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Comments on the Registration of Polymers

Huge amounts of polymers are being produced, imported and used in Europe. The plastic converter demand for the main types of polymers raised to over 51 million tons during 2017 and this represents only part of the total demand[1].
Polymers are the basic ingredients of a very wide range of materials and products (plastics, resins, paints etc.) to which people and the environment are widely exposed every day and will increasingly be exposed in the future as plastics and other polymeric products continue to build up in maritime and ocean ecosystems and production is predicted to continuously grow.

Despite this wide and growing exposure and rising concerns about their impact on health and the environment, there is no obligation to register polymers under REACH - and therefore provide information on their health and environmental hazards. This difference of treatment between polymers and monomers is due to an exception introduced in the original text of the REACH Regulation upon its adoption in 2007. At the time, polymers were considered to be less hazardous than monomers. Registration of polymers was also considered too complicated due to the high number of different polymer chains. The solution to the problem was simply postponed, as often in chemical regulation, by a REACH provision giving to the Commission the power to expand the registration obligations to polymers.

According to REACH (Art 138(2) the Commission may:
"present legislative proposals as soon as a practicable and cost-efficient way of selecting polymers for registration on the basis of sound technical and valid scientific criteria can be established, and after publishing a report on the risks posed by polymers in comparison with other substances; and the need, if any, to register certain types of polymer, taking account of competitiveness and innovation on the one hand and the protection of human health and the environment on the other. "

Two studies on the issue have already been developed for the Commission[2]. The Consultancies Wood and PFA, have been now contracted for a study on the development of criteria to identify and group Polymers Requiring Registration under REACH and their impact assessment.

This paper presents NGO's views on the registration of polymers.

GENERAL ISSUES

Registration cannot wait any longer

12 years have passed since the approval of REACH and still no information on the hazards of polymers has been made public through registration. Given the enormous and increasing amounts of polymers to which people and the environment are exposed to daily, increasing knowledge and transparency on the risks posed by polymers cannot be delayed any longer. Industry claims to have data showing the safety of polymers but do not share it due to confidentiality claims[3]. Therefore, it can be concluded that registration of polymers should not be a problem due to data availability and must not be delayed any longer.

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1 Plastics Europe, 2019. Plastics – the Facts 2018. An analysis of European plastics production, demand and waste data. https://www.plasticseurope.org/application/files/6315/4510/9658/Plastics_the_facts_2018_AF_web.pdf

2 European Commission, 2012. Review of REACH with regard to the registration requirements on polymers. http://ec.europa.eu/environment/chemicals/reach/pdf/studies_review2012/report_study10.pdf
European Commission, 2015. Technical assistance related to the review of REACH with regard to the registration requirements on polymers. Final report.
http://ec.europa.eu/environment/chemicals/reach/pdf/FINAL%20REPORT%20POLYMER%20SI671025.pdf

3 Oral claims during the workshop "Scientific and technical support for the development of criteria to identify and group Polymers Requiring Registration under REACH and their impact assessment", Brussels, 21 and 22 May 2019

The registration of polymers should follow the same principles of other chemicals

Registration is the bedrock of regulatory action on chemicals under REACH as it is the process that should ensure the generation and sharing of information on the hazardous properties of chemicals, their uses and the human and environmental exposure they result in. Without this information it is not possible to ensure safe management of polymers.

REACH Regulation is based on the **prevention principle**, shifts the **burden of proof** on the safety/risks of chemicals to industry and introduces the principle of **"no data no market"**: chemicals for which basic information on hazards and exposure is not provided should not be marketed in the EU. The manufacture, import and use of Polymers should follow the same principles.

To simplify the discussion we would like to introduce the phrase “A polymer system” since REACH include more than just monomers in its definition of a polymer.

The definition of a polymers under REACH, covers the substances taking part in the polymerization reaction as either a monomer or an initiator, together with the “*additives necessary to preserve the stability”* of the polymer and “*impurities deriving from manufacturing process*”. Examples hereof are stabilizers and catalyst residues. Moreover, from the definition of polymers in REACH its implied that the polymers contain a wide distribution of different chain lengths.

A polymer system has many things in common to the UVCBs currently being registered already today. Therefore, it is important to make use of the experience from registration as well as the enforcement efforts made so far of UVCBs, where a clear substances identity and composition is key.

Participation from independent scientists and experts is needed

Input is needed from scientists free from conflict of interests in order to refute or concur with scientific claims made by industry stakeholders regarding the definition and relevant hazard endpoints of polymers.

Polymers should be treated as chemical mixtures for hazard assessment

REACH (Art 3.5) considers a polymer as a substance consisting of molecules characterized by the sequence of one or more types of monomer unit. Such molecules must be distributed over a range of molecular weights, that are attributable to differences in the number of monomer units. A polymer can also contain additives necessary to preserve the stability of the polymer, oligomers, batch impurities, reaction by-products deriving from the manufacturing process, as well as catalysts and polymer production aids. Therefore, polymers include many different substances that may be present in different quantities even in each polymer batch produced by a same plant. In order to fully identify the health and environmental impacts of polymers and of substances effectively on the market, they should be treated as mixtures in the context of hazard assessment

Start with a preregistration process for transparency

In order to obtain basic information on the existing polymers in the EU market that would allow to frame the registration process, a mandatory preregistration process should be established as soon as possible in order to allow disclosure to ECHA of all:

- Identity of companies manufacturing or importing polymers
- Polymer formulations
- Production/import volumes
- All available Toxicological information on the polymer system, including:

    - The polymer as such
    - Included monomers
    - Other chemicals used in their manufacturing process categorised by classes (stabilizers, catalysts, lubricants, etc).
    - And known degradation products
- Uses of the polymers categorized by lifetime frames (single use, short time, durable) and dispersibility (for example, polymers used in cosmetics or food are highly dispersible).

Confidentiality claims should be limited to the strictly indispensable and submitted to ECHA alongside detailed and objective evidence that the conditions to justify confidentiality under REACH are met.

Polymers should be prioritized for registration on volume, leach-ability, level of complexity, life time frame and dispersibility

Based on the information provided through the preregistration process polymers should be registered in a stepwise process based on:

1. Production volume: prioritize high volume use polymers
2. Dispersibility: prioritize polymers with dispersible uses (cosmetics, food, detergents, fertilizers, etc.).
3. Leach-ability: prioritize polymers with presence of small leachable molecules
4. Level of complexity: prioritize polymers with higher number of constituents and chemicals used in manufacturing process, including monomers,.
5. Life time frame: prioritize polymers with short time uses

‘Information, including Endpoints, that must, a minima, be a compulsory part of the registration dossier’

- Clarity is needed on what must be tested (polymer mixture, extractables, leachates, etc).
- The whole life cycle impact of the polymers must be accounted for, including production process chemicals, leachates, degradation products.
- Two kinds of toxicity must be considered:
  1) chemical toxicity
  2) physical/particle toxicity (eg. like micro and nanos and PSLT (poorly soluble low toxicity))
- Persistence AND biodegradability of the polymers must be systematically tested for as they are of concern[4] given the global environmental threat posed by plastics. Biodegradability should be taken into account different trophic compartments including soil, water surface, deeper water, sediments, etc.
- Specific physical properties of polymers must be considered in hazard assessment such as size, form (similar to nanos) or capacity to be inhaled.
- Inhalable polymers are of concern due to particle size and reactive functional groups. This is already considered by USEPA Safer Choice Program. For example, risk to workers during manufacturing stage or inhalation risks during the use of polymers in dispersion of paints.
- New specific tests for polymers must be developed as most existing (eco)toxicological tests can not be performed on polymers, as most are insoluble solids
  Toxicity tests of polymer mixture must be performed.
- Scientific literature on oligomers and other non-intentionally added substances that are present in the polymer is very relevant when investigating hazard properties of polymers. Grouping should be used with caution and the precautionary principle must be employed whenever there is both scientific uncertainty and potential serious health and/or environmental consequences.

4 Cousins, I.T. et al., 2019. Why is high persistence alone a major cause of concern? Environmental Science: Process & Impact, 21, 781-792. https://doi.org/10.1039/C8EM00515J

The criteria proposed for exempting polymers from registration are not scientifically justified

The 1000 Da cut-off proposed by the consultants in the Workshop Thought Starter is not scientifically justified[5] : exemptions of hazard testing for large molecules require clear scientific justification which is not provided presently. Bigger molecules may be toxicologically relevant (E.g. fluoropolymers up to 1500 Da). EPA Safer Choice Program considers that molecular weight threshold should be higher when polymers are accompanied by permeation enhancing chemicals, for example in food contact materials.

Bioactivity is not always connected to chemical reactivity or chemical structure. Absence of biological relevance should be proven in order for polymers to be exempted.

Specific polymers such as Polyesters which has been mentioned in the discussions, should not be exempted from registration as there is very limited evidence of the lack of toxicity of polyesters. All polymers should go through the same process. The exemption is based on the assumption that they are hydrolysed but chemicals that may be released are unknown. Physical hazards of polyester, in particular of fibres should be considered due to their wide use in textiles and their capacity to be released in the environment via water[6].

COST AND BENEFITS OF REGISTRATION OF POLYMERS

The main objective of REACH is to protect people and the environment

When assessing the costs and benefits of registering polymers, it is important to remember that the purpose of REACH is to ensure a high level of protection of human health and the environment. The EU courts have confirmed that ensuring a high level of protection of human health and the environment is the primary objective of the regulation.

Legislation is a driver for innovation

As several reports, also regarding REACH, have established health and environment precautionary legislation is a driver rather than an obstacle for innovation, including innovation towards safer chemicals[7]. The results of the REACH Review showing the benefits of REACH Registration should also be considered in the report.

Benefits of polymers registration

The environmental impacts of polymers used in plastics should be included in the cost/benefit assessment of registration as the huge costs of cleaning up plastic pollution and costs for the environment are ultimately paid by society. Marine plastic pollution due to plastic waste has been estimated to costs between $3,300–$33,000 per tonne in reduced environmental value[6]. Information on persistence of polymers used in plastics will ultimately lead to improved risk **management[8].**

5 Groh, K.J. et al., 2017. Food contact materials and gut health: Implications for toxicity assessment and relevance of high molecular weight migrants. Food and Chemical Toxicology, 109, 1-18. https://doi.org/10.1016/j.fct.2017.08.023

6 Prendergast-Miller, M.T. et al., 2019. Polyester-derived microfibre impacts on the soil-dwelling earthworm Lumbricus terrestris. Environmental Pollution, 251, 453-459. https://doi.org/10.1016/j.envpol.2019.05.037

7 The Center for International Environmental Law (CIEL), 2013. Driving innovation, how stronger laws help bring safer chemicals to market. http://www.ciel.org/Publications/Innovation_Chemical_Feb2013.pdf
Center for Strategy and Evaluation Services (CESS), 2012. Interim Evaluation: Impact of the REACH regulation on the innovativeness of EU chemical industry. https://publications.europa.eu/en/publication-detail/-/publication/c862992b-9b32-4438-b188-72ce73981ed9/language-en/format-PDF

8 Beaumont, N.J. et al., 2019. Global ecological, social and economic impacts of marine plastic. Marine Pollution Bulletin, 142, 189-195. https://doi.org/10.1016/j.marpolbul.2019.03.022