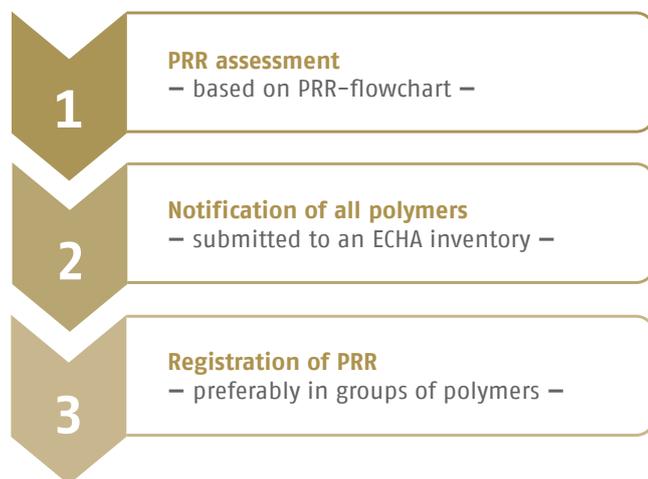


**THINK GLOBALLY – ACT LOCALLY**

REGISTRATION OF POLYMERS IN THE EU UNDER REACH

The polymers on the European market are currently exempted from Titles II (Registration) and VI (Evaluation) of REACH according to Article 2(9). However, they are subject to the provisions of Titles VII (Authorisation) and VIII (Restrictions). The European Commission has been looking for a practicable and cost-effective way to include certain polymers into registration under REACH since 2012. The Commission published the concept of "polymers requiring registration" (PRR) in 2019, and since then the Commission and the stakeholders (certain non-EU countries, EU-member state authorities, industry and expert groups) have worked together to establish a feasible REACH revision for polymer registration.

The foreseen polymer registration process currently has three designated stages:



PRR assessment

Under this proposed process, **each EU manufacturer or importer** of polymers should perform their own assessment of their polymer portfolio against the PRR criteria. The currently accepted criteria for the PRR decision are related to the chemistry of the polymers (molar mass, polydispersity, monomers, reagents, functional groups), to their physico-chemical properties (e.g. surface activity) and to the hazards posed (to mammals and/or the environment) by polymers or by their decomposition products. Although the final decision of the European Commission is still pending, the final PRR criteria is unlikely to change significantly. The outcome of the PRR assessment for a specific polymer may be either **PRR, non-PRR or precursor under strictly controlled conditions**.

Notification of polymers

All the polymers on the EU market should be notified to ECHA and included in a polymer registry, regardless of the tonnage. The purpose of this action is to allow the EU authorities to have an overall view on marketed polymers and their properties, and/or their hazards. For the time being the information required for the notification would include the following:

- name(s) and identifiers (e.g. CAS number)
- molar mass(es) and polydispersity index
- chemical composition (monomers, reactants, functional groups, stabilisers, impurities, unreacted monomers)
- structural information (repeating units, backbone, branching, SMILES notation)
- the PRR assessment
- other PRR assessment criteria (precursor controlled condition, functional groups equivalent weight, content of different oligomeric species, ionicity, surface activity, degradation products)
- physico-chemical data (physical state, solubility, viscosity, log Kow, hydrophobicity)
- any other relevant data on toxicity and ecotoxicity, environmental fate, bioavailability

Registration of polymers

In the last stage, all polymers identified as PRR should be registered under REACH. The registration requirements of standard substances also apply to polymers (e.g. tiered by tonnage bands), but ECHA also proposed a supplementary categorisation based on the molar mass:

- type 1 (Mn under 1,000 Da): standard requirements, similar to those of standards substances
- type 2 (Mn between 1,000 and 10,000 Da): reduced requirements, still under discussion
- type 3 (Mn over 10,000 Da): even fewer requirements, these polymers are considered to be less hazardous due to lower bioavailability



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REGISTRATION OF POLYMERS IN THE EU UNDER REACH

In order to reduce the amount of work and studies, the polymers can be grouped based on their overall hazard similarity ie. they are assessed on the basis of their chemical similarity, physico-chemical similarity and hazard similarity. The principle of "one substance, one registration" may be changed for many polymers to "one group of polymers, one registration", with a common set of information obtained from a limited number of test substances.

Actual status

In ECHA's view the polymer industry is responsible for PRR assessments, notification of polymers and grouping of similar polymers into one registration. Furthermore, the registrants themselves should decide which approach should be used for the preparation of a registration dossier for a group of polymers. However, building the **Polymer Information Exchange Fora (PIEF)** for joint registrations will be a very sensitive process since most of the information required for notification and registration is currently treated as confidential business information by manufacturers or importers.

Future expectations

The European Commission will come up with a proposal for the REACH revision by the end of 2023. The European Parliament decision might take about three years. The new regulation may come into force in 2026, mandatory notification in 2027–2029 and actual PRR registration in 2030 at the earliest. By then, ECHA should have established clear criteria for PRR, as well for the grouping of PRRs.

Even though these timings seem a long way off, the polymer industry should consider preparing for it now, since the amount of information required, combined with the huge number of polymers on the market (estimated to be between 100,000 and 400,000), make the deadlines rather tight. Once the REACH revision comes into force, the PRR assessments and the notifications will be needed promptly. Hence, at the very least, the collection of the necessary information and portfolio check should be performed without undue delay.

Service range – how we can support you

- Check of polymer status of products in accordance with the corresponding definition/rules in the EU and worldwide
- Evaluation of analytical data to identify and characterise polymers
- Evaluation of polymer properties
- Study concept management and study monitoring for physico-chemical, toxicity and ecotoxicity studies with polymers
- Hazard identification, classification & labelling (C&L) of polymers and classification in German Water Hazard Classes (Wassergefährdungsklassen, (WGK))
- Preparation of Safety Data Sheets for polymers
- Performing the assessment PRR versus non-PRR, as well as PLC versus non-PLC for non-EU markets
- Evaluation of grouping approach (e.g. based on chemistry, physico-chemical properties, toxicological and ecotoxicological profile)
- Development of risk assessment methods for polymers
- Preparation or update of monomer registration dossiers
- Preparation of submission dossiers for polymer registration and/or notifications (region-/country-specific)
- Pre-support on future Polymer Requiring Registration (PRR) registrations under EU REACH
- Monitoring of registration/notification requirements and other regulatory requirements on polymers in different countries
- Regulatory and technical support on microplastics

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