

The ECETOC Conceptual Framework for Polymer Risk Assessment (CF4Polymers) and Considerations on applicability of standard tools, test methods and models

ABSTRACT

Legislation is being developed within the EU to require environmental and human safety data for polymers. In view of the broad physico-chemical diversity of polymers, it is clear from a testing and assessment point-of-view there is no 'one size fits all' set of rules. The ECETOC Polymer Task Force has reviewed the state of global polymer regulation and the applicability of existing regulatory physico-chemical, ecological and toxicological test methods, tools and models for polymer hazard and risk assessment. In three Technical Reports (the ECETOC TR 133 series), the Task Force has summarized the state-of-the-art polymer regulation and testing. Importantly, the Task Force has proposed the *ECETOC Conceptual Framework for Polymer Risk Assessment (CF4Polymers)* that includes eight steps for aspects to consider in risk assessment and intelligent testing of polymers. The final (ongoing) part of the Task Force work aims to evaluate the CF4Polymers by seven case studies reflecting real-life examples of polymer risk assessment. Due to the wide range of polymer types and properties, there is no 'one size fits all' set of rules applicable to this diverse set of materials, leaving regulators and industry to apply rules on a case-by-case basis. Since the CF4Polymers has been designed flexibly and it is not prescriptive, its consideration is expected to support polymer risk assessment both during product stewardship and regulatory assessments.

INTRODUCTION and WORK TO DATE

In the EU, polymers are not currently subject to the same regulatory testing requirements as chemicals. In this regard, polymers are complex mixtures, in part defined by the variation in molecular weight, with their properties determined by physical form as well as chemical structure. The applicability of standard test methods and guidance for polymer hazard and risk assessment is not always clear.

When considering the safe use of a polymer, assessors need to consider aspects not relevant to non-polymeric substances and will need to consider on a case-by-case basis whether available tests are applicable to the specificities of the polymer. Aspects such as molecular weight range, swellability, solubility, cationicity and physical entanglement among other specific properties could be important.

CF4Polymers [TR 133-1]

Step 1: problem formulation

RA scope & protection goal definition

Step 2: polymer identification

Step 3: polymer component strategy

Step 4: grouping approach evaluation

Step 5: Determination of exposure scenarios

First part of exposure assessment

Step 6: Exposure characterisation

Second part of exposure assessment

Step 7: Hazard assessment

Hazard identification & characterisation

Step 8: risk characterisation

The Conceptual Framework for Polymer Risk Assessment (CF4Polymers) [TR 133-1] (ECETOC, 2019)

The CF4Polymers provides guiding principles for assessment of polymers with the aim of supporting regulators and assessors in developing state-of-the-art testing strategies and risk assessments of a broad range of polymers. The sequence of steps can be adapted as necessary depending on the risk assessment needs and/or data availability.

The Applicability of Analytical Tools, Test Methods and Models for Polymer Risk Assessment [TR 133-2] (ECETOC, 2020)

Provides a detailed review of the applicability of standard analytical tools, *in vitro* and *in vivo* test methods and *in silico* models to assess the physico-chemical, fate, exposure-related, ecotoxicological, and toxicological properties of polymers.

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ONGOING ACTIVITY – CASE STUDIES [TR 133-3]

Seven case studies have been identified to evaluate the framework of the CF4Polymers with respect to polymer grouping & risk assessment and to broaden understanding of the applicability & technical limitations of current tools, test methods and models (ECETOC, 2021).

Case Study	Polymer component(s) considered	Intended use(s) covered
CS1 – Polycarboxylates, polyacrylates, polymethacrylates	Polymeric substances, NIAS & IAS	Consumer use Cleaning products, hair fixatives, acrylic paints, coating products, waterless inks
CS2 – Cationic polymers: PQ-6 and PQ-10	Polymeric substances	Professional use Flocculant in STP Consumer use Personal care
CS3 – Polyolefins: Polypropylene	LMW components, NIAS & IAS	Consumer use Food contact materials
CS4 – BADGE polymers	Monomer, oligomer, LMW & HMW polymer	Industrial use Powder & solvent-based coatings
CS5 – Polyetherols	Polymeric substances	Industrial use Further reaction to give foams
CS6 – Surfactant polymers: Alkyl ethoxylates	Polymeric substances	Consumer use Laundry detergent Industrial use Water-based dispersions, textiles
CS7 – Polyurethanes & polyureas	Polymeric substance (as part of an end product containing active substances)	Professional use Microencapsulation, paint application

Key: **BADGE** - Bisphenol-A diglycidylether; **IAS** - Intentionally added substance; **LMW** - Low molecular weight; **HMW** - High molecular weight; **NIAS** - Non-intentionally added substance; **PQ** - Polyquaternium; **STP** - Sewage treatment plant

References

- ECETOC. 2019. The ECETOC conceptual framework for polymer risk assessment (CF4Polymers). May 2019. ECETOC TR No. 133-1.
- ECETOC. 2020. The applicability of analytical tools, test methods and models for polymer risk assessment. March 2020. ECETOC TR No. 133-2.
- ECETOC. 2021. Case studies putting the CF4Polymers in practice. Planned for Q3/2021. ECETOC TR No. 133-3.