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

The proposed Information Requirements follow a 3-tiered 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.
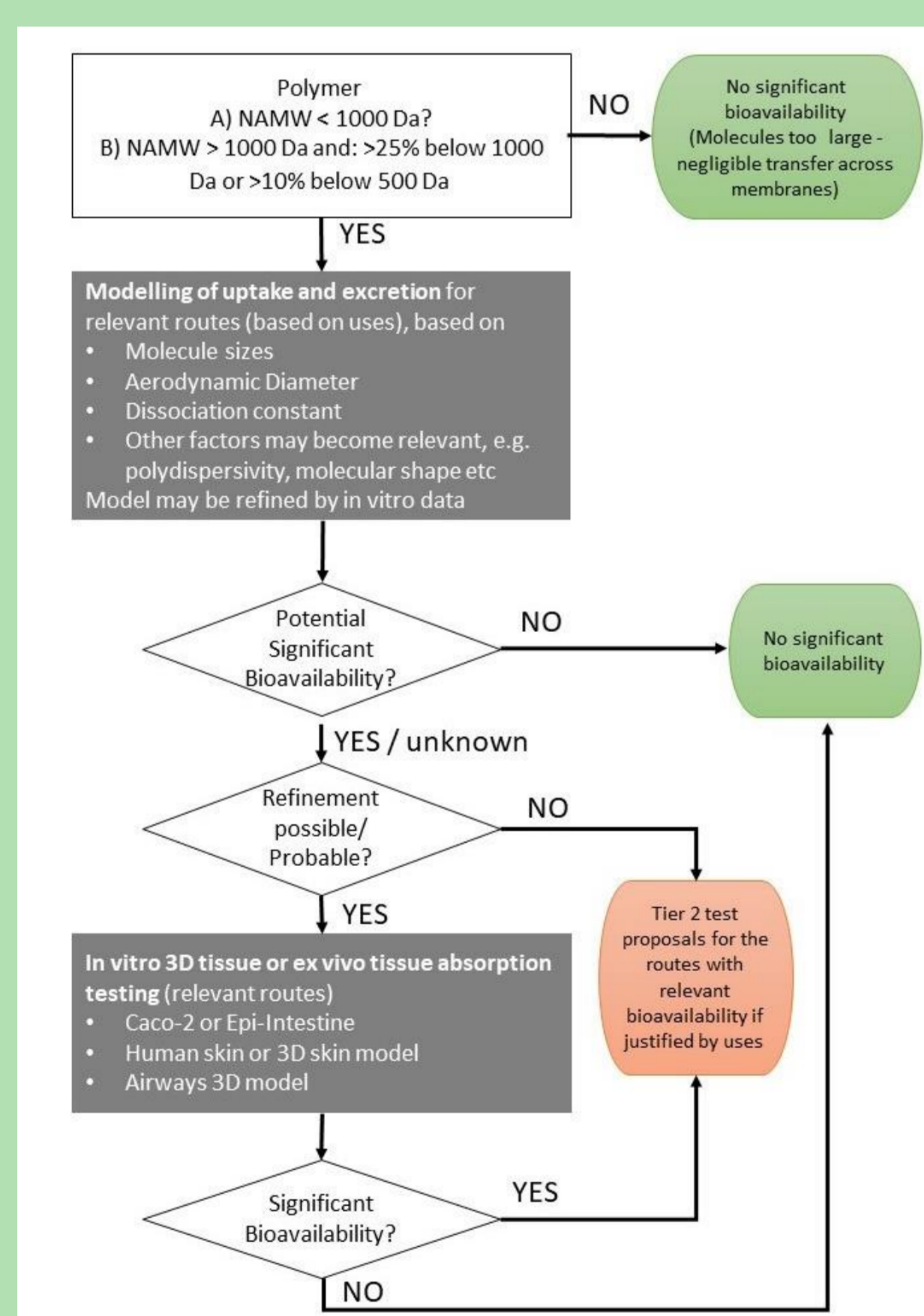

Figure 1: Overview of proposed three-tiered scheme for PRR Information Requirements

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

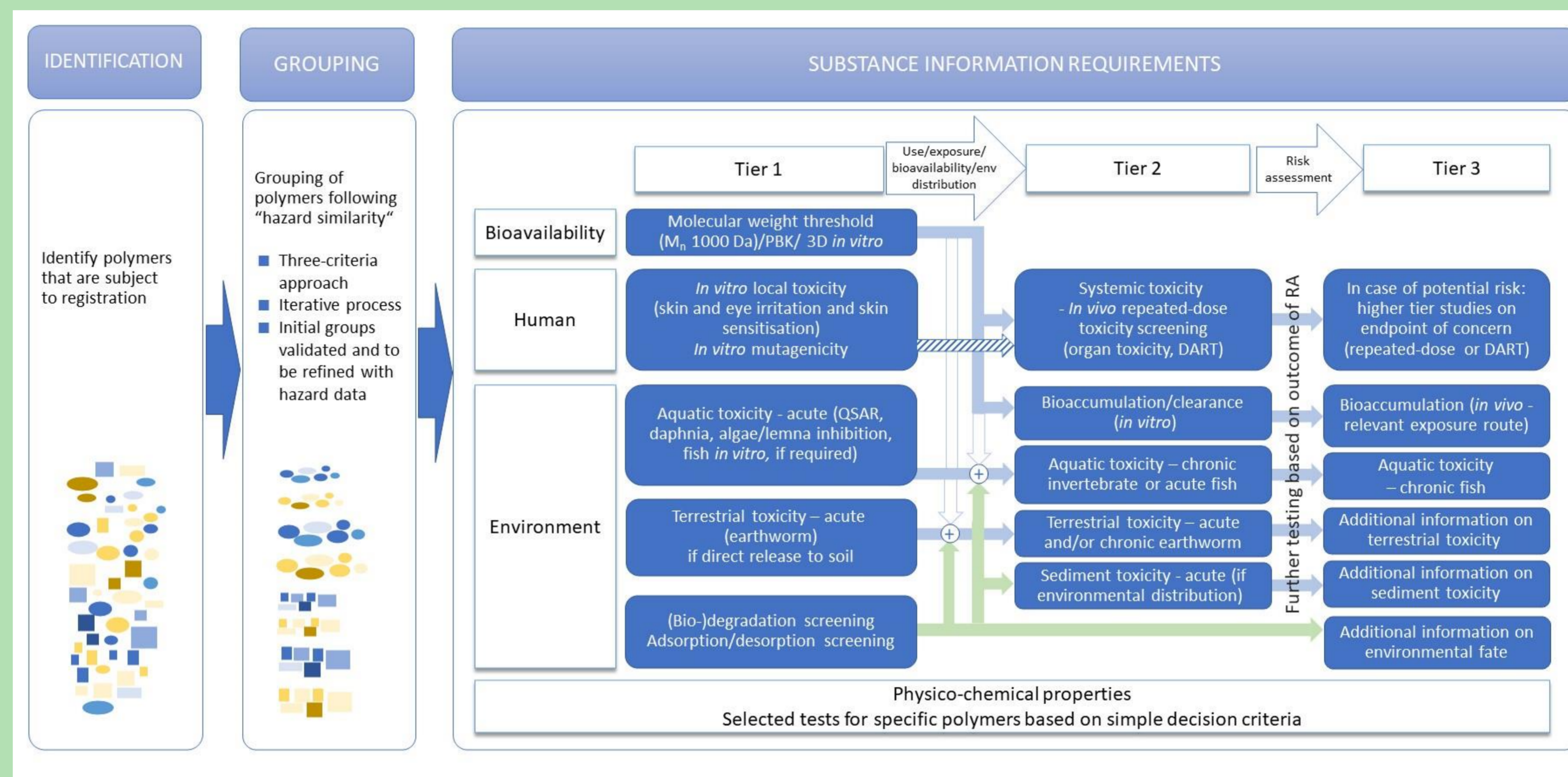**Figure 3:** Overview on physico-chemical data and appropriate trigger and dependencies for all Tiers, combining established and exploratory test methods.

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

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

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