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Non-confidential comments for Annex XV restriction report: Toxicity of per- and polyfluoroalkyl substances (PFASs), including fluoropolymers

Dear Madame or Sir,

I welcome this opportunity to provide input on the restriction proposal regarding per- and polyfluoroalkyl substances (PFASs). I prepared this submission on my own. I am a Professor of Pharmacology and Toxicology of the Brody School of Medicine at East Carolina University and a major portion of my laboratory research and scholarly activity concerns the immunotoxicity of PFASs. I also work closely with several non-profit organizations that are dedicated to enhancing the general public's understanding of PFAS and informing decision-makers on the hazards of PFASs so that they can make decisions to protect human and environmental health from PFASs exposures. I also have worked closely with community-based organizations concerned about their PFASs exposures and health concerns, and the North Carolina Department of Environmental Quality and the United States Environmental Protection Agency on scientific findings associated with PFAS. I also serve as a general toxicological expert for plaintiffs in legal cases. However, I am submitting these comments on my own and my opinions do not reflect my academic institution, any organizations with whom I work, or any legal entities with whom I may consult.

The restriction proposal is a great step forward for countries in Europe and will serve as a model by which other countries and regions can enact similar restrictions to reduce ongoing emissions that contribute to ongoing exposures to the public and to wildlife. My opinions contained herein are therefore supportive of the restriction proposal and is intended to strengthen the proposal, especially with respect to the toxicological hazards of PFASs and of fluoropolymers.

The restriction proposal notes that many PFASs have the properties of ecotoxicity and toxicity to humans and that many PFASs lack specific data on their toxicological properties. While I agree that differences in toxicological potencies appear to exist across the spectrum of PFASs that have been evaluated and that PFASs in combination appear to be more toxicologically potent than individual PFASs (see U.S. EPA, 2023). However, what is critical to note is that the PFASs that have been studied for their toxicity are able to elicit adverse health outcomes across a number of different organs and systems, thus leading to their "multisystem toxicants" status (see Fenton et al., 2020). This has implications for PFASs that have been understudied toxicologically and suggests that the absence of evidence for these understudied PFASs should not be misconstrued as evidence of the absence of toxicological effects. As indicated by Kwiatkowski et al. (2020), the multiple characteristics of concern of PFASs (persistence, bioaccumulation potential, mobility, and/or toxicity) should be considered when managing PFASs. Thus, the absence of toxicological evidence for one or more PFASs does not negate the other characteristics of concern that exist for all PFASs. I would like to suggest that the restriction proposal better emphasize these concerns with respect to toxicity as a characteristic of concern.

The restriction proposal also notes that beyond persistence, evidence of other hazardous properties of fluoropolymers is limited and that polymers can be considered as inert. I would like to emphasize that the phrase "fluoropolymers are inert" is largely dogma and is based on limited empirical evidence conducted largely to meet specific regulatory guidelines and not to truly investigate their toxicity. For example, the scientific literature includes numerous accounts of "Teflon granulomas" in patients who had received Teflon implants or injections to relieve various ailments. These case reports go back to the 1990s, with one of the most recent reports in 2022 (Kamp and Storck, 2022). In this 2022 case report, Kamp and Storck (2022) indicate that "Teflon has been proven to be able to extravasate and infiltrate into soft tissue to form an inflammatory giant-cell foreign-body reaction, a so-called Teflon granuloma." They also note a trend of decreasing Teflon injections since the early 1990s due to increasing case reports of Teflon granulomas. In 2021 the U.S. Food and Drug Administration (FDA) performed a systematic review of the literature regarding PTFE and found a paucity of data in experimental animals and recommended additional controlled trials for various PTFE materials across various uses (FDA, 2021). Thus, it appears as if fluoropolymers, like other PFASs, are inert, but also are interactive and result in alterations to physiology that can result in adverse health outcomes. Further data are required to fully address this potential concern for fluoropolymers.

References:

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