DATWYLER

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Response to Request for Comments
PFAS in Products Currently Unavoidable Use Rule

To Whom It May Concern:

Datwyler Pharma Packaging USA, Inc. (“Datwyler”) would like to express its appreciation for the opportunity to provide comment to the Minnesota Pollution Control Agency (MPCA) with regard to its planned new rules governing Currently Unavoidable Use (CUU) Determinations about Products Containing Per- and Polyfluoroalkyl substances (PFAS), Revisor’s ID Number R-4837.

Datwyler, as a leading provider of high-quality, system-critical elastomer components, is a strategic engineering partner for innovative systems in global markets such as Healthcare, Mobility, Connectivity, General Industry and Food & Beverage. Among other things, Datwyler components in billions of syringes and in every second car around the world make an important contribution to patient and driver safety under demanding conditions. Specifically for Healthcare, our sites in the Belgium, China, Germany, India, Italy, and the United States take great responsibility to help improve patients’ lives and see ourselves as a vital link between our customers and their patient. As a preferred solution partner to global pharmaceutical companies, Datwyler’s Healthcare components for vials, prefilled syringes, and cartridges in the pharma packaging industry provide customers with drug and packaging stability, compatibility, and container closure integrity in the pharmaceutical and biotech markets.

Beginning January 2032, products containing intentionally-added PFSA which are sold, offered for sale, or distributed in Minnesota are banned unless determined as CUU by the MPCA, by rule, under the authority of Minnesota Statutes 116.943, subdivision 5(c); and Minnesota Statutes 116.943, subdivision 9. In its rulemaking process to establish criteria and processes through which future decisions on what, if any, uses of intentionally-added PFAS will qualify as CUUs, the MPCA has posed a few questions to inform rulemakers of relevant issues that must be considered. Datwyler hereby respectfully submits the responses contained within this submission for consideration.

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

Yes – Datwyler requests the MPCA to further define the criteria by which PFAS-containing products can be classified as *essential for health, safety, or the functioning of society* so that manufacturers who are delegated with the responsibility to submit proposals for CUU determinations can be best guided when reviewing and preparing documentation about PFAS-containing products. In light of PFAS in medical devices and components, including but not limited to the elastomer closures and seals, Datwyler advises that the MPCA must keep in mind preservation of patient access to healthcare and protection of the medical supply chain.

Other rulemakers have provided a definition that *essential for health, safety, or the functioning of society* "means products or product components that if unavailable would result in a significant increase in negative healthcare outcomes, an inability to mitigate significant risks to human health or the environment, or significantly interrupt the daily functions on which society relies."[1] In this definition, there is a clear definition of how the essential nature of products can be assessed and which areas and industries necessitate a fundamental review as an all-out ban would be detrimental to a critical function the state impacts on behalf of the citizens of the state.

The definition also goes on to state that "[p]roducts or product components that are Essential for Health, Safety or the Functioning of Society include those that are required by federal or state laws and regulations." [2] With this additional criteria, there is less concern for an overlap in the potential for conflicting rules to make the essential determination too complex.

Lastly, the definition continues that "Essential for the Functioning of Society includes but is not limited to climate mitigation, critical infrastructure, delivery of medicine, lifesaving equipment, public transport, and construction." [3] These examples help drive understanding of some of the critical areas that lawmakers are considering and taking careful consideration to understand what and how a ban would affect these activities and industries.

As a manufacturer of fluoropolymer-coated elastomer closures for pharma packaging, Datwyler assents that such a definition strikes a good balance between environmental protection with patient access to healthcare and the protection of the medical supply chain, thus avoiding critical drug shortages on the market.

1,2,3 https://www.maine.gov/dep/spills/topics/pfas/PFAS-products/cuu.html

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

Yes – Datwyler urges the MPCA to consider the costs of the alternative itself as well as the costs of implementing such alternatives. In some cases, even if there a PFAS-free alternative available, lost business in the industry may not be able to be regained due to the nature and process of qualifying the alternative by submission to the relevant health authorities (e.g. US Food and Drug Administration) requiring too much investment of time, resources, and finances, with uncertainty of approval.

Further, the *reasonably available* criteria should not be viewed purely as economic feasibility – it should also encompass the technologic feasibility as well. In some cases, there is no functionally equivalent alternative to the current use of PFAS, even with extensive investments in current research and innovation.

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

Uncertain – Further definition and guidance is needed of what constitutes as a "small business" as well as for how long the unique considerations would be kept in place. These considerations may need to be determined with case-by-case rulings by the MPCA.

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

There exists an element of concern in the proposal to consider all -CF_2 containing materials, without differentiating between the macromolecular Fluoropolymers with other smaller PFAS. Posing a definition of "all -CF_2 containing materials" to be inclusive of polymeric PFAS (like PTFE, PVDF, and FKM), shows that there is a limit to the understanding of the safety potential for these materials.

Polymeric PFAS have been analytically tested and have been deemed non-toxic, not bioavailable, non-water soluble, and non-mobile molecules that do not exhibit environmental or human health implications like other PFAS may. Because of this, we believe that criteria such as these should be used in evaluating these materials. Many assessments have shown that, in the limited chance a suitable alternative can be identified, the critical performance characteristics frequently cannot be met by the alternative compared to fluoropolymer based materials.

Safety should be evaluated with to also include function of the alternatives. Any replacements should result in functionally equivalent products that either maintain or reduce the potential of causing harm to human health or the environment. Critical performance characteristics should be defined and demonstrated by the stakeholder within the CUU determination proposal.

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?

Datwyler stipulates that especially for critical infrastructure CUU determinations, such as those impacting Human Medicinal Products, should have a TIME-UNLIMITED determination. In other cases, the length of the determination should be decided keeping in mind the application and life-cycle impact to society. It must be kept in mind that if a change in determination status may create a dramatic shortage and unavailability of a critical need such as medicines, or else a re-evaluation would be detrimental to balancing environmental protection with the continuation of essential services provided to the citizens of Minnesota.

In the case of new developments, re-evaluation may be sought, but in certain cases like that of healthcare, such re-evaluations may prove unhelpful. For example, within healthcare, an estimated 1 of every 5 injectable drugs for human medicinal products around the world are manufactured with packaging systems utilizing a fluoropolymer barrier coated rubber closure due to the nature of the medicine being protected for delivery. As future medicines become even more difficult to stabilize and have more sensitivities, an increased usage of fluoropolymer coated rubber closures is expected. If these medicinal products were to be banned due to the closures used in their packaging systems not maintaining CUU determination, there would be a dramatic shortage and unavailability of life-saving injections (e.g., chemotherapies, mRNA vaccines, biological drug developments, future cell-and-gene therapies), especially with new developments and drugs that are targeting commercial use within the first years after PFAS restrictions are put in place. Restarting such stability and approval exercises is virtually impossible for all drug products currently using fluoropolymer-coated closures and will induce shortage of medicinal products available to patients needing these treatments in the field.

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?

Stakeholders, such as manufacturers of the products, should respond to a request for proposal by the MPCA and submit a proposal for a CUU determination for a PFAS-containing product to the MPCA's review and conclusion. Stakeholders should not be able to submit a proposal for a CUU determination to be obsoleted, but rather should be permitted to request for a re-evaluation on the subject CUU determination that the MPCA can then resolve whether or not to fulfil such request at its decision.

The proposals for CUU determination should provide information similar to that requested for PFAS reporting in Minnesota Statutes 116.943, subdivision 2(a). Due to the sensitivity of trade secrecy, Datwyler requests that the MPCA balance public availability of data and trade secrecy as part of the reporting requirements. In particular, in the requirements listed in Minnesota Statutes 116.943, subdivision 2(a), subsection 3, there is a request for identification of PFAS by its chemical abstracts

service (CAS) registry number “in the exact quantity determined”. Such a requirement may be excessive in this case as the focus should be on the clear demonstration of CUU requirements that the PFAS-containing product is *essential for health, safety, or the functioning of society* as well as how *alternatives are not reasonably available*. Datwyler recommends that proposals not focus on the listing of CAS numbers and instead focus on demonstrating how alternatives are not reasonably available.

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.

Looking at the unique and essential use of fluoropolymer coatings on elastomeric closures used for primary packaging to ensure compatibility with parenteral drugs, Datwyler welcomes the opportunity to submit a proposal for CUU determination for the product class of fluoropolymer-coated closures for primary packaging systems of medicinal products. Datwyler’s elastomer closures are essential packaging components for pharmaceutical and biotech drug products.

Parenteral/Injectable primary packaging systems of sensitive drug medicine intended to be injected (e.g., oncology chemotherapy, individualized cell/gene therapy, novel biological-based drugs, and other medicines sensitive to migrating substances from the rubber) depend on closures that have limited to no interactions with the drug medicines while maintaining barrier properties. Fluoropolymer coatings (applied with either the spray or film technology) create such an inert barrier between the rubber of the closure and the medicine within the packaging. Any changes by replacing parts with non-fluoropolymer alternatives would require development, qualification, validation, registration and approval, and are thus not economically feasible. There would also be a need by pharmaceutical and biotech companies to reallocate investment that would have gone to the development and manufacture of life-saving drug products as these companies would need to reallocate significant resource and refocus on substituting, revalidating and reregistering many parts of their process and products. The whole industry would also need to partake in a huge regulatory undertaking, further diverting attention and investment away from developing novel therapies for life-threatening diseases.

Not designating fluoropolymer-coated closures a CUU determination would severely limit the delivery and availability of medicines and life-saving treatments to the patients seeking treatment from healthcare professionals in Minnesota.

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

Yes – Datwyler would humbly request that the MPCA consider the proposal in response to question 7 to make an initial CUU determination in order to assist in the understanding and demonstrated application of the process by which the MPCA shall evaluate further proposals.

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

At this time, Datwyler seeks to reiterate to the MPCA that there exists an element of concern in the proposal to consider all -CF_2 containing materials, without differentiating between the macromolecular Fluoropolymers with other smaller PFAS. Posing a definition of "all -CF_2 containing materials" to be inclusive of polymeric PFAS (like PTFE, PVDF, and FKM), shows that there is a limit to the understanding of the safety potential for these materials. Datwyler highly advises that the MPCA consider clarifying the CUU criteria to allow for a streamlined review of such fluoropolymer uses that have been analytically demonstrated to be non-toxic, not bioavailable, non-water soluble, and non-mobile molecules that do not exhibit environmental or human health implications.

Datwyler keeps sustainability at the forefront of its vision and remains committed to balancing the need for environmental protection with the need for pharma packaging components designed to protect the efficacy and functionality of medicines, which is a complex challenge. Thank you for allowing us to provide these comments and for taking the time to consider these views during the rulemaking process. Datwyler admires the significant task being undertaken by the MPCA to balance environmental impacts of PFAS with maintaining essential functions of health, safety and a functioning society for all Minnesotans. Datwyler welcomes the opportunity to further engage with the MPCA and other stakeholders in this rulemaking process and offers to answer questions and provide technical perspectives in further discussions during the rulemaking process. If further information is needed about the materials included in this submission, please contact Roman Ventura by email at roman.ventura@datwyler.com.

Respectfully submitted,
Datwyler

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Review Log

Function	Name	Title	Date
M&ST	Bram Jongen	Vice President Materials & Surface Technologies	29 Feb 2024
Reg Affairs	Giorgio Morlotti	Chemical Compliance Manager	01 Mar 2024

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