Diana Rondeau

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?
IDEXX Laboratories, Inc.

If you represent a product manufacturer or industry group, what industry(ies) do you represent?
Human and Veterinary diagnostic devices, and water testing reagents and devices.

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?
Veterinary diagnostic devices, reagents and water tests that are used to ensure healthy pets, livestock and dairy food supply and safe drinking water for Minnesota residents and worldwide.

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)*
All products used in the research, development and manufacturing of FDA or USDA regulated products should automatically be placed out of scope and considered as CUU to reduce risks to disruptions in life saving diagnostics. Similar exemptions have been successfully included in other US state legislative proposals, including Maine and New Mexico. Additionally, both Maine and New Mexico have exempted products developed or manufactured for the purposes of public health, environmental or water quality testing.
Alternatively, IDEXX recommends expanding the definition to include “use of PFAS in products that are essential for health, safety, and the functioning of society, where the replacement of alternative substances to PFAS would require lengthy product approvals from regulatory agencies and would result in the product’s service to be unavailable”.

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)*

Replacing materials in a regulated product requires a data package submission to regulatory authorities for product registration to demonstrate product performance and label claims are maintained and identical to the PFAS containing product.
In many cases, the properties of the device manufacturing can influence performance properties, leading to a regulated requirement for all critical applications with the change of materials needing to be validated a time consuming and costly process for each manufacturing process and product claim). Even in cases where PFAS free version of components exists, these materials do not generally have like-for-like properties and changes would result in costly and time-consuming revalidations that may impact the quality of the final product.

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*)
Reasonably available only defines functionality, e.g., perform comparably, and therefore seems to duplicate the alternative definition. Reasonably available should also include volumes necessary to support commercial manufacturing scale, dual source suppliers (not just a single source in supply chain). Large manufacturers must consider supply chain availability prior to determining if the material is equivalent and then begin the lengthy work to validate and submit extensive regulatory packages for product change approvals.

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.")*
Requests should be grouped as used in regulated products to differentiate from consumer products. Our focus on human, veterinary health and water safety allies us with the Program’s environmental protection goals. Indeed, reduction of harmful environmental contaminants is at the core of our business. However, it is crucial that essential products such as IDEXX’s remain available and continue to be of the same high quality and performance as required in our heavily regulated environment. Notably, all our products are sold Business to Business, to professional users, such as accredited laboratories and Veterinary Clinics. Our products are handled in a laboratory setting, with full laboratory controls in place, including but not limited to the use of gloves and other Personal Protective Equipment.

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?
Categories should be as broad as possible (ideally, “materials used in regulated products”) to account for variable supply chain information and ensure no uses are restricted and ensure that these critical products remain available to Minnesota government laboratories, and veterinary clinics.

What safety or other standards require the use of PFAS in a product? *(Please include the specific citation)*
PFAS containing products, in particular fluoropolymers, are widely used in life science manufacturing and related research industries. The materials are used for chemical stability, chemical compatibility with solvents, low leaching potential, oleophobic properties, thermal resistance and mechanical properties of the polymers. Often, IDEXX is purchasing items like electrical components that use PFAS coating for high heat purposes and ensure safety of electrical product use. Any changes would require our vendor to validate, and then IDEXX would need to validate the component change as well.

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?

The administrative burden to reapply will be massive for small volume industries such as the Life Sciences industry which places many niche products on the market compared to other industries which sell large volumes of some bulk products. In cases where there are not sufficient administrative resources to meet the submission requirements, and it may require companies to stop shipments to Minnesota rather than risk regulatory non-compliance.

All products used in the research, development and manufacturing of FDA or USDA regulated products, or products used in EPA regulated government labs should automatically be considered as CUU to reduce risks to disruptions in the supply chain for critical diagnostic products approved to restore or protect the health and welfare of animals and people and the processes used to produce the products should be considered as necessary for health. Similar exemptions have been made in other US states such as Maine and New Mexico.

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.
More than 500 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 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.
More than 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).

PFAS free alternatives currently exist for some but not all fluoropolymer containing products used in diagnostic manufacturing; however, these have properties that do not make them suitable for every use case, requiring re-validations subject to regulatory approvals. Additionally, most often, PFAS is used in upstream materials (tier 2,3 or higher) in the supply chain, requiring negotiation and understanding of alternative availability in purchased components well before any operational or capital costs incurred by IDEXX.

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?

The majority of the PFAS use is in upstream supply chain, where first the feasibility of function must be determined (one example includes coating on PCB (printed circuit board). It can take years to determine if an alternative material will maintain and withstand high heat.

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.

Timing can be much more complex if numerous product lines are changing at once, with resource and regulatory roadblocks. For multiple products, it is not uncommon to see 5-7 years extend to 15+ years for all products to be validated and approved by regulatory authorities.

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)*
MPCA should issue a directive clarifying that all critical diagnostic products used to ensure the health and safety of people, animals and drinking water containing intentionally added PFAS that are regulated are outside of scope of the January 1,2032 phaseout. This will provide needed certainty to the animal health sector, government labs and other stakeholders, and the marketplace.

