Michael Winterling

Who is commenting? *(choose the best fit)*
Representative of a product manufacturer(s)

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

If you represent a product manufacturer or industry group, what industry(ies) do you represent?
Plastics used in medical devices (NAICS 326122), as well as high speed wire and cable products (NAICS 332618)

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?
Components and manufacturing aids used for medical devices. High frequency coaxial cable products used in telecommunications, semiconductor processing, and other high end electronics applications.

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 in the rule concept document prior to answering)*
There is probably a category of products that would link to a provision of economic or business development for society. Utilities seems more like basic services. Things like high speed computers, sensors or other technology that allow the local economy to compete in the global market, creating local jobs.

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 in the rule concept document prior to answering)*
Is there a consideration of the potential harm an alternative could cause due to the alternative's life cycle (source, use, end of life)?

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 in the rule concept document prior to answering*)
No

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.")*
If you are planning to make decisions about a product category, then you should have very narrow product categories. For example, a "medical catheter" includes basic catheters (such as ureteral catheters) that are made from non-PFAS materials as well as neurovascular microcatheters which are very specialized and require PFAS materials to perform as needed. Each application (or even the particular device) could have its own unique set of needs and challenges.

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?
It seems more efficient for all parties if submissions can be requested for multiple product categories, especially if the use, needs or application of the product are similar.

What safety or other standards require the use of PFAS in a product? *(Please include the specific citation)*
I am not aware of any standards requiring the use in medical applications, but many medical device designs approved by the FDA or other regulatory agencies rely on PFAS materials in both the design and/or manufacturing of the device and would be difficult to change.

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?

For medical devices, it is common for product design, development, and regulatory approval can take up to 10 years or even longer. Therefore 10 years would be more appropriate to allow time for the sourcing of alternative materials, design and approval of a new device.

The MPCA has developed a preliminary list of potentially eligible data categories that may be considered for trade secret requests. *(Please review the rule concept document for the list of potentially eligible data)*

- 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 information shared defending the use of PFAS (why PFAS is needed, where it is used, why it is better, how it is used) as well as the testing and evaluation results of testing alternative materials could be considered intellectual property and often this is a trade secret. If this information is openly shared, it could harm the company providing the information.

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)*
This is difficult to answer, PFAS has thousands of forms, from some of the safest biomaterials in use, to some smaller chain chemicals which have been shown to cause harm. In some cases no or minimal costs, in some cases there might be higher costs. The commissioner will need to balance any potential harm with the positive benefits to society. The commissioner will also have to consider the potential harm caused if critical products are forced to be discontinued without a suitable replacement.

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.
Less than 40 hours

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 <u>does not</u> 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.
101 to 500 hours

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).

We are evaluating alternatives, but have not yet found suitable alternatives for most applications. If we are successful, as a component supplier, there are likely 2-3 years of engineering resources to develop the product, then time to sell to the OEM device manufacturer, who then has to spend 3 to 10 years (depending if it is a change to an existing device vs new device). Order of magnitude, it costs us well over $1million USD to develop a product (not including capital equipment which could be a similar amount). Our customers would then need to spend 3-10 years to develop a product and get regulatory approval, which is likely 5 to 10 times our costs due to the increased complexity of the final device.

For manufacturers: Expenditure considerations when seeking non-PFAS alternatives (Part 2 of 2).

If you <u>have not</u> 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?

We have not yet identified a technically viable non-PFAS alternative to our products. We have already spent 3 years seeking alternative materials at a cost of more than $1.5 million USD.

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.

In the medical device sector, R&D can take 1-3 years, product development can take 1-2 years, clinical trials are often needed which can take 2-5 years depending on endpoints and enrollment, then regulatory submission and approval can take another year or so. For medical devices, a 10 year renewal period is much more realistic than a 5 year renewal period.

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)*
There should be consideration to a category of production or manufacturing aids for the unavoidable use rule. PFAS materials are used in many processes that are not part of the final device. These processes and ultimately the devices are only possible due to the unique properties of fluoropolymers or other PFAS materials. If these uses were to be banned, the end devices could not be made as designed.
There also seems to be little focus on the benefits to society. There should be more balance in this initiative to better understand both the costs and benefits to specific products to society.