

Comments on the PFAS European Restriction Proposal (Final Draft)

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 would like to submit the following comments for consideration and appropriate action.

Combining water and oil repellency, heat resistance, chemical resistance and 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, social infrastructure equipment (Medical equipment, industrial monitoring, control, analysis, measurement equipment, etc.), and primary packaging containers for pharmaceuticals. In many cases, PFASs are used for important and essential use for maintaining the functioning of society¹.

Allowing the use of PFASs to the 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 activities in the areas of batteries, clean hydrogen, low-carbon steel production, the circular bio-based sector, and the built environment² and PFASs are widely used as non-substitutable substances in these sectors 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 PFASs for which unacceptable risk to human health or the environment is not recognized, due to the following reasons.
- (2) The definition of PFASs in the Proposed Restriction is consistent with the OECD definition of PFASs, which refers only to chemical structure. However, the definition is too broad and does not take into account the diverse physical chemical and biological properties of different individual PFAS or PFASs subgroups, making it unsuitable for regulatory risk management purposes. 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

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 OECD, 2021, *Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances*:

- (3) Annex XV of the REACH states that “[t]he 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, it is not clear whether such a process has been followed for the regulated PFAS. If there is sufficient scientific basis for a finding that restricted PFASs pose an unacceptable risks to human health or the environment, the above hazard and risk assessment should be disclosed.
- (4) Although the Proposed Restriction refers to the persistence of PFASs, persistence does not in itself indicate harmfulness in terms of potential adverse effects or risks to human health or the environment. It is only when a substance has harmful effects that are detrimental to human health and the environment that the persistence and accumulation of harmful effects due to persistence becomes problematic. However, when a substance has no harmful effects in the first place, it is hard to state that there is an "unacceptable risk to health and the environment" caused by persistence. With respect to risks other than persistence, the Proposed Restriction does not identify the characteristics of individual PFASs, specific hazards, and the reasons why PFASs pose unacceptable risks. The Proposed Restriction also acknowledges that "for most PFASs there are insufficient data to adequately assess their effects on human health and the environment".⁴ The available data on bioaccumulation potential are not sufficient to demonstrate the bioaccumulation potential of all PFASs in the environment. 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 environmental policy by the European Union to take into account available scientific and technical data while adopting the precautionary principle.⁵ However, the Proposed Restriction does not clearly identify and characterize hazards, assess exposure, nor identify risks. Some uses of PFASs may be in enclosed spaces where exposure to the environment is restricted to very limited amounts, and the risk caused by such uses of PFASs to human health and environmental protection 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 and the environment, and thus the Proposed Restriction may not contribute to achieving the objectives of the REACH. We request that these assessments will be conducted sufficiently by the Risk Assessment Committee and during the review of the report after the public consultations period.
- (5) 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

Recommendations and Practical Guidance, <https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/terminology-per-and-polyfluoroalkyl-substances.pdf>

⁴ ECHA, *Proposal for a Restriction*, P13 1. Problem identification, however 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.

⁵ 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

proposal, to avoid ... replacement by other PFASs”.⁶ However, this explanation is materially erroneous in its assumption that all PFASs have equivalent hazards/risks. As noted above, the hazards and risks of PFASs are diverse, and the risk of substitution can be avoided by limiting the scope of regulation to those PFASs with equivalent hazards and risks that can be considered "unacceptable risks to human health and the environment"; including PFAS with no such recognized risks in the scope of regulation is not justified.

- (6) 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 use of Per Fluoro Octanoic Acid (PFOA) and Per Fluoro Octane Sulfonicacid (PFOS), but does not restrict the use of all PFASs. It is considered that there is currently no international consensus that all PFASs are hazardous or risky, and therefore, careful discussion is required in determining whether all PFASs are indeed hazardous or risky.

2. Consideration of socioeconomic impacts

- (1) Paragraph 1 of Article 68 of the REACH provides that when adopting a new restriction, "[a]ny 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)", "[t]he 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. 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, hence it is assumed that no alternative substance has been identified at this point, and therefore no quantitative socio-economic impact can be demonstrated for the restriction. Such impacts should also be fully considered.
- (2) If the Proposed Restriction are implemented as currently announced, will be implemented, 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 before being feasibly available, 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, research and development must be conducted through trial and error in the future, and even a 12-year grace period may not be

⁶ ECHA, *Proposal for a Restriction*, P20 1.1.2. Justification for grouping (stating that "[t]his 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.").

sufficient to confirm 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 risk, as indicated in 1.above, there are considerable differences among PFASs in terms of their direct and harmful effects and properties of PFASs, which are not recognized as common to all PFASs. In addition, many PFASs are considered to be non-substitutable substances in a wide range of sectors, and as indicated in 2. above, a full ban on their use, trade, etc. would be extremely trade restrictive. Therefore, a uniform finding of "an unacceptable risk to human health or the environment" for all PFASs, including PFASs that have not been proven to pose an unacceptable risk and PFASs that are used or may be used as non-substitutable substances, lacks sufficient scientific and rational basis, and it 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 sufficient grace period 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 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.