NGO position

REACH Requirements for polymer registration under REACH should include consideration of polymers' contribution to micro- and nanoplastics burden in the environment

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Summary

Contamination of our environment by micro/nanoplastics is constantly increasing and a growing body of evidence has started shedding light on the diverse harmful effects which could be caused by micro/nanoplastics exposure in living organisms, including people. Despite the growing awareness that failure to address this problem might have catastrophic consequences for environmental and human health, both the industry initiatives and regulatory actions that have been initiated in the EU so far have not yet provided any viable solutions to this problem. Therefore, further regulatory actions are urgently needed. One such option could be to include the consideration of secondary micro/nanoplastics' problematic into the discussion about the upcoming registration of polymers under REACH. Specifically, generation of micro/nanoplastics should be regarded as an inherent hazardous property of plastic polymers. The extent of micro/nanoplastics generation is influenced by both the physico-chemical properties of a given polymer and the external impacts experienced by the respective material/article during its life-cycle. Based on these characteristics, a polymer's contribution to secondary micro/nanoplastics burden in the environment could be estimated, followed by a proper risk assessment and decisions on potential risk mitigation actions, where necessary. However, for most polymers currently produced or imported into the EU, even the minimal data necessary for such estimation are currently lacking. Therefore, we suggest that a polymer's contribution to micro/nanoplastics burden should be addressed by a dedicated criterion when identifying polymers requiring registration, and that data necessary to estimate such contribution should be requested to be routinely submitted as part of a polymer's (pre)-registration package.

Background

Environmental pollution by plastics has been continuously attracting public attention and in recent years has spurred diverse regulatory actions and industry initiatives. Apart from the often well-visible pollution by macroplastics, such as bottles, plastic bags, cigarette butts, or fishing nets dispersed in the environment, a matter of ever-increasing concern is also the ubiquitous contamination by microplastics, which are now found in all geographical regions across all environmental compartments, including air, marine and freshwater habitats, soil, and biota, including humans (Akdogan and Guven, 2019; Amato-Lourenço et al., 2020; Bergmann et al., 2019; Shahul Hamid et al., 2018; Tekman et al., 2020; Zhou et al., 2020). Microplastics are small particles comprised of synthetic polymers or synthetically modified natural polymers. A distinction from large pieces of midi- and macroplastics is typically done based on arbitrary defined size ranges, with the upper size limit for microplastics frequently placed at 5 mm and the lower limit at 0.1-1 µm (Geueke, 2020). Even smaller plastic particles, sized in the nanometer range, are referred to as nanoplastics (Gigault et al., 2018). Both micro- and nanoplastics can be either intentionally produced (primary micro/nanoplastics) or generated from larger plastics objects (secondary micro/nanoplastics) (GESAMP, 2015; Hernandez et al., 2017b). Secondary particles can be generated as a result of "tear and wear" and subsequent further degradation processes, either during the use phase or at the end-of-life, which could include both littering in the environment following improper disposal, as well as landfilling, incineration, and recycling routes. The main sources of secondary micro/nanoplastics produced during the use phase include automotive tyres; road markings; pre-production plastics; washing of clothing; building paint; artificial turf; automotive brakes; fishing gear; marine paint (Hann et al., 2018; Kole et al., 2017). At the end-of-life, microplastics can be emitted by objects landfilled or littered and subjected to degradation in the environment, but can also be generated during incineration (Yang et al., 2020). Disposable plastics items are among the most frequently found litter objects detected in environmental audits, and microplastic objects found in the environment are most often comprised of widely used commodity plastics (Andrady, 2017). Since by a logical inference any further degradation of microplastics fragments would eventually create nanoplastics, it can be assumed that, similar to microplastics, nanoplastics are also ubiquitously present in the environment, and potentially at even higher levels (Koelmans et al., 2015). Indeed, experimental evidence has already been reported to demonstrate the formation of secondary nanoplastics, for example, from polystyrene products through mechanical breakdown (Ekvall et al., 2019) and from a biodegradable microplastic through abiotic degradation under environmentally representative conditions (González-Pleiter et al., 2019). A growing number of scientific studies have reported on various adverse effects which could be exerted by microplastics in humans and other living organisms, and nanoplastics could be even more hazardous because of their smaller size and correspondingly a higher uptake and interaction potential (González-Pleiter et al., 2019; Kelpsiene et al., 2020; Paul et al., 2020). In the remaining part of this document, the term 'microplastics' will be used to refer to both micro- and nanoplastics.

Current EU's measures do not yet properly address pollution by secondary microplastics

A host of academic scientists, governmental agencies, and non-governmental organizations have explicitly acknowledged the need to take urgent actions aimed at preventing environmental pollution by microplastics (Gallo et al., 2018; GESAMP, 2016; Hann et al., 2018; Prata et al., 2019; SAPEA, 2019; WHO, 2019). However, the so-far launched or planned initiatives in the EU do not yet provide an adequate treatment of the problem in its entirety. For example, the planned "microplastics restriction" addresses only the intentionally produced, primary microplastics. However, not the primary but secondary microplastics are responsible for the bulk of microplastics pollution (GESAMP, 2015; Kawecki and Nowack, 2019). Policy options for reducing releases of secondary microplastics during the use phase have been discussed in a 2018 report commissioned by the EU (Hann et al., 2018), but any corresponding measures have not yet been conclusively implemented. The EU's measure on single-use plastics, adopted in 2019, aimed to address emissions of secondary microplastics from littered objects. However, some of the worst offenders, such as plastic bottles or wraps, currently remain exempt due to the "lack of viable alternatives," while restrictions placed on plastic balloon sticks and cotton swabs are unlikely to sufficiently reduce the microplastics pollution burden if not coupled with other strong measures in the near future.

Microplastics-related risks should be considered during registration of polymers under REACH

Plastic polymers' propensity to generate microplastics has not yet been taken into consideration during the ongoing discussion on criteria which should be applied to identify polymers requiring registration under REACH (Wood and PFA, 2020). However, the ability to generate microplastics is in fact an inherent (hazardous) property of plastic polymers. The EU's chemicals regulation REACH requires that risk assessment of a substance takes into account all hazardous releases occurring under normal or reasonably foreseeable conditions of use. REACH provisions are underpinned by the precautionary principle and require from manufacturers, importers and downstream users "to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment." Registration within REACH is the process that aims to generate the hazard and exposure information necessary to understand the potential adverse effects on human health and the environment, and thus should assist in identifying hazardous properties and developing recommendations for risk management measures. This information should then be used by the relevant actors to support the application and implementation of Community legislation.

Considering the two facts that a) the release of microplastics from articles made of polymers can be plausibly expected, and b) microplastics have the potential to adversely affect human health and the environment, it becomes obvious that proper assessment of microplastics' release and the risks resulting thereof should be included into the overall risk assessment of a polymeric substance and thus should play a role when deciding which polymers should require (pre)registration and which kinds of data may need to be submitted.

Proposals for microplastics criteria and data requirements for polymer registration under REACH

A polymer's ability to generate microplastics should be taken into consideration when defining the criteria for both the so-called "polymers of low concern" and the "polymers requiring registration." Since most polymers can be reasonably expected to generate microplastics, minimal set of data allowing to estimate the resulting microplastics emissions and associated risks should be submitted for *all synthetic polymers* produced or imported in the EU. Therefore, the criteria for identification of polymers requiring registration, suggested in a recent report by the Wood and PFA consultancies (Wood and PFA, 2020), should be expanded to include:

- ***Criterion for polymers produced in extremely high volumes***, since these could result in high exposure to corresponding plastics and microplastics;
- ***Criterion for polymers having high propensity to generate large quantities of secondary microplastics, or to generate microplastics associated with a specific hazard***, as judged based both on the inherent physico-chemical properties of the assessed polymer as well as on its foreseeable downstream uses and other relevant life-cycle considerations.

Both the persistence and the ability to generate micro/nanofragments are an inherent property of many polymers, which can be influenced by their chemical composition and other physico-chemical characteristics, as well as external influences (Andrady, 2017). From this it follows that different plastic polymers could a) have differing propensities to generate microplastics, b) generate microplastics with differing hazard properties, and c) generate microplastics with differing environmental fate and behavior characteristics. Indeed, respective evidence has already been reported by several studies comparing not only different types of polymers but also the different grades of the same polymer types, resulting from differences in synthesis procedures and/or post-synthesis treatment of the produced polymeric material (Cai et al., 2020; Chubarenko et al., 2016; Garvey et al., 2020; Hernandez et al., 2017a; Matjašič et al., 2020; Roos et al., 2017; Vieira et al., 2020; Winkler et al., 2019; Zhu et al., 2019). Overall, the data available on this topic are still very limited and therefore further research, involving both empirical and modelling approaches, is required. In support of these efforts, submission of a minimal set of microplastics-related data should be requested for all polymers, as this will allow for a systematic assessment and evaluation and provide the necessary basis for computational models.

Ideally, the data and testing requirements should provide all information necessary to understand the polymer's propensity to generate secondary microplastics as well as to estimate their hazards and risks, considered in relation to both physico-chemical properties of the assessed polymer as well as its downstream uses and life-cycle specifics. The submitted data should allow characterizing the polymer's ability to generate microplastics not only during the production but also during incorporation into articles, use phase, and disposal phase, considering the most likely end-of-life scenarios. Since the quantity of generated microplastics can be expected to be directly correlated with the quantity of produced and used polymer of a given type, information on production volumes and downstream use quantities should also be provided, split by different expected uses. Submitted data should also provide for a broader understanding of both abiotic and physical degradation, bioaccumulation, and hazardous effects of microplastics. With regard to the latter, more emphasis should be given to understanding chronic toxicity effects of naturally generated microplastics, as opposed to acute toxicity assays performed with synthetically produced homogeneous particles, such as polystyrene microbeads (Waldman and Rillig, 2020). Based on the existing scientific evidence, specific consideration might need to be given to local inflammatory responses as well as effects on microbiota (Pirsaheb et al., 2020). For example, microplastics have been demonstrated to disturb gut microbiota and function in both mammals and fish (Fackelmann and Sommer, 2019; Lu et al., 2019; van Raamsdonk et al., 2020).

Conclusion

We conclude by reiterating that various polymers and a multitude of downstream uses have been clearly identified as the most likely and significant contributors to the rising environmental pollution by microplastics and the resulting adverse effects on human health and the environment. In our opinion, proper consideration of the produced or imported polymer's contribution to environmental pollution by secondary microplastics during the envisioned process for registration and risk assessment of polymers under REACH represents a golden opportunity to address the roots of this important contemporary issue on a systematic and fair basis. The collected data and experience will allow to identify and enforce appropriate risk management options necessary to mitigate the adverse effects on human health and the environment, which can only be expected to increase if this problem remains unaddressed. Reduction of environmental pollution by micro- and nanoplastics, both primary and secondary, should be firmly included among the targets pursued by the risk management for plastic polymers.

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