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1st EEB submission to uPFAS Public Consultation

This statement is prepared by the European Environmental Bureau (EEB), a network representing civil society interests to protect human health and the environment. With this contribution we aim to support an ambitious uPFAS restriction by providing further arguments on hazard aspects, strengthening legal justification for a broad restriction, and presenting additional information on scientific evidence that we think deserve more attention.

Goal and Scope

EEB supports the dossier submitter (DS) regarding the goal to assess the risk coming from PFAS substances throughout their entire life cycle, as well as choosing for the dossier a wide scope, including Fluoropolymers.

Industry argues for an exemption from the scope for products and uses which they consider as "safe" during the use-phase, which we'd like to respond to with a clarification of our interpretation of REACH Art. 2 (2). The fact that REACH is according to this article not applied to waste does not mean that the waste stage of a substance is outside the scope of REACH. Guidance documents on the considerations of recycling show that ECHA includes the End of Life (EoL) aspects in the assessment of substances. The DS stated themselves that "Like for other polymers, fluoropolymer microplastics can be formed during their use phase or end-of-life phase. It is therefore important not only to look at the use phase but the whole life cycle of fluoropolymers." (ECHA 2023 b, p. 219). The consideration for the entire life cycle is supported by the line of argumentation also applied in previous restriction dossiers such as the one for PFAS in firefighting foams[1] and the intentionally added microplastics[2][3]. This aspect also supports the decision to keep F-gases and their breakdown products such as TFA in the scope, since their different life cycle stages add to emissions and thus to the risk of PFAS in the environment.

We further support the idea that the restriction applies also for areas that are covered under other legislation. What industry often suggests is an interpretation of REACH Art. 2 in which REACH in general does not apply to substances covered by other legislation. This is, however, wrong, as Art. 2 is much more complex and nuanced, and this should be acknowledged. Furthermore, Art. 2 does not explicitly refer to the F-gas regulation, what takes away the base for arguing in favor of an exemption of F-gases from the scope based on the argument mentioned above. Finally, FPs are obviously covered by REACH, since not needing to be registered (REACH Art. 2(9)) does not mean they are not covered by restrictions under REACH, otherwise Side-Chain Fluorinated Polymers would not be covered by the PFHxA restriction either.

[1] "This will also ensure the grouping covers collectively the PFAS in its lifecycle from stock and precursors to the terminal persistent breakdown products (sometimes termed 'arrowhead')." (ECHA 2023c, p. 14).

[2] "RAC also considers that releases associated with the construction and end of life disposal of artificial pitches is relevant to consider, as this may lead to releases of microplastics in addition to those that occur during the service life of the pitch." (ECHA 2020, p. 57)

[3] "Microplastics have a concern similar that (sic) posed by the PBT/vPvB substances with non-threshold effect level. In this case, according to REACH regulation, manufacturers and importers shall minimise releases by applying the best risk management measures and OC throughout the life-cycle of the substance." (ECHA 2020, p. 71)

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Justification for a restriction under REACH

The claim by industry that a restriction is not needed as other pieces of legislation can address all life cycle stages is misleading. It is correct, that PFAS could be and is already addressed by different pieces of legislation besides REACH, but the conclusion that a restriction is not needed is false, as the following arguments lay down.

The DS has presented a discussion of possible regulatory measures to reduce the risk from PFAS for human health and the environment. This includes a consideration of other regulations outside REACH and CLP, including e.g. the Directive on the quality of water intended for human consumption (DWD), waste legislation, the Directive on industrial emissions (IED), etc. (ECHA 2023a, p. 70 ff.). The DS concluded that "A restriction is considered the most effective and efficient way to manage such a large and complex group of substances that are used in numerous applications" and since it also covers imported articles (ECHA 2023a, p. 74). Further, "these regulations could not prevent the manufacture, placing on the market and use of PFASs" (ECHA 2023a, p. 70) which the DS finds to be essential to reach a high level of protection. This analysis justifies in our opinion very well why the PFAS issue is not left to deal with for other legislation.

Also the argument by critics of a restriction that PFAS could be and is already "covered" by other legislation further says not much. Coverage could mean that certain emission levels and monitoring demands during the manufacturing stage are set (as in the IED) or that maximum concentrations for common exposure pathways to humans (as in the DWD) are defined. This, however, does not mean that a piece of legislation sufficiently addresses the issues identified.

The last point was already raised in the key issue discussion in RAC where the DS elaborated on their proposed exemption of the PPP, BP and MP from the scope with the justification that the respective regulations address the persistency issue. We interpret this in the way that if a non-REACH regulation that affects a substance does not sufficiently address the identified risk at the substance level, then the development of a restriction that includes the substance is justified (see REACH Article 2 argument above). We question whether the level of safety achieved in these three regulations is sufficient to justify their exemption from the scope.

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Hazards

Legal arguments pro P-sufficiency

This is not the first time that the industry has tried to downplay the high concern of persistency, by requiring further properties of concern to recognize the consideration of a restriction as justified (FFP4EU 2023). The practice of previous restrictions such as the one on intentionally added microplastics (ECHA 2020, p. 46) showed however, that this argument is not substantiated. The risk posed by microplastics was assessed based on: (i) their long-term persistence in the environment and (ii) the potential for this to give rise to a non-reversible pollution stock that is associated with environmental and/or human health risk. RAC confirmed the relevance of that approach, and found that the risk at stake justified a restriction in the framework of Article 68.1.

Some critics specify further that they see the development of an Annex XV dossier based on Article 68.1 not justified if it doesn't refer to hazard classes defined under the CLP. The practice of previous restrictions such as the DINP and DIDP restriction (restriction 52) from 2003, as well as more recent examples such as intentionally added microplastics. Also the restriction of Octamethylcyclotetrasiloxane (D4) and Decamethylcyclopentasiloxane (D5) (restriction 70) was based on the criteria of vPvB and PBT (COM 2018), which are not hazard classes in CLP (ECHA 2019, p. 26f.). Hence REACH enables the restriction of chemicals of which properties may not fit in the CLP categories, but which are still of concern due their intrinsic properties, and likely to pose an unacceptable risk to health or the environment. Persistence on its own is a serious concern that deserves the same treatment as the one applied to microplastics or other PFAS restrictions. Although persistency itself is sufficient to justify a restriction, the (self-)classification of 357 PFAS (ECHA 2023a, p. 21) for at least one of the five human health endpoints considered of most concern (Carc., Muta., Repr., Lact., STOT RE), supports the argument, that many PFAS have hazardous properties that also CLP covers.

References

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Fluoropolymers are polymers of concern

Fluoropolymer manufacturers claim that the majority of the chemicals they produce should be considered polymers of low concern following the OECD criteria and that PFAS emissions from manufacturing and end of life stages can be adequately managed through voluntary measures to be adopted by industry and other legislations (Korzeniowski et al., 2022).

The OECD criteria on polymers of low concern were developed in the 90s, as well as similar criteria adopted in other jurisdictions. However, scientific evidence and understanding of the hazards of polymers to human health and the environment has advanced in the last three decades (Groh et al. 2023).

For example, the OECD criteria threshold for molecular size (1000 Da) has been challenged by recent evidence showing systemic intake of higher molecular weight polymers, in particular in presence of enhancers. The OECD criteria threshold for oligomer content (2-5%) is way too high compared to REACH Regulation's threshold for considering a SVHC (0.1%). OECD criteria have focused on acute toxicity, however an increasing number of studies show chronic toxicity caused both by mechanical and chemical impacts of polymers. For example, chronic exposure to polymers and particles can induce local inflammatory reactions and other biological responses, even at very low uptake levels. Furthermore, chronic exposure to polymers is related to non-systemic toxicity manifestations. Scientists also highlight that OECD criteria do not consider that the mechanical degradation/weathering of polymers can also give rise to unknown and unexpected products and therefore the toxicity of the whole chemical mixtures released by polymers should be tested for chronic toxicity instead of only the virgin polymer (Groh et al., 2023; Almroth et al., 2021). Given the new scientific evidence, the OECD has recently started a process to update its criteria.

The severe pollution surrounding fluoropolymer manufacturing sites in the EU (Le Monde, 2023) gives testimony of the lack of capacity of the PFAS industry to avoid environmental emissions through voluntary commitments. The IED, which should avoid emissions during the manufacturing stage, does not cover all PFAS and depends on local authorities' views when establishing emission values.

Waste containing fluoropolymers is not labeled and therefore can't be differentiated from other waste streams, ending in landfills, municipal incinerators or recycling schemes. As stated in the Annex XV dossier, fluoropolymers are the main group of PFASs to enter the waste stage and waste stage emissions are highly uncertain. According to European waste statistics there are significant differences between EU Member States regarding the share of waste directed to the different treatment options of landfilling, incineration and recycling. Each of these waste treatment options however come along with their own risks of different type, but all risk reduction measures taken there can only address the end-of-pipe. A better way to address it is by restricting the substance from the beginning, as also the waste hierarchy supports, by prioritizing to avoid waste.

Therefore, given the concerns on the PFAS emissions of fluoropolymers during their whole life-cycle (Lohman et al, 2020), we consider that the dossier submitter's proposal to include fluoropolymers in the restriction with derogations for specific uses is the most effective approach to protect people and the environment.

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Emissions from the End-of-Life & fate of PFAS

Information on emissions from the End of life was one of the central gaps identified in the Annex XV dossier (reference). Below we highlight some findings that we think deserve more attention and some new evidence from literature on that matter .

Microplastics

The uPFAS Annex XV dossier mentions the release of PFAS as microplastics as one potential pathway to end up in the environment (ECHA 2023b, p. 30). Scientists are still trying to understand better the concerns related to MPs, but adverse effects are expected. Both, the fluoropolymeric microplastics as well as non-fluorinated microplastics containing PFAS add to the marine pollution, which is well documented in literature cited in the dossier (ECHA 2023b, p. 108). What we ask to be considered in the discussion is the twofold issue related to PFAS and microplastics.

Firstly, microplastics coming from fluoropolymers cause a concern just as microplastics in general, but further have some relevant characteristics. The most prominent fluoropolymer PTFE has a higher density (2.1-2.3 g/cm3) than seawater and freshwater, causing it to settle in sediment faster than other MP (ECHA 2023b, p. 221). This aspect should be given greater attention because the settlement in the sediment hampers the removal from the environment since human clean-up activities focus rather on the water surface and the upper water layers. This adds up to the environmental stock of pollution, which the DS acknowledged as an issue[4]. Further, a recent publication by Pramod Bahadur et al. (2023) studied six different human cell lines, which are representative of tissues and cells that directly or indirectly come into contact with MPs, and which were exposed to two different sizes of irregular shape PTFE microplastics (average diameter of 6.0 or 31.7 µm). The authors findings suggest that microplastics from PTFE associated toxicity may be specifically linked to the activation of the ERK pathway, which ultimately induces oxidative stress and inflammation. This shows that there is indication that

[4] "if releases of PFASs are not minimized, humans and other organisms will be exposed to progressively increasing amounts of PFASs until such levels are reached where effects become inevitable" (ECHA 2023a, p.13.)

Fluoropolymers are having concerning effects on human health and that therefore should not be excluded from the scope of the restriction.
Secondly, microplastics pose in general a threat to the environment, as they are prone to adsorb harmful substances, what was already recognized in the RAC and SEAC opinion on the intentionally added microplastics[5] (ECHA 2020). Microplastic particles are identified by the DS as a main transport medium for the global distribution of non-polymeric PFAS included in the matrix as additives (ECHA 2023b, p. 106). Fluoropolymer MP are however due to their minor adsorptive properties not a main adsorbing matrix and thus vectors for organic pollutants (ECHA 2023b, p. 220). A systematic review on PFAS in MPs and food contact materials found six papers in the time from 2010 to 2021 that address the occurrence and sorption/desorption of PFAS on MPs (Barhoumi et al. 2023). Studies confirm that also PFAS in the environment are adsorbed to microplastics and transported before being released again (Cheng et al. 2021), (Salawu et al. 2023). Due to their higher log KOC-values (>3.5), long-chain PFASs and cyclic PFAAs seem to be more prone to be adsorbed by particles (ECHA 2023b, p.109).
In the RAC opinion on microplastics it is stated that "the current scientific consensus on this issue would suggest that ingestion of microplastics does not significantly enhance bioaccumulation of POPs or other contaminant present in the environment" (ECHA 20020, p.41). PFOS and MPs were however detected in the guts of organisms, as the recent study by Navarathna et al. (2023) shows, suggesting MPs may transport PFAS into organisms after all.

Thermal decomposition

The DS summarizes in Annex B that thermal treatment of waste containing PFAS under conditions that comply with the BREF for municipal solid waste incineration (850 °C, 2sec residence) may not be suitable for the destruction of PFAS-containing waste (ECHA 2023b, p. 306f.). And the actual conditions in waste incinerators don't necessarily even comply with the BREFs. The DS stated further that "Limited PFAS releases from incineration plants are indicated in literature, and they depend on the type of material and type of incineration. Studies which take into account practical incineration conditions are scarce" (ECHA 2023b, p. 306f.).
Aleksandrov et al. (2019) tested PTFE combustion under typical waste incineration conditions and found no statistically significant evidence that the PFAS studied were created during the incineration of PTFE. The authors thus concluded that conditions of municipal solid waste incineration for PTFE are not resulting in PFAS emissions. The list of PFAS tested albeit was very limited and referred to PFAS which were not necessarily expected to be emitted from this combustion process. It however didn't include the Perfluoroalkanes (PFCs) CF4, C2F6, C3F6, C2F4, which are also PFAS. Wang (2022) takes in his PhD thesis a closer look at incineration of PFAS and lists these PFAS as end-products of thermal degradation of PTFE even at temperatures above 850 ºC (Wang 2022, p. 125). The PFCs, specifically tetrafluoromethane (CF4) and hexafluoroethane (C2F6) are also known to be very long-lived greenhouse gases with a high global warming potential. Wang (2022) identifies a strong implication of fluorinated products to escape thermal processes and to be released to the environment based on the lack of closed mass balances (>90% F accounted for) (Wang 2022, p. 16).

[5] "Hazards have also been associated with environmental pollutants, such as Persistent Organic Pollutants (POPs) or metals that adsorb/absorb to microplastic particles in the environment and which may subsequently be released if microplastics are ingested, leading to enhanced bioaccumulation and/or adverse effects from the 'transferred' substances." (ECHA 2020, p. 41)

EEB finds the arguments presented here to clearly support immediate action, and not to wait for end-of-pipe solutions. Instead there is a need to rectify the PFAS issue at source and to develop a broad and ambitious restriction for all PFAS included in the current scope of the dossier.

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