Environmental Assessment and Registration of Polymers: Scientific Issues and Implementation Challenges

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Polymers are typically large molecules consisting of repeating units of one or several monomer types, in diverse combinations and with a vast variety of structures. Polymers are present not only in plastics but encompass an array of soluble and insoluble species used in a host of different applications, including industrial processing, wastewater treatment, pharmaceuticals, detergents, cosmetics and personal care products. With current estimates ranging from less than 70,000 to 400,000 polymers on the EU market, polymers represent a large share of commercial chemical substances for which significant gaps still exist regarding their chemical identity and physico-chemical properties, as well as exposure, hazard and risk profiles.

Currently, the European Commission (EC) is working, in consultation with Member States and other stakeholders, on developing a legislative proposal for polymer registration under the EU's chemicals regulation REACH. The EC's proposal foresees establishing a set of criteria to identify the so-called polymers requiring registration (PRR) and polymers that can continue to be exempt from registration. Among PRRs, sufficiently similar, i.e., same, polymers can be grouped together into a single "PRR substance," but the grouping approaches have not yet been fully developed and agreed on. Registration dossiers for polymers are expected to include the PRR substance's identity and physico-chemical properties, along with exposure and hazard information for both human health and the environment. Since the existing information on polymers is largely incomplete, the upcoming polymer registration requirements in the EU can be expected to trigger substantial generation of new test

data in the coming decade. However, due to unique physico-chemical properties, polymers are often expected to behave differently from the low-molecular-weight organic substances that have traditionally formed the focus of environmental risk assessment. Therefore, adaptation of the existing test guidelines and approaches, as well as development of new tests and assessment concepts, has become necessary.

Against this background, the polymers session at the SETAC Europe 32nd Annual Meeting set out to discuss novel and adapted concepts and approaches needed for the environmental risk assessment of polymers, including fate and exposure analysis and modeling, structure-activity relationships, examples of risk assessments, analytical approaches, and perspectives from non-traditional toxicological effects endpoints currently not covered in standard information requirements.

The session started with Stefan Hahn from Fraunhofer ITEM presenting the framework for persistence assessment of polymeric substances, developed within the CEFIC-LRI ECO52 project, which aimed to develop guidance for persistence assessment of substances that are considered problematic to evaluate under the existing frameworks. Some of the essential components included in the final guidance include polymer profiling, considering the differences between natural and synthetic polymers, as well as weathering, and combined for evaluation with a weight-of-evidence approach.

Next, Hans Sanderson from Aarhus University summarized the work done in collaboration with The Procter & Gamble Company under the CEFIC LRI project ECO46 – iTAP. This project focused on improving aquatic risk assessment of cationic polymers, through enhancing both the empirical data basis and the modeling and prediction capacity. Using data on cationic polymers toxicity to fish and green algae, provided by the U.S. Environmental Protection Agency and Environment and Climate Change Canada, scientists developed multivariate models that allowed analyzing the relative contribution of key structural features to the overall toxicity. Their research showed that the aquatic toxicity of cationic polymers is governed not only by the charge density, with higher values leading to a higher toxicity, but also by a range of other attributes, including

- The presence of a cationic functional group in the pendant chain at positions one, four and five, which enhances the toxicity
- The molecular weight, where higher molecular weight was found to increase toxicity toward green algae but not fish
- The presence of different amines in the molecular building block, with primary and secondary amines resulting in a reduction of toxicity and quaternary amines resulting in an increase in toxicity against green algae.

The authors emphasized the urgent need to clarify the regulatory acceptance of previously developed multivariate models that are based on the charge density only as they cannot provide an accurate prediction of cationic polymers' toxicity.

Two more presentations focused on the Conceptual Framework for Polymer Risk Assessment (CF4Polymers), developed by a large consortium convened by the ECETOC. First, Jens Otte from BASF SE introduced considerations and examples for grouping polymers. He highlighted the existence of a large number of similar polymer structures that are manufactured from the same starting materials, following the same synthesis processes, and pointed out that chemical variations in a small part of a large macromolecule are not expected to lead to substantial differences in physico-chemical or biological properties. A new term, "hazard similarity," was then introduced as a central element for the grouping of different

polymers, which should be evaluated based on three criteria: chemical nature, physico-chemical properties, and ecological and toxicological properties. This approach was illustrated with three case studies covering bisphenol A diglycidyl ether (BADGE) polymers, polyetherols and surfactant polymers. Nathalie Vallotton from Dow Europe GmbH then exemplified the practical application of the CF4Polymers to the assessment of hazard and risk of cationic polymers.

Similarly to polymer sessions at SETAC conferences in previous years (see the summaries from 2019 and 2020) the work presented in this session continued to be dominated by contributions from industry-based scientists and industry-funded collaborative projects, such as CEFIC LRI. This comes as no surprise, since the industry was the first and main stakeholder alerted to the necessity of carrying out more research into environmental effects of polymers. Nonetheless, participation by government and academia is crucial to ensuring the balanced representation and independent verification of research data obtained. Indeed, raising the awareness across the SETAC community was one of the main goals when this session on polymers was first put together in 2020.

As session chairs, we were please to see a substantial increase in session attendance and contributions by both academic scientists and regulators this year. For example, Hattie Brunning from University of York presented a poster featuring the framework developed for assessing environmental fate and exposure of polymers, while Ula Rozman from University of Ljubljana, Slovenia, shared the results of a study on the ecotoxicity and biodegradability of several water-soluble polymers, performed with bacterium, microalga, aquatic plants and crustacean species. These developments demonstrate that the important challenge of understanding environmental fate and effects of polymers beyond microplastics has started gaining traction within the broader SETAC community.

With this, we look forward to a continued interest and a steady flow of diverse contributions to the next session on polymers that we are planning to organize at the SETAC Europe 33rd Annual Meeting in 2023 in Dublin. By then, the EC's definition of a polymer requiring registration will be developed in greater detail, providing a fertile ground for in-depth discussions at the session. We encourage the SETAC community to consider research on polymers as this is a vast and interesting domain where a lot of new knowledge can and should be developed.

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