

Comments on ECHA's proposed restriction for PFAS

Director, Material Industries Division, Manufacturing Industries Bureau, Ministry of Economy, Trade and Industry of Japan is closely following ECHA's proposed restriction for perfluoroalkyl compounds and polyfluoroalkyl substances (PFASs), published on March 22, 2023, and submits the following comments for consideration and appropriate action.

Combining water and oil repellency, heat resistance, chemical resistance and non-light absorbing properties, PFASs are widely used as water repellents, surface treatment agents, emulsifiers, fire extinguishers, coating agents, high-performance resins, elastomers, refrigerants and electrical insulators. And as fluoropolymers, fluoroelastomers and fluorine gases, they are used in a wide range of industrial applications including semiconductors, automobiles, electrical and electronic equipment, batteries, refrigeration and air conditioning equipment, solar photovoltaic energy system, social infrastructure equipment (medical equipment, industrial monitoring, control, analysis, measurement equipment, etc.), and primary packaging containers for pharmaceuticals. In many cases, PFASs are used in fields that are important and essential for maintaining the functioning of society¹.

Allowing the use of PFASs to an appropriate extent is also important for achieving the objectives of the European Green Deal, a comprehensive initiative involving a series of policies in various sectors aimed at making Europe climate neutral by 2050. In particular, the Horizon Europe program will promote research and innovation on transport, including batteries, clean hydrogen, low-carbon steel making, circular bio-based sectors and the built environment² and PFASs are widely used as non-substitutable substances in these areas as well. Therefore, we consider it important to maintain the use of PFASs for critical applications in order to achieve the objectives of the European Green Deal.

1. Appropriate risk assessment

- (1) Paragraph 1 of Article 68 of the REACH states that the REACH shall introduce new restrictions or amend existing restrictions where there is an unacceptable risk to human health or the environment that needs to be addressed. The current proposal to restrict PFASs (the "Proposed Restriction") does not fulfill the requirements of Paragraph 1 of Article 68 of the REACH in that it uniformly covers all PFASs including PFASs which do not pose significant risk to human health or the environment, as explained in the following.
- (2) The Proposed Restriction considers all PFASs as a single group. It justifies this grouping based on the structural similarity that all PFASs have very persistent property of the perfluorinated parts in their molecules. However, each individual PFAS or PFASs subgroups have different physical, chemical and biological properties, and have different usage, the hazards and risks are different for PFAS by PFAS. Moreover, the terminal degradation product of the environmental degradation of PFASs are not common for all PFASs. Therefore, it is not reasonable to consider PFASs as a single group for regulatory risk management purposes.

¹ European Commission, March 2023, *Final Report- Supporting the Commission in Developing an Essential Use Concept*, <https://op.europa.eu/en/publication-detail/-/publication/69d5ea0d-d359-11ed-a05c-01aa75ed71a1/language-en/format-PDF/source-283635189>

² European Commission, *Communication from the commission-The European Green Deal*, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52019DC0640>

- (3) The definition of PFASs to be in the scope of the Proposed Restriction is consistent with the OECD definition of PFASs, which refers only to chemical structure. However, it should be noted that the OECD itself has stated that "[the general definition of PFAS] also does not conclude that all PFASs have the same properties, uses, exposure and risks." ³
- (4) The Proposed Restriction explains that the EU experience has shown that if PFASs are regulated individually or in specific groups, they can be expected to simply be replaced by slightly different but similarly risky PFASs that are not subject to restriction and therefore it is necessary to regulate "all PFASs with equivalent hazards and risks in a single restriction proposal, to avoid ... replacement by other PFASs". ⁴ However, this explanation is erroneous in its assumption that all PFASs have equivalent hazards and risks. The hazards and risks of PFASs are diverse, and the risks of substitution can be avoided by regulating those PFASs that pose "unacceptable risks to human health or the environment". Therefore, the Proposed Restriction that covers all PFASs including PFASs with no significant risks in the scope of regulation is not justified.
- (5) Annex XV of the REACH states that "the risks to be addressed with the restriction shall be described based on an assessment of the hazard and risks according to the relevant parts of Annex I and shall be documented in the format set out in Part B of that Annex for the Chemical Safety Report". However, as for the Proposed Restriction, such a process has not been followed for individual PFAS or PFASs subgroups involving the diverse physical, chemical and biological properties. The assessment of the hazard and risks required by related provisions of REACH is not adequately conducted.
- (6) Although the Proposed Restriction refers to the persistence of PFASs, it is not reasonable to conclude that a substance poses risks to human health or the environment only because it has the property of high persistence. The risks of a chemical substance should be assessed not only on the basis of the magnitude of its persistence, but also on the basis of its other hazards such as human health effects or ecotoxicity. Even if a substance has the property of high persistence, when it has no other harmful effects, a conclusion of risk assessment will not be that there is an "unacceptable risk to human health or the environment". It is not reasonable to conclude all PFASs involve "unacceptable risk to human health or the environment" without assessment of the properties of individual PFAS other than persistence. The Proposed Restriction also acknowledges that "for most PFASs there are insufficient data to adequately assess their effects on human health and the environment". ⁵
- (7) While the Proposed Restriction may take into account the precautionary principle, Paragraphs 2 and 3 of Article 191 of the Treaty on the Functioning of the European Union (TFEU) obliges

³ OECD, 2021, *Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance*, <https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/terminology-per-and-polyfluoroalkyl-substances.pdf>

⁴ ECHA, *Proposal for a Restriction Version 2*, P21 1.1.2. Justification for grouping stating that "this observation provides the main motivation to include all PFASs having equivalent hazard and risk in a single restriction proposal, to avoid regrettable substitution by other PFASs."

⁵ ECHA, *Proposal for a Restriction Version 2*, P13 1. Problem identification stating that "[a]lthough for most PFASs there are insufficient data to adequately assess their effects on human health and the environment, increasing research efforts that progressed beyond PFOS and PFOA reported similar adverse effects for other PFASs."

environmental policy by the European Union to take into account available scientific and technical data while adopting the precautionary principle.⁶ However, although there are the diverse physical, chemical and biological properties of different individual PFAS or PFASs subgroups, the Proposed Restriction does not clearly identify and characterize hazards for individual PFAS or PFASs subgroups, assess exposure, nor identify risks. Some PFASs are used only in enclosed spaces where exposure to the environment is restricted to very limited amounts, and the risks caused by such uses of PFASs to human health or environmental is even lower. The lack of risk identification may also lead to the possibility of replacing PFASs with non-PFAS alternatives that pose a higher risk of adverse effects on human health or the environment, and thus the Proposed Restriction may not contribute to achieving the objectives of the REACH. Again, it is not reasonable to consider PFASs as a single group for regulatory risk management purposes. We request that these assessments will be conducted sufficiently for individual PFAS or PFASs subgroups by the Risk Assessment Committee and during the review of the report after the public consultations period.

- (8) It should be noted that the Stockholm Convention on Persistent Organic Pollutants (POPs Treaty) – a treaty that shares common objectives with the Proposed Restriction and to which 186 countries and regions are parties – restricts the production and use of some PFASs such as perfluoro octanoic acid (PFOA) and perfluoro octane sulfonic acid (PFOS), but does not restrict the production and use of all PFASs. It is considered that there is currently no international consensus that all PFASs pose significant risks, and therefore, careful discussion is required in determining whether all PFASs are indeed posing significant risks.

2. Consideration of socio-economic impacts

- (1) Paragraph 1 of Article 68 of the REACH provides that when adopting a new restriction, "any such decision shall take into account the socio-economic impact of the restriction, including the availability of alternative substances". The socio-economic impact includes, according to Annex XVI of the REACH, "the impact on industry (e.g., manufacturers and importers)", "the impact on all other actors in the supply chain, downstream users and associated businesses in terms of commercial consequences, ... taking into account general trends in the market and technology", and "wider implications on trade, competition and economic development (in particular for SMEs and in relation to third countries)". We understand that these points will be taken into account in the consideration by the Socio Economic Assessment Committee. Since the socio-economic impacts of the PFAS restriction is extremely high, we request that the above process in particular be conducted carefully and be fully assessed and reflected in the final proposal. As it is expected that each industrial sector, industry association, and individual companies involved in PFASs will submit their opinions to the public consultations, we request that those opinions be contemplated and that the adverse socio-economic impact be minimized. As mentioned above, PFASs are used as "essential use" in a wide range of industries and no alternative substance has been identified for many PFASs at this point. Therefore, no quantitative socio-economic impact can be demonstrated for the restriction. Such impacts should also be fully considered.

⁶ Official Journal of the European Union(C 202/132), 6 July 2016, *Consolidated version of the Treaty on the Functioning of the European Union Part Three - Union Policies And Internal Actions Title XX – Environment Article 191 (ex Article 174 TEC)* https://eur-lex.europa.eu/eli/treaty/tfeu_2016/art_191/oj

- (2) If the Proposed Restriction is implemented as currently announced, trade in essential goods in which PFASs are used will be severely restricted and supply chains around the world will be severely disrupted. It should be noted that even if alternative substances are currently being developed, it will take a considerable amount of time availability is assured, as subsequent demonstration and evaluation will need to be repeated in both of upstream and downstream industries. In addition, for substances for which alternative substances have not yet been identified, future research and development must be conducted involving trial and error, and even a 12-year derogation period may not be sufficient to ensure their feasibility and availability. In this regard, a "review clause" should be considered that would allow for an extension of the transition period in the event that a suitable alternative substance cannot be practically available by the prescribed date.

3. Consistency with the WTO/TBT Agreement

- (1) Article 2.2 of the TBT Agreement stipulates that "technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create."
- (2) Although some PFASs are considered to have significant risks, there are considerable differences among PFASs in terms of hazards and risks. However, as indicated in Section 1 above, the Proposed Restriction uniformly covers all PFASs including PFASs which do not pose significant risks to human health or the environment, without sufficient scientific and rational basis. Furthermore, as indicated in Section 2 above, since many PFASs are used in a wide range of sectors and no alternative substance has been identified for many PFASs, a full ban on their use, trade, etc. across all PFASs would be extremely trade restrictive. Therefore, the Proposed Restriction which would introduce a uniform restriction on the manufacture, use or placing on the market of all PFASs, including PFASs that do not pose significant risk to human health or the environment would be inconsistent with Article 2.2 of the TBT Agreement as the Proposed Restriction is more trade-restrictive effect than necessary to fulfil the legitimate objectives.

We believe that the EU will provide a reasonable interval in accordance with Article 2.12 of the TBT Agreement when introducing the Proposed Restriction. In light of the above, we further request that the EU appropriately consider and examine the comments already submitted or to be submitted by industries and other stakeholders and limit the scope of the restriction to an appropriate range for the regulatory objectives of protection of human health and the environment.