Statement on the registration of polymers under REACH

Authored by and signed by members of the scientific community, April 2021

People and the environment are widely exposed to polymers, the main constituents of plastics, as these chemicals continue to build up in terrestrial and ocean ecosystems and production is predicted to continue increasing (Geyer et al., 2017), resulting in emissions to our waterways of up to 53 million metric tons (Mt) per year by 2030 (Borrelle et al., 2020). Apart from plastics, polymeric substances are present in many other materials, products and applications, including but not limited to silicones, coatings, paints, detergents, household and personal care products, agricultural fertilizers and wastewater treatment, often leading to direct releases into the environment.

Although polymers are manufactured and used in Europe in extremely high quantities (e.g. plastic production in Europe has been around 60 million tonnes per year over the last years (PlasticsEurope, 2020)), not enough is known about their identity, uses, physical, chemical, and hazardous properties, particularly because polymers have so far been exempt from registration under the European chemicals regulations REACH. To finally initiate the polymer registration process, currently the European Commission (EC) is developing a proposal on how and which polymers to register (Wood and PFA-Brussels, 2020).

As scientists working in the fields of polymer chemistry, ecotoxicology, environmental chemistry, conservation biology, environmental sciences, marine biology, atmospheric pollution, food packaging and sustainability assessment, we would like to provide our expert opinion on the proposed process and criteria for identification of polymers requiring registration (PRR) under REACH, as reflected in the discussion documents from the Competent Authorities for REACH and CLP (CARACAL) subgroup on polymers (CASG-polymers), including the modified PRR flowchart proposal referred to as “New Figure 3.2” in the EC’s “BACKGROUND DOCUMENT for the CASG-polymers meeting 16 Dec 2020 14:00-17:30” (see https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/6381dbc9-2e88-4034-a86d-f5fd20f9ac70/details, accessed 11.04.2021) and the EC’s document “An initial thought starter on REACH information requirements for Unique Polymers Requiring Registration” (see https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/2f699825-5e4a-4d0c-87e6-a015c4da3645/details, accessed 11.04.2021).

The main goal of the process should be to ensure a high level or protection of human health and the environment

In order to ease the burden on industry, the approach followed by the EC seeks to limit registration obligations to a reduced number of polymers identified as “polymers requiring registration (PRR)” based on a defined set of criteria. However, following the criteria outlined in the Wood/PFA report, only ca. 6% of the estimated 200’000 polymers on the EU market might require registration, while most of the polymers used in highest quantities and contributing majorly to the current plastic crisis and growing pollution with micro- and nanoplastics would not require to undergo any registration process at all (see e.g. Annex G of the Wood/PFA report (Wood and PFA-Brussels, 2020)). This concerns, for example, polyolefins such as polyethylene (PE) and polypropylene (PP), as well as polystyrene (PS), polyvinyl chloride (PVC), polyethylene terephthalate (PET) and polyamide (PA) plastics (Gaylarde et al., 2021; Jones et al., 2020). This omission also disregards the indications that a number of high production volume polymers (such as PS and PVC) can have negative impacts in human health, including carcinogenic effects, and impact organisms in the environment at levels of medium to high concern (Rodrigues et al., 2019). To ensure a high level of protection to human health and the environment, the EC should provide a framework for the registration of all polymers in a stepwise process, giving priority to those manufactured in highest volumes and thus likely to result in the highest exposures.

In addition, while the registration of polymers under REACH concerns the polymers themselves, these materials cannot be considered as ‘pure’ in that plastic polymers typically contain not only the known, intentionally added substances (IAS) but also non-intentionally added substances (NIAS), which are often unknown and may include reaction side products and byproducts, degradation products, as well as other impurities and contaminants (Nerin et al., 2013; Horodytska, et al., 2020; Geueke et al., 2018a,b), some of which may be toxic. An example of hazardous IAS is antimony (Sb), which is commonly used to regulate polymerization in production of PET in the form of antimony oxides or antimony acetate (Dodd, et al., 2013; Groh et al., 2019). Sb can leach from plastic products, like PET water bottles, at levels that exceed safety limits for chronic daily intake (Chapa-Martinez et al., 2016). One example of NIAS are polycyclic aromatic hydrocarbons (PAHs) which have been found in virgin polystyrene (PS) and may be generated during its production (Van et al., 2012; Li et al. 2017). PAHs in PS can also be a result of contamination, as was demonstrated by Rochman et al. (2013).

The registration process should be based on scientifically grounded assumptions

Scientific justifications for the criteria to be used for deciding, which polymers should be registered and which information should be provided, as currently outlined in the Wood/PFA report and subsequent EC communications, are not always clear. Recognized data gaps and uncertainties should result in the most protective approach applying the precautionary principle.

Several criteria for Polymers of Low Concern require reconsideration

The EC’s approach proposes to exempt the so-called polymers of low concern (PLC) from being considered for registration. Recently, the EC has communicated its choice of applicable PLC criteria in a document “PROPOSAL FOR AN EU-DEFINITION OF A POLYMER OF LOW CONCERN (PLC)” (see https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/f7233cb1-f7d8-429e-a7c8-0dc285b24045/details). Most of the justifications presented in this document refer to “the purpose of maximum international harmonization,” while the underlying scientific knowledge or industry data are not discussed in any detail. For example, exposure and risk should be estimated using, as far as possible, scientific and quantifiable approaches, but these are not used as reference for defining what is of "low concern.” As another example, a recent publication by Lohmann and colleagues (2020) has discussed whether fluoropolymers are “really of low concern” as has been proposed in an earlier publication by Henry et al (2018) and included in the Wood/PFA report (2020), despite the observation that degradation of side-chain fluorinated polymers can lead to formation and leaching of PFAS. Lohmann and colleagues (2020) note that the current PLC concept is “*derived from the characteristics of substances and articles but does not cover problems occurring during production and disposal. Specific fluoropolymer articles could hence technically meet the definitions of a PLC, but still pose significant concerns to human health and the environment due to emissions occurring during the life cycle*” (Lohmann et al., 2020). We further observe that several other of the proposed PLC criteria need to be reconsidered based on the most current scientific understanding and recognition of the remaining uncertainties, even if this would mean that the EU legislation would become the only legislation worldwide currently applying the resulting protective criteria. This concerns, for example, the proposed exemption for polyesters, the criteria defined around the 1000 Da threshold, or the permissible levels of low molecular weight oligomers (for details, see respective subsections below).

General exemption for polyesters from an approved list is not scientifically justified

The EC proposes to consider all polyesters made of monomers included on the “safe” list as being PLC regardless of their molecular weight, oligomer content or any other considerations, and thus effectively exempts polyesters from consideration as potential PRRs. With this, the EC refers to the “(dynamic) list of approved polyesters applied by Australia, Canada, USA and China" but does not provide any direct link to this list, nor does it define what the process would be for evaluating, adding or removing specific substances from this list. Polyesters comprise a wide group of polymers, which have drastically variable properties with regard to molecular weight distribution and oligomer contents as well as potential hazardous properties of these low molecular weight species and the overall exposure potential. For example, the potential toxicity of cyclic oligomers found in many polyesters has not yet been sufficiently characterized to allow making any generalizing exemptions (Zhang et al., 2018; Ubeda et al., 2017; Ubeda et al., 2018; Ubeda et al., 2019; Ubeda et al., 2020; Liu et al., 2021; Canellas et al., 2021). We further note that the underlying assumption that all polyesters will (quickly) degrade into their corresponding monomers in the natural environment has not yet been convincingly proven for all cases, and it has also been demonstrated that some polyester monomers may have other detrimental effects on the environment (Kim et al., 2001). Moreover, the influence of UV light and other abiotic influences may result in the generation of other degradation products of polyesters in the environment (i.e., not only monomers), whose properties and toxicity are not yet characterized either (Sørensen et al., 2021). In addition, many polyester-based products, notably textiles, are known to generate high amounts of secondary microplastics, which should be taken into consideration as well (Carr, 2017; Hernandez et al., 2017; Zhang et al., 2021) as they can become airborne (Liu et al., 2019; Kapp et al., 2020) and spread globally to remote environments (e.g. Sanchez-Vidal et al., 2018; Barrows et al., 2018; Allen et al., 2019; Bergmann et al., 2019).

Degradation of polymers under environmental conditions to substances of concern

We support that polymers that are likely to degrade under environmental conditions to substances of concern should be prioritized for registration. Substances of concern should include hazardous substances beyond the REACH Candidate list, because scientific evidence shows how a wide range of polymers degrade in the environment into hazardous chemicals not included in this list (Zhang et al., 2018; Lohmann et al., 2020; Ubeda et al., 2020). Moreover, micro- and nanoplastics resulting from degradation of macroplastics should also be treated as degradation products of concern (see also below).

Criteria for identification of polymers requiring registration (PRR) should consider the polymers’ contribution to micro- and nanoplastics burden in the environment

Micro- and nanoplastics should be considered as substances of concern due to their persistency (Cousins et al., 2019). Their size makes them readily available for ingestion and potentially liable to transfer within food chains (Gallo et al., 2018). Therefore, polymers’ ability to generate microplastics should be taken into consideration when defining PLC and PRR criteria. The NGOs European Environmental Bureau and International Chemical Secretariat have summarized relevant scientific evidence in support of their position on microplastics and polymers in the document “Requirements for polymer registration under REACH should include consideration of polymers’ contribution to micro- and nanoplastics burden in the environment,” submitted as a follow-up to the 1st meeting of the CARACAL subgroup on polymers (see https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/b8ae7ada-c4e8-4541-96d8-506fc30dc419/details).

Molecular weight thresholds for determining the testing data requirements for a given PRR should be revised, taking into account current scientific understanding and remaining uncertainties

The EC proposes to divide all polymers into three groups based on their number average molecular weight (MWn), i.e., Type 1 with MWn <1’000 Da, Type 2 with MWn between 1’000 and 10’000 Da, and Type 3 with MWn above 10’000 Da. The Type 2 and Type 3 polymers are proposed to have drastically reduced or completely waived requirements for test data to be submitted upon registration. This grouping approach and its implication with regard to testing requirements are not fully supported by the most current scientific understanding and hence should be reconsidered and refined, with transparent demonstration of proper justifications and accommodation of any remaining uncertainties. For some polymer groups, defined cut-offs may need to be increased even if the overall assumption of the importance of high systemic uptake would remain. For example, in the case of fluoropolymers, the “no-uptake” threshold of 1’000 Da should be increased to 1’500 Da, because the molecular volume of fluorocarbons is smaller than that of hydrocarbons with the same molecular mass (EFSA CEP Panel, 2016). Consequently, the 10’000 cut-off may need to be reconsidered for fluoropolymers as well. In the case of polyethylene glycol (PEG) polymers, it has been suggested that higher molecular weight PEGs may undergo so-called “molecule folding” leading to more condensed molecules and consequently higher uptake possibilities (Pelka et al., 2017; Nascimento et al., 2021). Whether any other polymers may exhibit similar behavior has not yet been subject of targeted testing, to the best of our knowledge. Further, with regard to intestinal permeability, it has to be kept in mind that (i) surfactants and several other agents currently used as direct or indirect food additives could lead to higher permeability and consequently a higher uptake of both low and high molecular weight species, and (ii) increased intestinal permeability has been reported in vulnerable population groups, including both the elderly and the newborns, as well as people suffering from certain chronic diseases prevalent in Western population (reviewed in (Groh et al., 2017)). Moreover, adverse immune reactions to high molecular weight substances can occur even at very low uptake levels, and non-systemic toxicity manifestations, e.g. those occurring without any uptake, are also possible (see also below). With regard to the environment, toxicity and other adverse effects of high molecular weight substances cannot be excluded at the moment either (Arp and Knutsen, 2020; Freeling et al., 2019; Huppertsberg et al., 2020) and therefore also require proper consideration, under provision of adequate testing data. Overall, the above-reviewed evidence suggests that the molecular weight thresholds used to define the three polymer groups with corresponding testing requirements, and especially the 1’000 Da cut-off, could be outdated and need to be revised, taking into account the most recent scientific evidence as well as any remaining uncertainty.

Non-systemic toxicity should not be neglected

Apart from the effects resulting from internal uptake of polymers, the possibility of adverse effects occurring in the absence of uptake should also be considered and properly assessed. These may include, e.g., local inflammatory reactions and other surface interactions, as well as effects on host microbiota or microorganisms in the environment (Jin et al., 2018. Jin et al., 2019). In addition, epithelial tissues (e.g. skin) can be exposed and lead to adverse reactions via dermal contact, as, for example, with ε-caprolactam, which is used in the synthesis of polyamides, nylons, polyurethane (Dodd et al., 2013), and is a known toxicant that can cause skin irritation in humans (Tiplica et al., 2020). Furthermore, some polymers with specific physico-chemical properties, such as low solubility in water, could also give rise to non-systemic toxicity similar to those of carbon nanotubes and other nano-materials such as TiO2 and SiO2, referred to as poorly soluble, low toxicity (PSLT) particles. Once ingested or inhaled, such particles are only poorly cleared out by the body, which may lead to accumulation and invoking of adverse reactions such as inflammation or cancer. Therefore, the potential PSLT properties of polymers must be properly identified and addressed in the decision on which polymers should be registered, and the resulting registration requirements for polymers must be aligned with those summarized by the European Chemicals Agency (ECHA) in the Guidance on information requirements and chemical safety assessment. Appendix R7-1. Recommendations for nanomaterials applicable to: Chapter R7a Endpoint specific guidance" (see https://echa.europa.eu/documents/10162/23047722/appendix_r7a_clean_draft_caracal_en.pdf/427b5fd4-f930-4273-8197-66dfbc1b2943, accessed 12.04.2021).

Cut-off values for the content of low molecular weight constituents are too high

The EC proposal suggests that polymers with MWn above 1'000 Da should be identified as PRRs if they contain ">10% oligomer content of molecular weight below 500 Da or >25% oligomer content of molecular weight below 1'000 Da." However, the 10% and 25% cut-off values are too high, as most high molecular weight polymeric products with such high levels of low molecular weight oligomers would not maintain their structural integrity due to high migration and deterioration of the material. The criteria proposed by Wood & PFA report (2020) also differ from those formulated in a technical report on polymer registration published by the EC in 2015, where lower cut-offs (>2% and >5% for molecular weights below 500 Da and 1'000 Da, respectively) were proposed for the Type 3 polymers (i.e., those with MWn >10'000 Da). Wood & PFA explained their decision to adopt the same, high % cut-offs for both Type 2 and Type 3 polymers with reasoning that the differing cut-offs for the two MWn ranges are "*difficult to reconcile scientifically as there is no reason to suppose that the low molecular weight oligomers present in polymers with MWn >10'000 Da would be any more hazardous, and thus warrant a lower cut-off content, than the low molecular oligomers present in polymers with MWn<10'000 Da.*" We agree with the observation that there seems to be no clear reason to adopt different % cut-off values for Type 2 and Type 3 polymers, but we strongly disagree with the arbitrary decision to adopt higher instead of lower values for % cut-offs. Hence, we suggest that the % cut-off values for identifying both Type 2 and Type 3 polymers as PRRs should be >2% for oligomer content of molecular weight below 500 Da and/or >5% for oligomer content of molecular weight below 1,000 Da. At this point, it is also worth noting that in Japan an even stricter criterion, i.e., a single cut-off of 1% for oligomers with molecular weights below 1'000 Da is used for all polymers. We also stress that mixtures containing hazardous substances of very high concern (SVHCs) are identified as hazardous if SVHC content is above 0.1%. Therefore, once more data and experience with hazard assessment of oligomers and other low molecular weight constituents, including non-intentionally added substances (NIAS) present in polymers, will become available, even a further reduction of the 2% and 5% cut-off values may need to be considered.

In addition, as mentioned above, polymers typically contain substances other than the intended polymeric chains of monomers themselves, including, for example, residues of known IAS used during production and processing, as well as a variety of NIAS, which are often unknown and poorly characterized. While not the focus of current discussions, we feel that both the NIAS and some IAS used during production are important to consider and should not be neglected, especially with regards to overall assessment of a polymer's toxicity, which could result from exposure to low molecular weight constituents leaching from this polymer.

Threshold for identifying PRRs among surface-active polymers needs discussion

We support the criterion for identifying the surface-active polymers as PRRs but emphasize that additional discussion regarding the chosen threshold of 45 mN/m reduction in surface tension may be necessary. The 45 mN/m reduction in surface tension has been previously set as a threshold to identify surfactants in general, particularly in the context of the EU Detergents Regulation. However, whether the unchanged threshold can be directly applied to the field of polymers requires further consideration and potentially empirical investigation. In this regard, the ECETOC's TR133-1 report on polymers also acknowledges that "*[r]esearch work is merited to evaluate if this regulatory threshold would qualify as a criterion to distinguish potentially eye / skin irritating surfactant polymers from PLC*."

Several important criteria for PRR identification are currently missing

Several important criteria have been excluded from the PRR identification scheme proposed by the EC currently (as compared to the earlier EC proposals as well as legislative schemes in some other countries), without providing a detailed and transparent justification for such exclusion. This concerns, for example, omission of (i) criterion for anionic and amphoteric polymers, (ii) criteria for impurities and for stability-preserving additives present in polymers, (iii) criterion for water-absorbing polymers, (iv) criterion for elemental limitations, (v) criterion for nanopolymers, (vi) criterion concerning generation of secondary micro- and nanoplastics, and (vii) criteria for high production tonnage and widespread use.

Ensuring transparency

The latest EC proposal states that companies should document their assessment of whether their polymers require registration or not. These assessments, together with the supporting evidence, are to be shared with ECHA. We support this procedure and further call for (i) obligatory inclusion of data on production volumes and downstream uses as well as (ii) provision of public access to the collected information. Given the current lack of systematic information on polymers produced or imported into the EU, such mandatory notification procedure for all polymers marketed in the EU would provide a sorely needed overview of this high-volume chemical sector. This will also ensure objectivity and transparency when making decisions on identification of polymers requiring registration, as well as allow for a proper oversight by authorities, ECHA, academia and other stakeholders. Sharing of the collected data will enable broader analyses by scientists and other stakeholders. This in turn will allow refining the cost-benefit analysis (currently limited by many uncertainties), testing and optimizing the currently proposed PRR criteria, and facilitating further development of hazard assessment and grouping approaches, which would ultimately improve the efficiency and societal value of the overall procedure for registration of polymers under REACH.

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