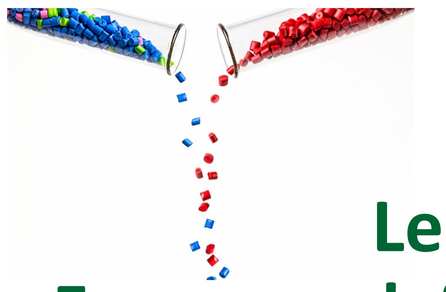

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Learnings from Case Studies Putting the ECETOC Conceptual Framework for Polymer Risk Assessment (CF4Polymers) into Practice

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ABSTRACT

An ECETOC Task Force entitled **'Assessing the human health and environmental safety of polymers'** has been working on the topic of polymer safety assessment since January 2018, and has published three reports (ECETOC, 2019; ECETOC, 2020; ECETOC, 2021). In the third report (ECETOC, 2021) the ECETOC Task Force developed a series of case studies for a range of polymer types and applications. The case studies evaluated: (1) the usefulness of the CF4Polymers presented in ECETOC TR No. 133-1 (ECETOC, 2019) for the safety assessment of different types of polymers; and (2) the information on the applicability of tools, methods and models for the hazard and risk assessment of polymers presented in ECETOC TR No. 133-2 (ECETOC, 2020). The case studies were not intended to document a comprehensive risk assessment for any specific polymer. Rather, publicly available data and unpublished company data were collated and assigned to the eight steps of the CF4Polymers to evaluate the scientific usefulness and comprehensiveness of the process through use of concrete examples.

The case studies covered different types of polymers and/or different types of intended uses, and comprised the following: Case Study 1 – polycarboxylates, polyacrylates and polymethacrylates; Case Study 2 – cationic polymers; Case Study 3 – polyolefins; Case Study 4 – solid bisphenol-A diglycidylether (BADGE) polymers (solid BADGE epoxy resins); Case Study 5 - polyetherols (PEOLs; or polyether polyols); Case Study 6 – surfactant polymers; Case Study 7 – selected professional and consumer uses of polyurethane and polyurea.

Overall, the case studies confirmed the value of the CF4Polymers as a consistent framework for risk assessment of polymers whilst providing flexibility for applicability to different types of polymer as there is no "one size fits all" approach, thus highlighting the need for critical case-by-case assessments. Learnings from the case studies are being leveraged by industry in the context to the CARACAL Subgroup for Polymers to help design a polymer registration framework for future incorporation in REACH 2.0.

SCOPE

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

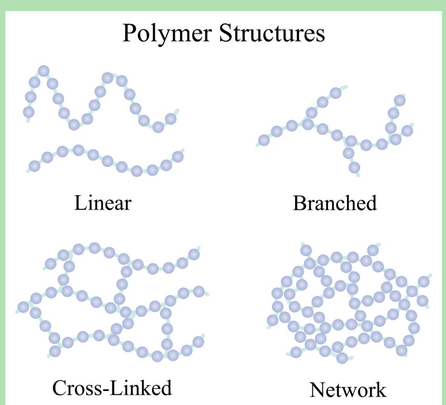

Figure 1 : Some examples of the seemingly infinite diversity in 1-, 2- and 3-D structure of polymers

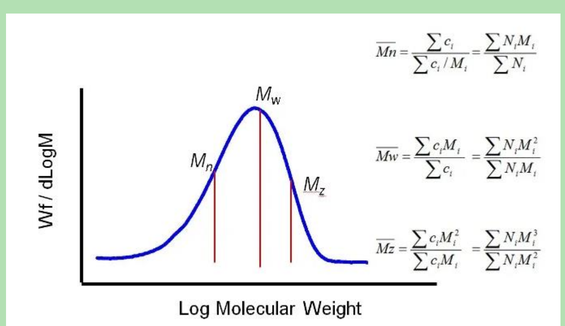

Figure 2: Average molecular weight (MW) of a polymer can be defined in different ways. The ratio of Mw/Mn is called 'polydispersity'.
(https://www.azom.com/article.aspx?ArticleID=12255)

LEARNINGS

- ✓ Polymers represent a large and broad aspect of the chemical space. This necessitates **a careful characterisation of the materials** as well as their **complex uses,** while taking into account that some **polymer products can change form during different life cycle stages.** Many polymers types are **complex mixtures** where IAS and NIAS contribute to, and in most cases are responsible for, expressed hazard properties. This can cause **significant analytical and testing challenges.**
- ✓ Generally, the case studies have confirmed the value of the eight steps of the CF4Polymers for the hazard and risk assessment as applied to a diverse spectrum of polymers. There is **no 'one size fits all' hazard and risk assessment process of polymers.**
- ✓ In the same vein, the case studies have demonstrated that there is **no 'one-size-fits-all' approach to determine if any given tool, test method or model is applicable to all polymers**. The report does highlight the need for critical, case-by-case, assessment of the suitability and relevance of models, methods and concepts by qualified and experienced professionals involved in the assessment of products containing polymers.
- ✓ The case studies have also shed some light on the conditions for grouping of polymers for the purpose of registration under REACH 2.0. **Polymer grouping requires consideration of what can be regarded as 'sufficiently similar' for the purpose of hazard assessment**, and/or of which grouping criteria are fit-for-purpose from a safety perspective. Such criteria may vary between different types of polymers.
- ✓ Consistently, case studies 4, 5 and 6 showed that application of the grouping approach requires sufficient hazard data density for the key endpoint(s) and benefits from a continuum of properties across the given group of polymers. **Whenever grouping of polymers is performed, it is necessary to have an understanding of key hazards (if any),** and not only their structural and physico- chemical properties.
- ✓ **Exposure characterisation can be very complex for polymers** - on account of their diversity and wide range of uses. Nonetheless, these steps are **not inherently different** from the general approach for exposure assessment undertaken for any non-polymeric substance.
- ✓ Hazard testing should not be conducted if it does not contribute meaningful data for hazard and risk assessment purposes. For example, **if the polymer is unlikely to become systemically bioavailable, the relevance of systemic toxicity tests is questionable**.

CONCLUSIONS/NEXT STEPS

- ✓ Polymer registration, testing and regulatory risk assessment cannot be based on a simple copy/paste from the current REACH approach for non-polymeric industrial chemicals. Polymers have unique properties and requirements that demand careful consideration of the materials under assessment. A one-size-fits-all approach is therefore inappropriate.
- ✓ Some regulatory assessment endpoints (cf. REACH Annexes VII-X) are not directly applicable to polymers - modified testing methods may be required or a different testing logic.
- ✓ The ECETOC Task Force is contributing to the current CARACAL discussions on polymers requiring registration (PRR), by developing specific guidance on standard information requirements (SIRs), choice of testing methods and sample preparation (e.g. extraction testing).

ECETOC. 2019. The ECETOC conceptual framework for polymer risk assessment (CF4Polymers). May 2019. Technical Report No. 133-1.

ECETOC. 2020. The applicability of analytical tools, test methods and models for polymer risk assessment. March 2020. Technical Report No. 133-2.

ECETOC. 2021. Case Studies Putting the ECETOC Conceptual Framework for Polymer Risk Assessment (CF4Polymers) into Practice. September 2021. Technical Report No. 133-3.

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