

Opinion against the EU/ECHA PFAS Restriction Act

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Sanming Hexafluo Chemicals Co., Ltd., a manufacturer of fluorinated chemicals in China, has been committed to the R&D and production of environmental-friendly oxy-composed fluorinated chemicals, and has made certain contributions to the replacement of PFOA and PFOS. We continuously support national & international chemical regulation and EU's efforts to reduce the risk of hazardous substances. We are also seriously striving in order to meet ECHA's requirements of chemicals. However, we believe that the PFAS restriction proposed by five EU members is too radical & excessive, as it proposed to restrict more than 10,000 organic fluorinated compounds (PFAS).

Therefore, we intend to make the following comments on ECHA's open consultation, which expresses the concerns about the radically proposed PFAS restrictions:

REACH Term 68 (1) refers to the scope of unacceptable risks on human health or environment that need to be restricted.

The proposal cites "persistent chemicals, biological concentrations, mobility, potential for long-distance transport, accumulation in plants, global warming potential, and toxicological effects" as the arguments/reasons for the restriction. Among all these properties, "persistence" applies to all targeted organic fluorine compounds (PFAS), but others are only associated with certain compounds. Therefore, we hold against the proposal to mark all the PFAS as "risk to human health or the environment" and restrict solely according to the attribute of "persistence".

In addition, some arguments regarding fluorinated compounds are also incorrect. For example, it would be inappropriate to mark all the organic-fluorinated chemicals as having the properties of biological concentration potential and toxicological effects. To implement new restricting regulations over PFAS, there has to be quantitative analysis and discussion on each type of PFAS's risk on human health and the environment.

The proposed PFAS restriction would be violating some of the in-force European/international rules and agreements for the following reasons:

1. The proposed restriction will hinder the implementation & accomplishment of the EU Green Deal:

Having features such as anti-water/oil, heat-resistance, chemical-resistance, non-absorption, etc., PFAS have been broadly used in waterproof agents, surfactants, emulsifiers, fire extinguishers, coatings and extensive industrial applications such as

semiconductors, automobiles and batteries. Many of these applications are considered as "basic applications" in modern society.

Making full use of PFAS is critical to the EU Green Deal, which is a comprehensive initiative, including a series of policies and regulations in different fields that were made to achieve Europe climate neutral by 2050. For example, the "Horizon Europe" project has supported research and innovation activities in the area of transportation, including batteries, clean hydrogen, low-carbon steel manufacturing, and periodic biological environments.

Therefore, we believe that the proposed restriction on all PFAS, including the PFAS that have essential benefits to the EU Green Deal, will be intrinsically blocking the implementation and accomplishment of the EU Green Deal.

2. The PFAS restriction proposal is based on classifying all the PFAS as one single category.

When classifying PFAS as one single category, the proposed restriction would be restricting most of the PFAS that have not been evaluated as "having unacceptable risks", which is a violation of the *REACH Term 68 (1)*:

REACH Term 68 (1) made it clear that, only when a specific substance has been proved to have unacceptable risk to human health or the environment risk according to annex 13 and annex 15 (and by cross-reference annex 1 and annex 13) can we implement a restriction. The risk assessment includes hazard identification, feature recognition and exposure risk assessment.

By classifying PFAS as one single category, the proposed PFAS restriction would be restricting many PFAS that did not been through a risk assessment and do not have unacceptable risks, which is a blatant violation of *REACH Term 68 (1)*.

Specifically, the proposed PFAS restriction is based on OECD (Organization for Economic Co-operation and Development)'s definition of PFAS, which, as the proposed restriction acknowledged themselves, merely based on chemical structure and did not take the hazardous features or risks of PFAS into consideration.

Consequently, the definition covers about 10,000 substances that have very different physical, chemical, and biological properties. This extended definition did not take specific PFAS or subgroups of PFAS with distinct features into account and is therefore not suitable for regulatory risk management purposes.

Actually, even the OECD itself acknowledges that this definition "does not draw conclusions that all PFAS have the same use, exposure and risk attributes" and that it can only be used as a starting point for reference as it "may be seen as too extended".

In particular, based on OECD's PFAS definition, it is legally and scientifically impractical to conduct risk assessment. By classifying all PFAS as one single category without considering specific and different attributes of different PFAS subsets, the proposal recognized "persistent" as the "critical hazardous attribute" that "triggers equal hazards". However, "persistence" is neither a sign of hazardous attribute nor

a indication of a risk. Being persistent does not justify a determination that a substance is of same concern as PBTs/vPvBs. It also can not be considered as an "unacceptable risk" defined by *REACH Term 68 (1)* to justify the proposal.

Therefore, "persistence" can only be used to support the proposal when it's in conjunction with other attributes included in REACH/CLP regulations, such as bio-accumulation, eco-toxicity and not separately.

Except the property of being persistent, the proposed PFAS restriction did not identify any other hazardous attributes of PFAS in common. It only complemented some of the properties of non-PFAS substances. In fact, the evidence provided on the proposal only refers to some subsets of PFAS (mainly long-chain PFAS) and lacks of other PFAS subsets' data, which is not convincing to restrict all the PFAS.

For example, on page 28, the proposed restriction acknowledges that "for most PFAS, data on bio-accumulation behavior is absent, or insufficient," so the provided data on the bio-accumulation potential of PFAS is insufficient to confirm the bio-accumulation of all PFAS in the environment.

As for the eco-toxicity, the proposal was noted that PFAS includes a large number of different substances with heterogeneous properties and their eco-toxicity assessment is very complicated. It then concludes that bio-accumulation potential and eco-toxicity are expected to differ between different PFAS due to the "high diversity" of PFAS, and yet did not draw a comprehensive conclusion with B/Vb & T criteria for each PFAS substance (page. 47).

Lacking of sufficient evidence, the proposed PFAS restriction have failed to conduct risk assessments (including hazard identification, feature recognition and exposure risk assessment) to demonstrate the unacceptable risks of all PFAS substances that are proposed to be restricted. In some applications, PFAS can be used in enclosed spaces, where the exposure to the environment is extremely limited, and the risk for human health and environment is even smaller. It is also possible that, without describing the specific risks of each PFAS, the proposed restrictions will eventually lead to non-PFAS alternatives, which are likely to be even more harmful to human health and the environment.

Reference:

- [1] Henry, B. J.; Carlin, J. P.; Hammerschmidt, J. A.; Buck, R. C.; Buxton, L. W.; Fiedler, H.; Seed, J.; Hernandez, O. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. *Integrated Environmental Assessment and Management*, 2018, 14, 316-334.
- [2] Korzeniowski, S. H.; Buck, R. C.; Newkold, R. M.; El Kassmi, A.; Laganis, E.; Matsuoka, Y.; Dinelli, B.; Beauchet, S.; Adamsky, F.; Weilandt, K.; Soni, V. K.; Kapoor, D.; Gunasekar, P.; Malvasi, M.; Brinati, G.; Musio, S. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: fluoroplastics and fluoroelastomers. *Integrated Environmental Assessment and Management*, 2023, 19,

326-354.

[3] Andersen, M. P. S.; Kyte, M.; Andersen, S. T.; Nielsen, C. J.; Nielsen, O. J. Atmospheric Chemistry of (CF₃)₂CF-C≡N: A Replacement Compound for the Most Potent Industrial Greenhouse Gas, SF₆. *Environmental Science and Technology*, 2016, 51, 1321-1329.