

July 31, 2020

Comments for call for evidence on PFASs

Dear Sirs and Madams:

On behalf of Japan Cosmetic Industry Association (JCIA) representing interest of more than one thousand Japanese cosmetic companies, I would like to express my sincere gratitude to your great efforts to tackle the emerging issues such as PFASs to protect and preserve the global environment. At the same time, we concern serious negative consequences to international cosmetic industry caused by the upcoming restriction of PFASs in near future. We are submitting the following comments for call for evidence on PFASs.

1. Definition of PFASs

According to Supplementary-Document-to-CfE provided by ECHA, as the scope of the Call for Evidence on PFASs, “**Substances that contain at least one aliphatic -CF₂- or -CF₃ element**” have been selected, shown as the general structure formulas in Figure 1.

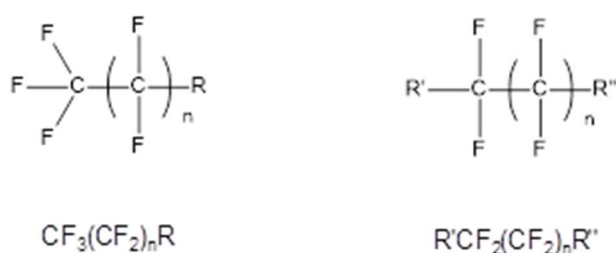


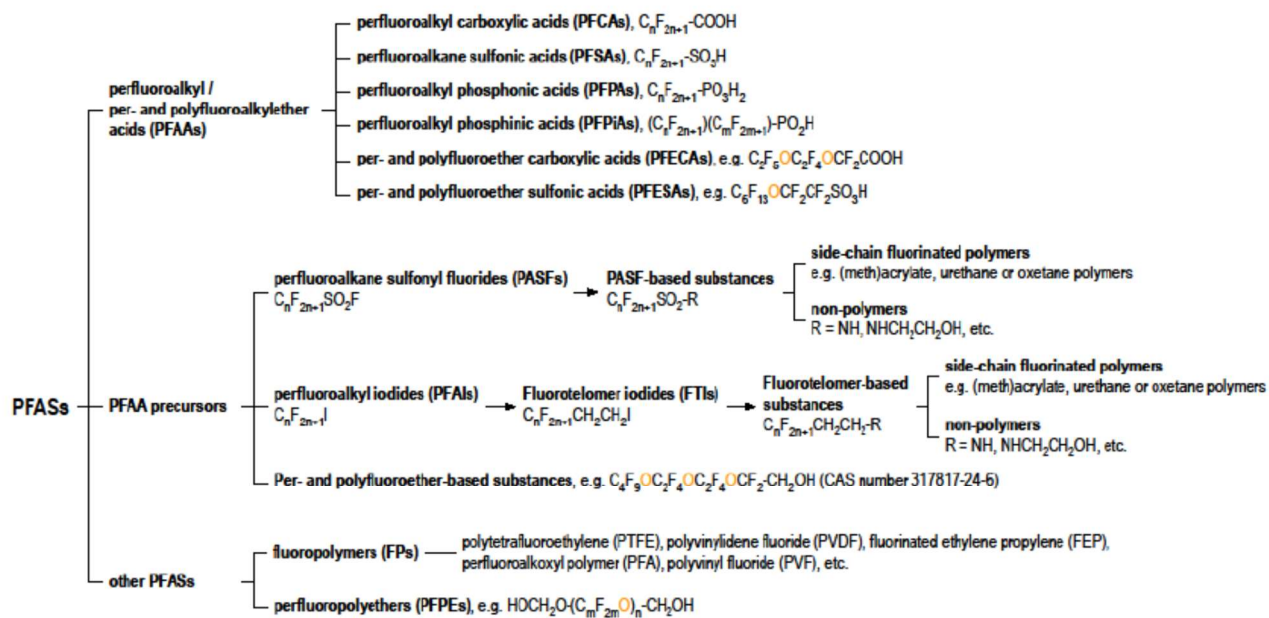
Figure 1. General structure formulas representing the scope of PFAS relevant for this Call for Evidence. R, R', R'' = any chemical group, $n \geq 0$.

The definition on PFASs in the call for evidence is very broad enough to include more than 4,700 substances. It is even broader than the OECD definition which provides internationally harmonized recognition. Considering the difference from OECD definitions and a wide range of chemical structure of substances defined in the REACH restriction call for data, JCIA hopes the authorities of five countries to reconsider their definition.

OECD discloses a new comprehensive Global Database of Per- And Polyfluoroalkyl Substances (PFASs)¹ which includes 4,730 PFASs and their methodology report². According to the OECD methodology report, it focuses on those PFASs that contain a perfluoroalkyl moiety with three or more carbons (i.e. $-\text{C}_n\text{F}_{2n-}$, $n \geq 3$) or a perfluoroalkylether moiety with two or more carbons (i.e. $-\text{C}_n\text{F}_{2n}\text{OC}_m\text{F}_{2m-}$, n and $m \geq 1$). It is noted that OECD definition on PFASs excludes a perfluoroalkyl moiety with one or two carbons (i.e. $-\text{C}_n\text{F}_{2n-}$, $n = 1$ or 2). In other words, $\text{CF}_3(\text{CF}_2)_n\text{R}$ and $\text{R}'\text{CF}_2(\text{CF}_2)_n\text{R}''$ ($n = 0$ or 1) in the definition of the authorities of five countries is not included in OECD definition. The schematic overview of the structural

categories of identified PFASs by OECD is shown as the Figure 2 of the report.

a) Commonly recognised per- and polyfluoroalkyl substances (PFASs)



b) Other highly fluorinated substances that match the definition of PFASs, but have not yet been commonly regarded as PFASs

perfluorinated alkanes (C_nF_{2n+2})

perfluorinated alkenes (C_nF_{2n}) and their derivatives (e.g. [(CF₃)₂CF]₂C=C(CF₃)(OC₆H₄SO₃Na), CAS number 70829-87-7)

perfluoroalkyl alcohols (C_nF_{2n+1}OH; e.g. (CF₃)₃C-OH, CAS number 2378-02-1), perfluoroalkyl ketones (e.g. C_nF_{2n+1}C(O)C_mF_{2m+1}) and semi-fluorinated ketones (e.g. C_lF_{2l+1}C(O)C_mH_{2m+1})

side-chain fluorinated aromatics, e.g. C_nF_{2n+1}-aromatic rings

some hydrofluorocarbons (HFCs, e.g. C_nF_{2n+1}C_mH_{2m+1}), hydrofluoroethers (HFEs, e.g. C_nF_{2n+1}OC_mH_{2m+1}) and hydrofluoroolefins (HFOs, e.g. C_nF_{2n+1}CH=CH₂) that have a perfluoroalkyl chain of certain length

Figure 2. Schematic overview of the structure categories of identified PFASs

PFASs are theoretically known to be highly persistent, because the carbon-fluorine bonds are one of the strongest chemical bonds in organic chemistry. Experimental data have shown some of them are highly persistent in water/soil/sediment or any other relevant environment.

However, the chemical structure of PFASs is widely diverse and that may lead widely diverse of physiochemical or hazardous characteristic property of PFASs. In fact, it has been reported that some PFASs have different physicochemical properties such as water solubility depending on the chain length, and as a result, have different bioaccumulation potential. The following statements can be found in the report on perfluoroalkyl substances by The Agency for Toxic Substances and Disease Registry (ATSDR)³ and UNEP⁴.

- short-chain species have relatively good solubility in water and alcohol³

- The bioaccumulation potential of perfluoroalkyls is reported to increase with increasing chain length³
- The short-chain substances are not as bioaccumulative as the longer-chain substances such as PFOA and PFOS.³
- PFAAs (perfluoroalkyl acids) with shorter chain are in general less bioaccumulative.⁴

As can be seen from these facts, short-chain PFASs have lower bioaccumulation. The definition on PFASs of the authorities of five countries is very broad so that it is possible to include a substance whose has low or no bioaccumulation. It is appropriate and reasonable to exclude them from the scope. With this in mind, the PFAS scope should be consistent with OECD definition as mentioned above.

2. Justification of restriction

In the Supplementary-Document-to-CfE, it is described that only environmental hazardous characteristic property common for all PFASs is persistency. And, it says *“All PFASs subject to the description above (as defined in Section II.) are, or ultimately transform into, persistent substances.”*

According to REACH article 67&68 and guidance on restriction: unacceptable risk to the environment should be judged with case by case approach, not only fate but also toxicity(hazard) and exposure scenario throughout the whole life cycle of the chemicals. Thus, the only “persistent” is not the basis for restriction under REACH.

Substance listed in Annex XVII are restricted under REACH described in the Title VIII as “RESTRICTIONS ON THE MANUFACTURING, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, PREPARATIONS AND ARTICLES”. Annex XVII contains 70 entries (as of July 2020). There is no substance registered in this Annex for the reason of persistency only.

As quoted above, general principle of restriction of chemicals under REACH is to restrict chemicals not only based on persistency, but by comprehensive environmental risk assessment. Restriction of PFASs only by persistency is not consistent with the principles of the existing regulatory framework for restriction of substances.

In addition, the definition on PFASs here is very broad so that it is possible to include a substance whose persistency in laboratory or environment is remaining unproven. Scientific

evidence is not enough for each substance among PFASs proposed to restrict, from the standpoint of persistency.

In conclusion, only substances which fulfill the criteria defined, like PBT/vPvB, should be regulated under REACH restriction and more than 4,700 substances defined as PFASs should be assessed not as one chemical group but as an individual substance one by one or smaller chemical groups. Finally, regarding the use information for analysis of REACH restriction, we highly hope the competent authorities of five countries will consider environment impacts with science-based approaches.

We highly appreciate the opportunity to present our opinions on this call for evidence and sincerely hope taking into the consideration those comments.

Respectfully yours,

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References:

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