

A proposal for a three-tiered approach for Standard Information **Requirements for Polymers Requiring Registration under REACH**

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Introduction

Polymers are a divers set of chemistries, part of our daily life and provide a multitude of technical functionalities. As part of the EU Commission's Chemical Strategy for Sustainability (CSS), there are efforts to develop environmental and human health standard information requirements (SIRs) for man-made polymers requiring registration (PRR) under the revised Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) Regulation. By their nature, polymers are different to small and discrete molecules and conventional risk assessment approaches cannot be applied to most polymers. To address this, the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) Polymers Task Force has published a trilogy of technical reports (TRs) to enable polymer risk assessment (see QR) codes below): (1) Conceptual framework for polymer risk assessment; (2) review of standard analytical tools and test methods and their applicability to polymers; (3) seven case studies.

With the current communication, we provide a conceptual three-tiered proposal to generate data to assess individual and groups of polymers requiring registration (PRR). Groups of polymers can be obtained following the proposal made in TR 133-3.

Overview on Proposed Scheme for PRR Information Requirements IDENTIFICATION GROUPING SUBSTANCE INFORMATION REQUIREMENTS Use/exposure/ Risk Tier 2 Tier 3 Tier 1 bioavailability/env Grouping of assessment distribution polymers following "hazard similarity" Molecular weight threshold Bioavailability (M_n 1000 Da)/PBK/ 3D in vitro Identify polymers Three-criteria that are subject approach R In case of potential risk: In vitro local toxicity Systemic toxicity to registration Iterative process (skin and eye irritation and skin In vivo repeated-dose of higher tier studies on Human endpoint of concern Initial groups toxicity screening sensitisation) (organ toxicity, DART) repeated-dose or DART) validated and to *In vitro* mutagenicity be refined with hazard data Bioaccumulation/clearance Bioaccumulation (in vivo Aquatic toxicity - acute (QSAR, (in vitro) relevant exposure route) daphnia, algae/lemna inhibition, fish *in vitro*, if required) Aquatic toxicity – chronic Aquatic toxicity ---invertebrate or acute fish - chronic fish Terrestrial toxicity – acute Additional information on Terrestrial toxicity – acute ----Environment (earthworm) terrestrial toxicity and/or chronic earthworm if direct release to soil Additional information on Sediment toxicity - acute (

The proposed Information Requirements follow a 3tiered testing scheme, assessing physico-chemical properties, systemic bioavailability, human health toxicity, environmental fate, and ecotoxicity. Tier 1 of this approach is entirely based on *in silico* and *in* vitro methods (and short-term aquatic toxicity testing using invertebrates). The decisions for further studies and the next tier are based on considerations of a polymer's properties and effects, combined with systemic bioavailability estimates, and use and exposure considerations. This results in a flow of experiments guided by defined criteria rather than a predefined unspecific lists of tests.





Figure 2: Tiered Approach for Assessment of Systemic Bioavailability as integral part of Tier 1, with focus on human health.



Figure 1: Overview of proposed three-tiered scheme for PRR Information Requirements

Pre-evaluated data or standard for all polymers	State of the substance at 20 °C / 101,3 kPa via visual inspection		Phys-chem data produced during PRR assessment		
Tier 1 Selected phys-chem tests for specific polymers based on simple decision criteria	Only for liquid polymers (at 20 °C), low molecular weight oligomers Only for liquid polymers (at 20 °C),	Boiling point	Only for solid, granular, and water- insoluble products; aqueous dispersions Only if surface active structural elements		Granulometry Surface tension /
	low molecular weight oligomers Only if polar structural elements are present	Water solubility via TOC	are present (e.g. polar/apolar blocks) Depending on chemical composition and particle size		surface activity Adsorption / desorption
	Only for polymers with labile functional groups (e.g. esters)	Hydrolysis	Use established waiving criteria Flash point, flammability, explosiveness, spontaneous combustibility, oxidizing properties		
Additional Tests (to be explored)	Use as alternative method for adsorption / desorption	Hetero- agglomeration	Only for water-soluble polymers with charged or surface-active functional groups		Interaction with lipid membranes
Tier 2 and 3 Further testing triggered by toxicological effects	Only if aquatic toxicological effects observed.	Relative density	Only if aquatic toxicological effects observed. Identification of leachates		Detailed water solubility tests
	Only if aquatic toxicological effects observed. Test in relevant media.	Dispersion stability	Only if toxicological effects observed and hydrolysis proven in Tier 1. Identification of selected degradation products		Detailed hydrolysis tests

Figure 3: Overview on physico-chemical data and appropriate trigger and dependencies for all Tiers, combining established and exploratory test methods. The proposed tiered testing scheme offers the advantage of targeted testing:

- I. Only relevant information is generated in higher tiers as determined by the data of the lower tier;
- II. Compared to predefined, standard requirements, this will generate all the relevant information which may have been missed by a pre-defined, general trigger, such as production volume;
- III. At the same time, the generation of information not relevant to the risk assessment is not required, including vertebrate animal tests. The proposed tiered testing scheme allows for risk assessments based on non-vertebrate animal data, if this is sufficient for a reliable assessment.

CONCLUSIONS/NEXT STEPS

- The proposed approach aims at an optimum balance of different aspects: a tiered approach with no vertebrate animal testing at Tier 1, followed by justified, limited and targeted vertebrate testing in higher tiers considering systemic bioavailability estimates, use and exposure considerations and material properties first.
- The proposed scheme provides a basis for modern and considerate data generation for the next decade as well as an adequate level of protection of humans \checkmark and the environment. Based on discussion with regulators and stakeholders, including animal welfare organizations, and application in case studies, the approach will be further refined.

Further Work by ECETOC on Polymer Risk Assessment:



ECETOC. 2019. TR133-1: The ECETOC conceptual framework for polymer risk assessment (CF4Polymers). May 2019.





ECETOC. 2021. TR 133-3: Case Studies Putting ECETOC Conceptual the Framework for Polymer Risk Assessment (CF4Polymers) into Practice. September 2021.

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