative is prohibitive – for example because the only suitable alternative for a particular application is a precious metal – that cost differential would indicate that the alternative is not “reasonably available.” To use an example relevant to Minnesotans, if the price of a home appliance increases two- or three-fold because a more expensive material is needed to achieve required functionality, that price differential is relevant in assessing whether the alternative is "reasonably" available.

We propose the following alternative definition:

Reasonably available. *“Reasonably available” means that one or more alternatives to a PFAS* ***for the specific application and condition of use being evaluated*** ~~*can perform comparably to the PFAS being considered for replacement in a product or component and*~~ *is currently available in sufficient quantity* ***and at substantially the same cost as the PFAS.*** *PFAS alternatives that are in use in* ~~*equivalent*~~ ***identical*** *products or components* ***for identical applications may be*** ~~*are*~~ *considered “reasonably*

available." Conditions of current reasonable availability may change over time as a result of new research or innovation.

8. When considering the proposed definition of "product category", how broadly should the agency group product categories? (Examples: "vehicles" versus "sedans, SUV's, vans, trucks, RV's" or "printers" versus "receipt printers, thermal printers, label printers, residential printers, commercial printers, etc.")

MPCA should not dictate how products must be grouped into categories. Product manufacturers are in the best position to understand what specific set of performance characteristics provide the most appropriate basis on which to segregate similar products into different categories. Therefore, manufacturers should be permitted to identify the particular product category for which they are seeking a CUU determination. Moreover, if MPCA anticipates that CUU determinations will be manufacturer-specific, there is no need for MPCA to establish uniform product categories to be used by all manufacturers.

To accomplish what is described in the paragraph immediately above, MPCA may need to reconsider whether allowing manufacturers to use existing standardized systems, such as the North American Industry Classification System, Harmonized Tariff Codes, or others, that industry uses broadly to describe its products and the uses of its products.

Giving manufacturers the ability to identify the industries in which its product will be used will create enormous efficiencies. Consider, for example, the scenario in which the manufacturer of an engine gasket receives a CUU determination for the gasket. Separate CUUs should not also be required for the engine manufacturers that use that gasket in their products.

9. Should each request for a CUU determination be limited to a single product category, or should applicants be allowed to submit a request for a CUU determination for multiple product categories?

MPCA should allow applicants to submit a request for a CUU determination for multiple product categories. MPCA can accept or reject the CUU rationale for each product category separately. In general, given the large volume of requests likely to be submitted, MPCA should seize every opportunity to make the submission process more efficient.

10. What safety or other standards require the use of PFAS in a product? (Please include the specific citation)

Standards very rarely dictate the use of specific substances. Instead, they define performance specifications. A manufacturer can select the substance, engineering, or other design features to meet the performance specifications.

If the purpose of this question is to identify standards to be listed in the final regulations, MPCA must ensure that the list of standards in the regulations is illustrative and not exhaustive. Also, in addition to considering published standards in assessing alternatives, it is equally important to consider customer specifications, since those are typically intended to ensure the safety, reliability and/or durability of the finished product.

11. The agency is seeking feedback on the potential that the initial positive CUU determination duration for existing products will expire eight years from the date of issuance regardless of product category. This is intended to stagger renewal deadlines and ease the administrative burden of processing renewals.

- **Do you have any concerns about unintended consequences with this proposal?**
- **Do you have any alternative recommendations to stagger renewal deadlines?**

To address concerns about the excessive administrative burden associated with CUU renewals, MPCA should simplify the renewal process as described elsewhere. Specifically, if there is no new information to include in a renewal request (i.e., if the information provided in the renewal request would be substantially the same as the information in the original CUU request), the applicant should be allowed to submit a certification to that effect in lieu of submitting a complete application package again. CUU exemptions should be automatically renewed within 30 days of submission of a certification unless, during that time period, MPCA receives comments providing new information, not addressed as part of the original CUU determination, that materially alters the assessment made in the original CUU determination. This process change should substantially reduce the administrative burden for MPCA as well as the burden on regulated entities.

12. The MPCA has developed a preliminary list of potentially eligible data categories that may be considered for trade secret requests. (Please review the list of potentially eligible data prior to answering)

- **Do you have any concerns about unintended consequences with this proposal?**

- **Do you have any alternative recommendations for data that should or should not be eligible for trade secret requests?**

The list should also include specific pricing and cost of production information. Also, the list should be illustrative ("including, but not limited to") instead of exhaustive.

13. What are the potential ongoing costs to society if the commissioner issues a positive currently unavoidable use determination for the continued use of PFAS within a product or product category? (For example: environmental, human health, or remediation costs)

MPCA must acknowledge that, for certain categories of products and materials, the granting of CUU requests will result in substantial cost savings for society. This is especially true for fluoropolymers and products made with fluoropolymers – which are used, almost uniformly, to enhance the durability and reliability of the products into which they are incorporated. This means less waste generation and less consumption of virgin resources (from increased durability and reliability of products), lower healthcare costs (from increased safety of products and processes), as well as lower maintenance costs and lower replacement costs for public and private infrastructure. These costs are separate from, and in addition to, the huge economic costs that would result from the unavailability of key technologies such as semiconductors.

On the other side of the ledger, the societal costs of continuing use of fluoropolymers are minimal. Because of their biological inertness, there are no significant adverse health outcomes (and therefore no significant healthcare costs) associated with the use of products containing fluoropolymers. Similarly, the "lifecycle" costs of fluoropolymers are unremarkable. Beginning of life concerns (ie, pollution associated with the manufacture of fluoropolymers) can be addressed by imposing and enforcing adequate emissions controls on fluoropolymer manufacturing facilities – similar to any other manufacturing facility. Furthermore, since fluoropolymers are no longer manufactured in MN, pollution from ongoing manufacturing operations should not be a concern for the state. Similarly, the societal costs associated with disposal of fluoropolymers are also unremarkable – since studies (Henry et al) demonstrate that FPs can be safely disposed of in landfills (as EPA has itself suggested) and ongoing studies also indicate that incineration is a viable method for destroying FPs.

14. For manufacturers: Administrative cost of requesting a CUU determination (Part 1 of 2). Please provide your best estimates or rough orders of magnitude (for example "approx. 200 hours"). Precise accounting data is not necessary to answer this question.

If your company currently possesses information regarding intentionally added PFAS (to the CAS number level) for all components in your product lines, please estimate the number of technical staff hours that were required to establish this baseline.

- **Not applicable**
- **Less than 40 hours**
- **40 to 100 hours**
- **101 to 500 hours**
- **More than 500 hours**
- **Other (please specify)**

No response.

15. For manufacturers: Administrative cost of requesting a CUU determination (Part 2 of 2). Please provide your best estimates or rough orders of magnitude (for example "approx. 200 hours"). Precise accounting data is not necessary to answer this question.
If your company does not possess information regarding intentionally added PFAS (to the CAS number level) for all components in your product lines, please estimate the number of technical staff hours needed to obtain this data from your Tier 2 or 3 suppliers for a single product line.

- **Not applicable**
- **Less than 40 hours**
- **40 to 100 hours**
- **101 to 500 hours**
- **More than 500 hours**
- **Other (please specify)**

No response.

16. For manufacturers: Expenditure considerations when seeking non-PFAS alternatives (Part 1 of 2). Please provide your best estimates or rough orders of magnitude (for example "primary cost is CapEx"). Precise accounting data is not necessary to answer this question.
If you have identified a technically viable non-PFAS alternative for one of your products that contains intentionally added PFAS, does implementing this alternative require Capital Expenditure (such as purchasing new molds, retooling machinery) or primarily Operational Expenditure (such as purchasing more expensive raw materials)?

- **Please estimate the ratio of Capital Expenditure to Operational Expenditure (or indicate which category is the dominant cost driver).**

No response.

17. For manufacturers: Expenditure considerations when seeking non-PFAS alternatives (Part 2 of 2).
If you have not identified a technically viable non-PFAS alternative for one of your products that contains intentionally added PFAS, have you conducted a Research & Development (R&D) feasibility study?

- **If so, what was the cost of that study?**

No response.

18. For manufacturers: Research and development safety validation cycles.

- **What is the typical duration of the R&D and safety validation cycle for a reformulated product in your sector (from concept to market entry)?**
- **Does this cycle align with the 5-year renewal period typically associated with regulatory exemptions?**
- **If not, please explain the specific technical barriers that would require a longer validation period.**

No response.

19. Please provide any additional information or documentation needed to support your answers to any of the questions posed.

No response.

20. Do you have any additional questions or comments regarding the PFAS in products: Currently unavoidable use rule? (Please note that we may be unable to respond to specific questions regarding rule content in this phase of the rulemaking process).

Eligibility

We have a comment regarding the "Eligibility" section of the Draft Rule Concept Summary. In that section, MPCA states, *"In order for an applicant to be eligible to request a CUU determination, the use of PFAS in their product must meet the statutory definition of "currently unavoidable use."* However, the definition of "currently unavoidable use" makes it unmistakably clear that a product is not CUU until the Commissioner determines it to be CUU by rule. It would therefore be impossible for a product to meet the application eligibility criteria for the designation its manufacturer seeks via the act of applying unless it had already received a CUU determination by the Commissioner.

We recommend that MPCA either remove the "Eligibility" section or rewrite in a way that ties back to the manufacturers act of applying for a CUU determination. For example:

"A manufacturer of a product containing intentionally added PFAS is eligible to apply for a CUU determination for a product or group of products if the manufacturer meets the statutory definition of "manufacturer."

Applicant information

Regarding the last sentence of the first paragraph, if CUU determinations are manufacturer-specific rather than product specific, the burden on MPCA (and the regulated community) will be multiplied manyfold. Absent the option for collaboration among manufacturers making similar products, each manufacturer of a fungible product will submit an individual CUU proposal, resulting in multiple CUU proposals being submitted for the same product. In addition, this approach would disproportionately impact smaller companies that are not, for example, members of a trade association that might potentially file a CUU proposal on behalf of its members.

We recommend that MPCA adopt a mechanism for a joint submission as is allowed in the reporting rule.

CUU information

The term "extreme" in the third bullet is subjective and misleading. We recommend using the phrase "specific conditions of use." See also our response to question 7.

Extreme conditions of use

As noted immediately above "extreme" is subjective and misleading. A more useful construct is "specific conditions of use," a proposed definition of which we offer here based on MPCA's proposed definition of "extreme conditions of use."

~~Extreme~~ Specific conditions of use. *"~~Extreme~~* ***Specific*** *conditions of use" means* ***operating or environmental conditions that necessitate the use of PFAS, including but not limited to*** *~~an environment that results in one or more of~~ the following:*

A. *High or low operating temperatures, or both;*
B. *High or low material pH, or both;*
C. *High corrosivity not covered under item B;*
D. ***Low****~~Potential~~ reactivity with one or multiple chemicals;*
E. *High or low operating pressures, or both;*
F. *High tear, crack, or other stress potential;*
G. *High or the possibility of high friction or vibration;*
H. *High or sustained humidity or moisture;*
I. *High or concentrated voltage requiring dielectric strength;*
J. *Elevated radiation levels;* ***or***
K. *High exposure to oxygen with risk of oxidation or fire~~; or;~~*
L. *~~Others the commissioner may designate~~.*

The applicant must also provide information **known to or reasonably ascertainable by the applicant** regarding any safety or other standard**, including customer or end user specification,** that requires the use of PFAS in their product. They must include the applicable citation to the standard and describe why PFAS is needed to meet that requirement. It is important to distinguish whether PFAS is actually required to meet that standard **or specification**, or if the manufacturer is choosing to use PFAS to meet the standard **or specification**. The applicant will also be asked to assess whether any alternatives could be used to meet the standard **or specification** instead of the intentionally added PFAS.

Assessment of alternatives

We suggest replacing the second sentence of the second paragraph with the following:

Applicants are cautioned that applications that rely solely on simplicity or convenience of PFAS as justification that there re no reasonably available alternatives may not be sufficient to demonstrate that the use of the PFAS is currently unavoidable.

We also suggest a new bullet in the list of considerations in an alternatives assessment:

- An assessment of any negative health, safety, or environmental outcomes, including life cycle impacts, that may be associated with use of an identified alternative as compared to the PFAS used.

Finally, we suggest modifying the bullet about transition timeline as follows:

- An estimated timeline needed for transition to an alternative, **including the time needed for any required regulatory approvals**; and

Additional information required

Information regarding jurisdictions outside the US is not relevant - and could be misleading - in assessing whether a particular use of PFAS is essential to the functioning of society in the US.

Also, regarding the second paragraph, in a group submission, each manufacturer should only be responsible for certifying the accuracy of the data contributed by that manufacturer. We caution that asking each member of a group to certify for every other member of the group will severely limit the number of group submissions, which is an important tool for reducing administrative burden to MPCA.

Finally, we recommend the following changes to the last paragraph:

All manufacturers represented in a request for a CUU determination must certify that the data they submit or **submitted to** the applicant **who** submits on their behalf is accurate and complete **to the extent known to or reasonably ascertainable**

CUU Determination Process

Deadline

Regardless of the specific deadline that's adopted, if a CUU application is submitted within the deadline and MPCA fails to make a final determination prior to January 1, 2032, the applicant should receive a conditional CUU determination that is valid until 6 months after the date on which MPCA makes a final determination on the CUU application.

Timeline

The text suggests that an applicant will have 30 days to submit revisions to corrections or deficiencies identified by the commissioner. MPCA should give itself the discretion to extend that deadline if

circumstances warrant (e.g., if the requested information is especially difficult to collect, new product testing is required, etc.).

Also, regarding the rebuttal period described in the second paragraph, he applicant must also be allowed to address any preliminary conclusions made by MPCA. Otherwise the applicant has no opportunity than potential opponents to address any of MPCA's preliminary conclusions prior to the actual rulemaking.

Duration

MPCA states that CUU determinations for novel products will expire five years from the date of issuance. We question the difference in the duration of a CUU determination for existing and novel products. A shorter duration will act as a disincentive for innovation. If novel products get a shorter exemption than existing products, manufacturers will have less incentive to develop new products for the MN market.

Renewal

See our response to question 11.

Due diligence

Records should not be required to be maintained beyond the period of effectiveness of the CUU determination. Once a CUU determination expires, any recordkeeping obligation associated with the CUU determination should also expire.

Regarding the last sentence of this section, a manufacturer should only be required to attest to the accuracy and completeness of the data it provided to the group submission. See our last comment beginning "Finally," under **Additional information required**.