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Polymer Risk Assessment: Considerations from an ECETOC Polymers Task Force.

ABSTRACT / BACKGROUND

Polymers are part of our daily life and provide a multitude of technical functionalities, are versatile, complex and cover a broad spectrum of chemistries and molecules. Polymers cover a broad spectrum of molecules, often with medium to very high molecular size such as celluloses, waxes and resins. By their nature, polymers pose technical/scientific challenges for risk assessment, and conventional risk assessment approaches may not apply to the majority of polymers.

An ECETOC Task Force has proposed the ECETOC Conceptual Framework for Polymer Risk Assessment (CF4Polymers) that includes eight steps for risk assessment and intelligent testing of polymers. Subsequent case studies confirmed that due to the wide range of polymer types and properties, no 'one size fits all' set of rules is applicable, leaving regulators and industry to apply rules more on a case-by-case basis. The review of the ECETOC Task Force pointed to key differences in scoping and informing the risk of chemicals versus polymeric substances, as these represent a different chemical universe. Taking the current approaches under the REACH regulation as a starting point, specific considerations to advance the safety assessment of polymers are discussed.

TYPES OF RISK ASSESSMENT

Polymer products are versatile and complex and are generally not present as mono-constituent substances, influencing the focus of risk assessment and regulatory requirements.

Complex polymer products consist of:

- the polymeric substance (polymeric macromolecules)
- intentionally added substances (IAS; e.g. stabilisers)
- non-intentionally added substances (NIAS; e.g. impurities)

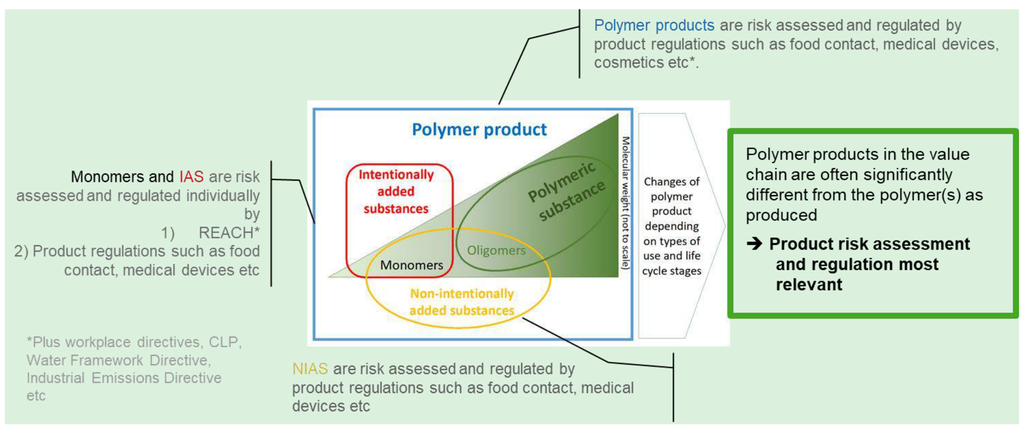
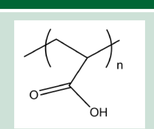
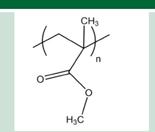


Figure 1: Components and aspects of polymer products covered by the ECETOC Conceptual Framework for Polymers (CF4Polymers)

ENVIRONMENTAL RISK ASSESSMENT SCOPING

The focus of the risk assessment varies depending on the use of the product and potential exposure to humans and the environment. The two polyacrylate polymer products outlined in Table 1 illustrate how varied the scope of the risk assessment can be based on product use, phys-chem properties and polymer form in the finished product.

Table 1: Illustrative examples of diversity of uses and properties of polyacrylate polymers.

Type of polymer	Polyacrylic acid homopolymers	Acrylate copolymer
Structure – Repeating Unit		
Example use	Home care- scale control agents/water softeners	Transparent thermoplastic used in acrylic paints
Solubility	High water solubility	Water insoluble
IAS	IAS depend on application, require a specific review	
Scope of risk assessment	Polymeric substance with wide-dispersive use	Durable application, environmental exposure not expected. Case-by-case IAS assessment

BIOAVAILABILITY CHALLENGES

Effects in human and environmental species may result from physical effects and/or intrinsic toxicity of polymers. Beyond external exposure, the interaction with target tissues is influenced by the uptake of substances into organisms. A strengthened assessment of systemic bioavailability is essential to support prioritisation of polymer components requiring additional testing information.

Method	Challenges for **high molecular weight** substances/materials
Modelling uptake based on 1.molecule size, particle sizes 2.Partitioning & solubility 3.Dissociation constants, charge	1.Multitude of structures / complex mixtures, variability in measurements, lack of computational models for >1000Da 2.Methods to generate and select data on phys-chem properties are lacking
In vitro or *ex vivo* absorption testing • Caco-2 or Epi-Intestine • *Ex vivo* skin or 3D skin models • Airways 3D models	• Constituents unavailable as such • Detecting and quantifying polymer constituents in complex matrix of tissue models • Quantitative *in vivo* and *in vitro* models for non-diffusion absorption processes such as endocytosis

ENVIRONMENTAL FATE CHALLENGES

There is a need to advance 1) laboratory testing methods to characterise the fate of natural and synthetic polymers, and 2) exposure assessment tools for polymers having a wide range of use, including benefits in durable application. Figure 2 summarises current gaps.

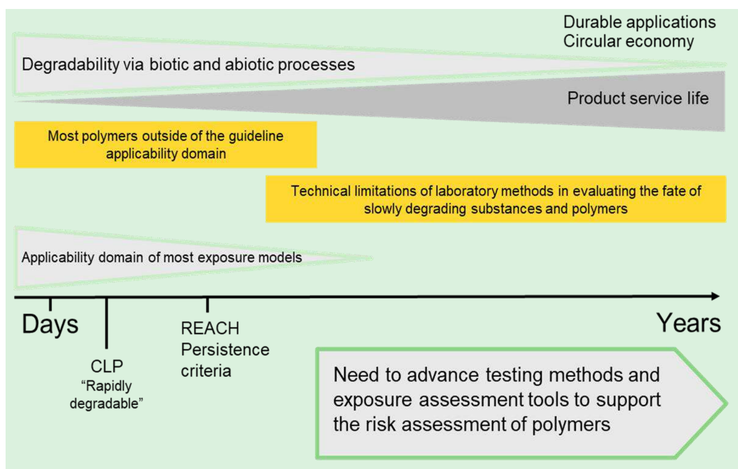


Figure 2: Current and future technical challenges in characterising exposure to polymers

The assessment of degradation would classify wood as persistent, which illustrates the lack of applicability of assessment methods and criteria.

Several research projects focus on the evaluation of methods and criteria to high molecular weight substances.

- ❑ LRI ECO64 focuses on evaluating degradation testing approaches.
- ❑ Screening methods see poster 3.07.P-Th301

Traditional metrics such as Kow, Koc used to inform exposure models are not relevant for most polymers.

- ❑ Research proposed to advance science on polymer distribution - LRI ECO 63

CONCLUSIONS

The objective of expanding the registration of polymers, for example in the REACH regulation, raises questions on the **type of information** required to purposefully support the safety assessment of polymers requiring registration (PRR), as produced.

Adequate scoping and improved characterisation of bioavailability are key priorities to support targeted generation of testing information.

Within the field of environmental fate assessment, there is an opportunity to **define degradability expectation for different types of polymers** considering the sector of use: rapid biodegradability is desirable for down-the-drain uses, while long-term resistance is desirable for applications where durability is key.

The ECETOC Polymers Task Force **welcomes comments and encourages multi-stakeholder scientific discussion**.

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ECETOC Polymers Task Force publications:

ECETOC. 2019. **TR 133-1:** The ECETOC conceptual framework for polymer risk assessment (CF4Polymers). May 2019.

ECETOC. 2020. **TR 133-2:** The applicability of analytical tools, test methods and models for polymer risk assessment. Mar 2020.

ECETOC. 2021. **TR 133-3:** Case Studies Putting the CF4Polymers into Practice. Sep 2021.

Otte JC, Hollnagel HM, et al. 2023. Three-tiered approach for standard information requirements for polymers requiring registration under REACH. Regul Toxicol Pharmacol.;144:105495.