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May 18, 2023

VIA E-MAIL

Mark Margerum
17 Statehouse Station
Augusta, ME 04333-0017

Re: Posting Draft of Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances (“Proposed Rule”)

Dear Mr. Margerum:

On behalf of Gujarat Fluorochemicals Limited (“GFL”), Akin respectfully submits these comments to express support with important modifications of the Proposed Rule published on February 14, 2023 by the Maine Department of Environmental Protection (“DEP”) providing “additional guidance on the notification requirements and sales prohibitions for products and product components containing intentionally added PFAS pursuant to 38 M.R.S. 1614 [(Maine’s Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution (the “Act”))].” GFL and GFL Americas, LLC (a U.S.-based wholly-owned subsidiary), manufacture certain fluoropolymers, a distinct class of PFAS used primarily in industrial applications, and provide comments herein on: (1) the inherent safety of those fluoropolymers produced without the use of fluorinated polymerization aids; and (2) the overbroad definition of PFAS included in the Proposed Rule that does not distinguish between these inherently safe fluoropolymers and PFAS of concern (“PFOC”). As currently drafted, the Proposed Rule risks prohibiting from sale in Maine a broad swath of products that are “essential for health, safety or the functioning of society,”¹ yet in which the addition of fluoropolymers does not create a risk to human health or the environment, including renewable energy, transportation (air and surface), electric vehicles, semiconductors, food and water treatment technologies, safe chemical processing, and pharmaceutical and medical devices.²

¹ Section 2 (I) of the Proposed Rule defines products and product components that are “Essential for Health, Safety or the Functioning of Society” as 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 environment, or significantly interrupt the daily functions on which society relies.

² The broad category of products that are “essential for health, safety or the functioning of society” and in which fluoropolymers are crucial and irreplaceable are many. Fluoropolymers are essential to the manufacturing of solar panels and windmill blades for clean energy systems. In electric vehicles, fluoropolymers are critical for optimal performance of lithium-ion batteries and hydrogen fuel cells. Without fluoropolymers, sustainability goals would be seriously compromised. Due to their resistance to harsh chemicals, fluoropolymers are essential for manufacturing semiconductors, providing an impurity-free environment. Without fluoropolymers, the semiconductor industry will be unable to produce microchips that allow for the development of modern electronic devices such as mobile phones, laptops and many other high-tech equipment. Fluoropolymers are utilized in water filtration systems (which avoids

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Fluoropolymers Exhibit Different Toxicological and Environmental Profiles from PFOC and Should Not Be Regulated as If They Were the Same

The Proposed Rule defines PFAS broadly to encompass all “substances that include any member of the class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom.” While this definition includes per- and polyfluoroalkyl carboxylic acids (“PFOA”) and sulfonic acids (“PFOS”), which are toxic, bio-accumulative, persistent and mobile, it also includes fluoropolymers, a distinct class of PFAS – 38 in number – such as polytetrafluoroethylene (“PTFE”), polyvinylidene difluoride (“PVDF”), fluoroelastomer (“FKM”) and perfluoroalkoxy alkanes (“PFA”).³

Fluoropolymers are high molecular weight, safe substances. Because of their negligible solubility in water and high molecular weight, fluoropolymers cannot bio-accumulate in the human bloodstream.⁴ Fluoropolymers are inert, do not degrade to or leach PFOC under intended use conditions or under the environmental conditions at the end-of-life phase of their application and pose no risk to human health and the environment when disposed of in landfills.⁵

Fluoropolymers are non-mobile, non-bio-accumulative, non-toxic chemicals that do not pose any risk to water quality, human health or the environment and fulfill the thirteen criteria established by the Organization for Economic Cooperation and Development (“OECD”) to be regarded as “Polymers of Low Concern.”⁶ Similarly, a regulatory management option analysis (“RMOA”) published by the UK’s Health

the need to use chemicals for water treatment), and in food processing systems to guarantee adequate sanitary conditions and protect consumers from harmful contamination. Catheters and medical implants contain fluoropolymers due to their biological compatibility, inertness and durability. Furthermore, the production of medicines and vaccines requires ultra-pure conditions which can only be achieved with equipment based on fluoropolymer materials. Because fluoropolymers are unmatched in resistance to chemical attack and performance under wide temperature variations, they are the safest, most secure material for processing and containing chemicals. Fluoropolymers are found in all kinds of industrial equipment, as well as joints and gaskets to secure operation and containment of chemicals. Further, fluoropolymers contribute to both fuel efficiency and safety, playing a key role in systems such as brakes in cars or wing flaps in aircrafts. They are also the best option available (due to their high resistance and high flexibility) to protect electrical cables in aircrafts, where high reliability of such cables, which can be exposed to thermal as well as chemical pressure, is fundamental. Lastly, fluoropolymers are used in highly efficient air conditioning and refrigeration systems, as well as in heat pumps. Food processing and water filtration systems require fluoropolymers to ensure high purity of the different streams they handle. Fluoropolymers also play a key role in modern construction systems, used in many buildings to boost durability and sustainability.

³ Fluoropolymers account for a small portion of the 9,000 PFAS. See Appendix A to this letter.

⁴ Chemservice Technical Report: Analysis of Alternatives to Fluoropolymers and Potential Impacts Related to Substitution in Different Sectors of Use; Version 1, July 19, 2022.

⁵ *Id.*

⁶ Henry, Barbara J., et al. “A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers.” *Integrated Environmental Assessment and Management* 14.3 (2018): 316-334; and Korzeniowski, S. H., et al. “A Critical Review of the Application of Polymer of Low Concern Regulatory Criteria to Fluoropolymers II: Fluoroplastics and Fluoroelastomers.” *Integrated Environmental Assessment and Management*

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and Safety Executive (“HSE”) in April 2023 suggests that the current regulatory framework for PFAS in the UK could be streamlined by providing exemptions for fluoropolymers since comprehensive, reliable evidence of their low hazard or safe use is available and because they are particularly important to the industrial, automotive, aerospace and defense sectors.⁷

Further, a recent study conducted at the Karlsruhe Institute of Technology in Germany demonstrated that at end-of-life, fluoropolymers can be completely thermally destroyed at standard incineration conditions. This is yet another important distinction between fluoropolymers and PFOC, which are currently perceived as “forever chemicals” because of their resistance to standard incineration and for which select innovative companies are only beginning to develop methods of destruction at end-of-life.

To the extent there may be a valid concern related to fluoropolymers, it is the use and emission of fluorinated surfactants (also called PFAS polymerization aids) in the polymerization of certain fluoropolymers.⁸ Today, technologies exist to produce several fluoropolymers including PTFE, PVDF, FKM & PFA without the use of PFAS polymerization aids. GFL uses such technology to produce the four fluoropolymers delineated above (PTFE, PVDF, FKM and PFA) largely without fluorinated polymerization aids, and by the end of this year will produce its entire fluoropolymer portfolio without the use of these aids. Even if valid, banning the entire class of fluoropolymers based on the limited use of PFAS polymerization aids is a regulatory overreaction for the reasons described above. DEP would be better served to restrict the use of PFAS polymerization aids in the creation of fluoropolymers, and allow the continued use of these safe fluoropolymers manufactured without such aids.

In summary, the Proposed Rule should not apply to fluoropolymers since they are non-mobile, non-bio-accumulative and non-toxic, can be produced without the use or emission of PFOC, and can be efficiently destroyed at end-of-life. Simultaneously, the Proposed Rules must restrict the intentional use of PFAS polymerization aids in the production of fluoropolymers.

(2022). The thirteen criteria considered by OECD when making a Polymer of Low Concern determination are: polymer composition, molecular weight, percentage of oligomer, electrical charge, Reactive Functional Groups (“RFG”), Functional Group Equivalent Weight (“FDEW”), low molecular weight leachables, water/lipid solubility, particle size, polymer stability, thermal stability, abiotic stability, and biotic stability. The vast majority of fluoropolymers used today meet all of the OECD Polymer of Low Concern criteria and are non-toxic; non-bio accumulative; non-mobile; insoluble in water; thermally, chemically and biologically stable; durable; and not Substances of Very High Concern (“SVHC”).

⁷https://www.hse.gov.uk/reach/rmoa.htm?utm_source=press.hse.gov.uk&utm_medium=referral&utm_campaign=corporate-push

⁸More than 50% of fluoropolymers do not require the use of polymerization aids at all during manufacturing. Of those fluoropolymers that are manufactured with the use of polymerization aids, only some use PFAS polymerizations aids. Even within that subset, many manufacturers are developing methods to replace PFAS polymerization aids with non-fluorinated aids.

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DEP Should Use its Legislatively Granted Discretion to Refine the Definition of PFAS in the Proposed Rule to Exclude Fluoropolymers

There is no single, globally-harmonized definition for PFAS. The Proposed Rule relies on the structure and atomic composition of PFAS and specifically the carbon–fluorine (“C–F”) bond found in PFAS. As stated above, these C-F bond-based definitions cover a broad group of about 9,000 substances. While fluoropolymers do share structural similarities with other PFAS, these structural similarities or the existence of a C-F bond across chemical substances in itself is not representative of a risk to human health and environment.⁹ Whether a PFAS is a cause of concern to human health and environment is determined by other traits such as its potential to bio-accumulate and to be persistent and/or mobile in the environment. Using these rationale, it makes sense to identify and include certain PFAS, such as PFOA and PFOS as PFOC due to their solubility in water, bio-accumulative properties, and toxicity. It does not make sense, however, to sweep up all fluoropolymers into the same definition for the reasons described above.

The United States Environmental Protection Agency (“U.S. EPA”) acknowledges the importance of categorizing PFAS and regulating them commensurate to their toxicity and impact in its PFAS Strategic Roadmap for the years 2021 to 2024 (“Roadmap”). One of four guiding principles of the Roadmap is to “ensure science based decision making.” The Roadmap notes that the current body of science ties only specific PFAS to significant hazards and that there are significant gaps in the understanding of impacts of other PFAS. It states, “[r]egulatory development, either at the state or federal level, would greatly benefit from a deeper scientific understanding of the exposure pathways, toxicities, and potential health impacts of less-studied PFAS.”

The state of the science should inform the Proposed Rule’s provisions. DEP should use its authority to “exercise [...] significant agency discretion or interpretation in drafting” as granted by the Act to expressly exclude fluoropolymers from the definition of PFAS in the Proposed Rule to avoid unintended health, safety and commercial consequences. This step is consistent with the science and would obviate the need for multiple product-by-product analyses/exclusions while reducing the administrative burden on DEP;¹⁰ all with no decrease in the protection of human health or the environment.

GFL appreciates that, by providing an exclusion from its prohibitions for the use of PFAS in a product if that use is a “currently unavoidable use,” the Act contemplates that some uses of PFAS

⁹ A OECD report, which defined PFAS as fluorinated substances that contain in their structure at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), that is, with a few noted exceptions, any chemical with at least a perfluorinated methyl group (–CF₃) or a perfluorinated methylene group (–CF₂–; OECD, 2021), acknowledges that the term “PFAS” is broad, general, and nonspecific, and does not inform whether a compound presents risk or not, but only communicates that the compounds under this term share the same structural trait of having a fully fluorinated methyl or methylene carbon moiety. While some of these substances have been shown to be of concern to human health and the environment, not all the substances in this vast group exhibit the same toxicological properties.

¹⁰ 38 M.R.S. 1614 (5)(C) authorizes DEP to issue rules exempting products in which the use of per- and polyfluoroalkyl substances (“PFAS”) is a “currently unavoidable use.”

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are essential for health, safety, or the functioning of society. But that exclusion mistakenly assumes that the presence of any PFAS necessarily creates a risk to human health and the environment that should only be permitted when the present use is unavoidable. That is not the case with fluoropolymers. Therefore, without this important and legislatively authorized interpretation of the definition of PFAS, the Proposed Rule may well result in an unnecessarily broad prohibition of safe, non-mobile, non-bio-accumulative, non-toxic chemicals.

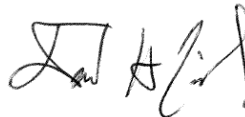
At a minimum, DEP must begin to exercise its authority to identify and exempt from § 5(C) of the Proposed Rule “Prohibition on Sale of Products,” broad categories of products made with fluoropolymers and without PFAS polymerization aids that are “essential for health, safety or the functioning of society.” This will send a strong signal to the market that Maine will lead by protecting its citizens and ensuring that critical products are still readily available for sale in the State.

Conclusion

In sum, with important modifications the Proposed Rule can be a scientifically-driven, consumer-minded one that ensures protection of human health and the environment for the citizens of Maine. With such modifications, the Proposed Rule would avoid unnecessary and adverse consequences to the large number of industrial applications in which the addition of fluoropolymers does not create a risk to human health or the environment, and helps support industries and innovation essential for health, safety or the functioning of society, including renewable energy, transportation (air and surface), electric vehicles, semiconductors, food and water treatment technologies, safe chemical processing, and pharmaceutical and medical devices.

GFL would be pleased to answer any questions and to provide additional technical assistance as the DEP refines this Proposed Rule.

Sincerely,



David H. Quigley

Appendix A

Per- and polyfluoroalkyl substances (PFASs)

