

**Comments on the EU’s proposed restriction for PFASs
(Provisional Translation)**

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Subcommittee on Environmental Risk, Committee on Environment
Keidanren (Japan Business Federation)

Keidanren is a comprehensive economic organization with a membership comprised of around 1,500 companies and industrial associations representative of Japan. Its members are diverse; they span the full range of manufacturing industries including chemicals, textiles, electrical and electronics, automotive, steelmaking, paper, cement, machinery, and shipbuilding, as well as service industries including electricity, oil, and gas supply; mining; and construction. As a result of globalization, our member companies’ supply chains cover a wide geographical area, including the EU.

On behalf of the Subcommittee on Environmental Risk Response, the organization within Keidanren responsible for environmental risk policy, we submit the comments below as part of the public consultation¹ on the proposed restriction for PFASs (the “Proposed Restriction”) announced by the European Chemicals Agency (ECHA) in March this year.

(1) Relevance of assessing effects on human health or the environment

The Proposed Restriction² sets out an approach of treating all PFASs as a single group and banning their manufacture, placing on the market, and use. The relevant definition of PFASs is based on the OECD publication *Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance* (2021),³ this definition, however, classifies PFASs according to their chemical structure,⁴ and not according to their harmfulness or other properties.

As noted in “1. Problem identification” and other parts within the Proposed Restriction, for most PFASs there are insufficient data to adequately assess their effects on human health and the environment. The Proposed Restriction assesses inability to degrade fully and high

¹ <https://echa.europa.eu/de/restrictions-under-consideration/-/substance-rev/72301/term>

² [Annex XV reporting format 040615 \(europa.eu\)](#)

³ <https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/terminology-per-and-polyfluoroalkyl-substances.pdf>

⁴ OECD, *Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance*, p. 19

persistence as “hazardous properties,”⁵ but it has not been proved that these properties have adverse effects on human health or the environment.

In our opinion, regulation should not simply treat all PFASs as a single group and uniformly ban their manufacture, placing on the market, and use. Instead, the risks of each individual substance in terms of their effects on human health or the environment should be assessed based on scientific findings before considering what regulation is required. Note that Article 68, paragraph 1 of REACH also stipulates that new restrictions shall be introduced, or existing restrictions shall be amended, where there is an unacceptable risk to human health or the environment arising from the manufacture, placing on the market, or use of substances.

In particular, the restriction should not apply to substances that are not absorbed by the human body as their high molecular weight makes them virtually insoluble in water, such as fluoropolymers, or to those fluorine gases for which no hazards can be identified.

(2) The need for sufficient consideration of socio-economic impacts

PFASs possess various properties not found in other substances, such as heat resistance and chemical stability, and have therefore been used as essential materials in a wide range of applications including energy (fuel cells, lithium-ion batteries, etc.), semiconductor manufacturing, automotive components, machinery and devices of all kinds, telecommunications, healthcare, construction, and household goods. If the manufacture, placing on the market, and use of PFASs were to be uniformly banned, economies and societies could be severely impacted. The concern is that their exclusion from markets while alternative substances remain unfeasible or unavailable could not only cause wide-ranging negative impacts on people’s daily lives and hinder the achievement of green transition as a policy objective, but could also affect countries’ ability to ensure their own energy security and economic security.

Furthermore, as supply chains continue to extend their global reach, such a restriction could severely disrupt the international trade for products in which PFASs are used. Creating more obstacles to international trade than are necessary to fulfil a legitimate policy objective is inconsistent with Article 2.2 of the Technical Barriers to Trade (TBT) Agreement.⁶ Therefore,

⁵ The Proposed Restriction, pp. 20–21

⁶ “Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. . . . In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information, related processing technology or intended end-uses of products.”

this restriction should not be introduced without thoroughly examining the balance between impacts on supply chains and international trade, and necessity in terms of fulfilling policy objectives, including consistency with the TBT Agreement and the EU's other international obligations.

In addition to the above, we regard the restriction's exceptions and derogations as inappropriate. The Proposed Restriction allows a five-year derogation in the case of PFASs for which alternative substances are in the development phase or are not available in sufficient quantities and a 12-year derogation in the case of PFASs for which alternative substances have not yet been identified. It also allows time-unlimited derogations that apply only to certain specific uses. However, alternative substances even in the development phase are not necessarily able to be deployed, and sometimes development can take longer than expected. Moreover, identification and development of alternative substances imposes an additional burden on companies. This uncertainty and the additional burden on companies are further reasons why thousands of different PFASs should not be made subject to the restriction as a single group.

(3) Conclusion

For the reasons outlined above, PFASs subject to the restriction should be limited to substances for which effects on human health or the environment have been established by means of scientifically based risk assessment, while also taking socio-economic impacts into account.

Moreover, substances that will be subject to the restriction should be determined by considering a broad range of expertise, including opinions submitted as part of the public consultation, cautiously assessing whether alternative substances are available for each. In conjunction with this approach, the necessary provisions should be put in place to ensure that a PFAS can be excluded from the scope of the restriction or its derogation period can be extended if socio-economic impacts become apparent following introduction of the new restriction or there is insufficient prospect of an alternative substance being developed and implemented during the derogation period.

Additionally, to avoid disruption of global supply chains and negative impacts on international trade, it is essential to conduct exhaustive discussions according to WTO procedures (e.g., via the TBT Committee), premised on ensuring consistency with the TBT Agreement and other international rules. At the same time, it is necessary to engage in adequate dialogue with the national governments and private sectors of Japan and other countries with an interest in this issue, and incorporate their opinions into the restriction.