Action 5: Avoid additional requirements for polymers – develop a holistic strategy first

The Issue?

Polymers are long-chain substances made from small molecules called monomers, varying in structure and properties from synthetic plastics to natural biopolymers like starch. Under the REACH Regulation, they are exempt from registration due to their stability and lower risk, but they remain subject to other measures like restrictions, authorisations, and hazard classification under the Classification, Labelling and Packaging of substances and mixtures (CLP Regulation), with safety information shared through safety data sheets.

The current challenge with polymers

- Polymers are incredibly complex compounds substantially different from small molecules. Current REACH registration requirements are designed for small molecules like substances. Therefore they cannot simply be re-used for polymers. Existing testing methods to generate data on substance properties and grouping approaches are neither suitable nor adapted for polymers.
- There are a few hundreds of thousands polymers on the EU market. Additional legislative requirements for polymers would add significant burden to agencies and industry, while potentially jeopardising the goals of the EU Roadmap to phase out animal testing by introducing new testing requirements.
- While polymers are exempt from REACH registration, hazards and risks associated with them are already regulated in areas that require special scrutiny under the current EU regulatory framework for chemicals. Notably, all polymers are subject to the CLP Regulation and hence their hazards are also assessed/evaluated. The hazard information is then shared in the supply chain through safety data sheets. The Annex below shows various European legislative tools already addressing specific aspects of polymers.

Challenges to include polymers under REACH registration requirements

While polymers were not originally foreseen for registration, Article 138(2) gives the European Commission the possibility to present legislative proposals "as soon as a practicable and cost-effective way of selecting polymers for registration on the basis of sound technical and valid scientific criteria can be established". In our view, this is not the current situation due to several factors:

- The number of polymers in the EU Market is substantial, estimated to be between 200,000 to 400,000, compared to the current 23,000 substances registered in REACH.
- Standardised testing methods have not yet been defined and adapted to polymers, and method development and assessment for regulatory fitness will require resources and time, including expertise on New Approach Methodologies (NAMs) in the effort to phase out unnecessary animal testing. To our knowledge, none of the currently available non-animal methods have been validated with polymers.
- The number of existing Contract Research Organisations (CROs) and laboratory capacity is insufficient to deal with the testing requirements for such a large number of polymers.
- Significant additional resources will be required for the European Chemicals Agency (ECHA) to deal with polymers, as the number of companies that need to register their polymers with ECHA, will expand significantly due to the broad use of such materials. Currently, Agencies

and industry are already struggling to implement and enforce the REACH processes for 23,000 substances.

- SMEs would face great difficulties to gather and submit all the new obligations, leading to further administrative burden, lack of competitiveness of European companies and significant costs. [1]

Even if the European Commission were to move forward with a notification-only approach, the exact number of notifications to be submitted to ECHA would be significantly higher than the number of existing polymers, as the same polymer might be notified several times by different companies. This would lead to a massive bottleneck of notifications in the ECHA system.

The Solution

First create a coherent holistic strategy with a problem definition

Before taking any action on polymers, an overall strategy to streamline any regulatory approach is needed.

Recently agreed and proposed legislation already addresses polymers and their applications, as listed in the Annex. It is important to now identify if there are still any gaps, define the problem, if any, and then see if there is a need to come forward with any requirements under REACH, and if so, which ones. This approach would be aligned with the vision for simplification and burden reduction.

[1] Upon an access to documents request by the NGOs, the European Commission released a redacted Impact Assessment. The document mentions a notification cost per dossier ranging from 750 EUR to 4000 EUR (depending on the notification requirements). Assuming that for each polymer there would be at least 5 notifications, the cost of notification would be in billions.

Annexes

Background

What are polymers? Polymers ("poly": many, "meros": part) are long chain substances that are built from small reactive molecules called monomers which bond to each other through chemical reactions, called polymerisation. Polymers can show large differences such as chain length, chemistry and three-dimensional structure that lead to a variety of physical and chemical properties. They range from synthetic such as polyethylene, polystyrene,... - to natural biopolymers such as starch, cellulose, lignin which results in a significant number of existing polymers on the market. They are often tailor-made for a specific application (uses can range from a lunch box formed by plastic polymers to cleaning detergents which contain soluble polymers to improve the performance) and as such are unique in offering this flexibility.

Current status of polymers under REACH: When the REACH Regulation was adopted, polymers were exempted from registration. Polymers were regarded as lower concern than monomer substances due to their specific properties such as their high molecular weight and stability (for instance, polymers are often so big that they will not be taken up into organisms in case of exposure).

However, polymers are not exempted from other regulatory measures such as restriction and authorisation (one example of such a measure is the current REACH Restriction for synthetic polymer microparticles, which restricts the use of specific types and forms of polymers in products placed on the European market). In addition, all polymers are subject to CLP and hence their hazards are also assessed/evaluated. The hazard information is then shared in the supply chain through safety data sheets.

Different European legislative tools already address specific aspects of polymers

The table below illustrates some examples of where polymer types or uses have been addressed and which provisions were included.

Legislation	Description	Key Provisions
REACH Regulation	Addresses the registration, evaluation, authorisation, and restriction of chemicals, including microplastics. This regulation aims to ensure that chemicals used in products do not harm human health or the environment.	- Restrictions on the use of synthetic polymer microparticles in products - Registration of monomers and non-monomer reactants that are added during polymer production (substances that are added to a polymer for the purpose of adjusting or improving the appearance and/or the physico-chemical properties of the polymeric material.
Classification, Labelling and Packaging of Chemicals Regulation (CLP)	Revised in 2024, It sets out common rules for consumers and workers to enable them to make informed decisions when purchasing or using dangerous products and incorporates the classification criteria and labelling rules agreed at UN level, the Globally Harmonized System of Classification and Labelling of Chemical (GHS) .	Polymers are subject to all CLP rules
Single-Use Plastics Directive (SUPD)	Adopted in 2019, this Directive aims to reduce the	- Ban on specific single-use plastic items (e.g., cutlery, plates, straws).

	environmental impact of certain plastic products, particularly those contributing to marine litter.	- Consumption reduction measures. - Marking requirements for products. - Mandatory recycled content in plastic products. - Separate collection and clean-up costs for litter.
Packaging and Packaging Waste Regulation (PPWR)	The Regulation focuses on addressing its predecessor's shortcomings in reducing packaging (of not just plastic) pollution. It does so by establishing recyclability as a license to operate from the design stage.	- Establishes recyclability for every material used to make packaging by mandating a Design for Recycling guideline and Recyclability at scale. - Mandates recycled content targets for the plastic part of packaging. - Mandates composability for certain applications. - Mandates reusability for transport packaging. - Reaffirms previous recycling targets set per material. - Sets further bans on single-use applications.
Food Contact for Polymers (EU) No 10/2011	Regulation on plastic materials and articles intended to come into contact with food that lays down detailed compositional requirements. Guidances provided by EFSA.	- Lists authorised substances in polymers (monomers, additives, polymer production aids etc.). - Also lists specific migration limits to ensure safety.
Drinking Water Directive (EU) 2020/2184	Directive setting quality standards, monitoring requirements and provisions for materials in contact with drinking water.	- Quality standards for drinking water to protect human health. - Regular monitoring and reporting of water quality by Member States - Promotes Transparency in water quality information.

The table above shows that different regulations already tackle several polymer types or uses, including reporting requirements and setting targets on recyclable contents. In many cases, we see a repetition of information requirements for the same polymers. One example is the reporting requirements set up in the REACH Restriction on synthetic polymer microparticles and the upcoming Regulation on plastic pellet loss. These duplications or contradictory requirements bring excessive burden to companies, EU and National Competent Authorities who will have to enforce these requirements. For this reason and to avoid such contradictions, a holistic strategy is needed.