A CRITICAL REVIEW OF THE APPLICATION OF POLYMERS OF LOW CONCERN AND REGULATORY CRITERIA TO FLUOROPOLYMERS

Background

The regulation of per- and poly-fluoroalkyl substances (PFAS) is a growing topic of interest. Some believe the most appropriate approach to regulation or consideration of potential risks is to lump together both polymeric and non-polymeric categories of PFAS, treating them as if they were a single class of substances.

Fluoropolymers often are grouped into the highly broad PFAS classification without regard to distinct characteristics that qualify them as meeting the globally accepted criteria for *Polymers of Low Concern* (OECD, 2009; BIO by Deloitte, 2015).

This new, peer-reviewed paper published in Integrated Environmental Assessment and Management (IEAM) drives further clarity on the broad group of chemistry known as PFAS. The authors conducted a thorough review of the regulatory history of the hazard assessment of polymers and non-polymers, as well as the scientific foundation for the resulting paradigm ("polymers of low concern"). This paper articulates a clear and compelling scientific basis for segregating fluoropolymers from other per- and poly-fluoroalkyl substances (PFAS). Separation of fluoropolymers from the larger list of as many as 3,000 substances grouped into five different classes of PFASs is based upon the authors' demonstration that fluoropolymers constitute a distinct class within the PFAS group and, therefore, should be considered separately.

Findings

Fluoropolymers are:

- High molecular weight polymers (well over 100,000 Da,) incapable of crossing the cell membrane.
- Stable in terms of their chemical, photochemical, hydrolytic, oxidative and biological qualities including negligible residual monomer and oligomer content and low to no leachables, in addition to being thermally stable under intended conditions of use.
- Insoluble in water and not subject to long-range transport in the environment.
- Neither bioavailable nor bioaccumulative as evidenced by toxicology studies on PTFE.

Forty years of clinical history of more than 40 million implanted PTFE medical devices demonstrates no chronic toxicity or carcinogenicity, reproductive or developmental or endocrine toxicity.

The new paper — A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers — brings together:

- fluoropolymer toxicity data
- human clinical data, and
- physical-chemical-thermal-biological data

for review and assessment to show that fluoropolymers satisfy globally recognized assessment criteria to be considered "Polymers of Low Concern."

The authors definitively conclude that "*. . . fluoropolymers are distinctly different from other polymeric and non-polymeric per- and poly-fluoroalkyl substances and should be separated from them for hazard assessment or regulatory purposes.*"

The paper further establishes that "*Grouping fluoropolymers with all classes of PFASs for 'read across' or structure activity relationship assessment is not scientifically appropriate,*" when a complete good quality data set exists, as it does for fluoropolymers.

For Consideration

Mission

Advance consideration of this issue such that greater understanding and recognition of the unique characteristics of fluoropolymers can result; and further promote acceptance that those characteristics qualify the designation of these substances as **Polymers of Low Concern.**

The authors seek to provide perspective and context in this important discussion and invite interested groups and individuals for dialogue. Through webinars, presentations or individual briefings, valuable and needed collegial consideration of this issue can occur in order to:

- **Foster thoughtful consideration** among scientific and lay audiences about the distinctions and value of fluoropolymers.
- **Increase understanding** of the significant differences between fluoropolymers and other per- and poly-fluoroalkyl substances.
- **Develop consensus** in support of the scientific validity of treating fluoropolymers as distinct from all other PFAS.
- **Apply reason** to regulation and policy related to fluoropolymers, thereby preventing fluoropolymers (including PTFE) from inclusion in overly broad regulations and restrictions of PFAS.

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