HEAL comments on proposal to identify 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acylhalides as an SVHC

Reasons for proposing

- Equivalent level of concern having probable serious effects on the environment (Article 57f)
- Equivalent level of concern having probable serious effects on human health (Article 57f)

HEAL fully supports the proposed identification of this set of substances as substances of very high concern for the reasons outlined in the supporting dossier, which we find very strong and comprehensive[1].

The so-called "GenX process" has increasingly been used as a replacement for PFOA since 2012. This process includes the compounds HFPO-DA, the precursor FRD-903, and the ammonium salt FRD-902. In water, FRD-902 and FRD-903 dissociate to HFPO-DA. We use the term "HFPO-DA" here to include these other components of the GenX process, as well as the potassium salt. HFPO-DA is a very persistent and very mobile substance in the aquatic environment; thus use of GenX will lead to long-term and worldwide contamination, with exposure potentials not only in the polluted communities, but around the world. (HFPO-DA appears to be an excellent example of the "persistent—mobile—toxic" PMT/vPvM criteria proposed last year by Germany). Exposure to HFPO-DA can happen through water ingestion, air pollution or the consumption of food wrapped in GenX-containing materials. The GenX chemicals have been linked to a series of concerns for human health, including toxicity for the liver, the kidney, the blood, and the immune system. It is also suspected that GenX may be a carcinogen for humans – which necessitates further investigation in other studies than that performed for the rat so far.

GenX chemicals are regularly found in European waters – surface water, groundwaters, drinking water - recent examples include sampling in Dutch waters (close to a fluorochemical production plant near Dordrecht)[2] as well as Italian (Veneto) waters – as highlighted in the dossier. This raises concerns about wide dispersion in the environment and broad exposure of the population via the environment. The European biomonitoring initiative HBM4EU has prioritised PFAS as a group of chemicals to monitor and stressed the concern linked to ever increasing use of GenX as a replacement to PFOA in its scoping document, noting especially the "expected increase in production and use" as GenX replaces existing PFAS compounds and processes, and that GenX is "partially used in food contact materials"[3].

The potential endocrine disrupting effects of the PFAS chemicals are the source of grave concerns for human health. Although endocrine-disrupting properties of the GenX chemicals have been little studied thus far, they appear to be broadly similar to those of the earlier PFAS like PFOA and PFOS. The binding assays by Li et al. (2019), described in the Annex XV report, indicate that HFPO-DA and HFPO-TA bind human and mouse PPARγ, an important route of toxicity for GenX compounds, in a way similar to PFOA. They also demonstrated dose-dependent PPARγ-mediated luciferase transcription activity, with HFPO-DA having an activity level similar to PFOA, as well as increased lipid accumulation and adipogenesis activity, particularly in human cells. These results indicate a similar concern for PPAR-mediated HFPO-DA activity to that of PFOA and PFOS.

[1] https://echa.europa.eu/documents/10162/ef1b1606-b234-2ce5-e159-2ab89d61bfbc
[2] https://www.ncbi.nlm.nih.gov/pubmed/28853567
[3] https://www.hbm4eu.eu/mdocs-posts/scoping-documents-for-2018/

More recently, a study by Conley et al (2019)[4] in Sprague-Dawley rats concluded that "HFPO-DA exposure produced multiple effects that were similar to prior toxicity evaluations on PFAS, such as perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA)", although requiring higher concentrations. Moreover, these results are relevant: the blood concentration in the lowest dose group was only 4x higher than documented occupational exposures.

In sum, these GenX compounds share the same troubling persistence, mobility, and toxicity with the earlier (now phased out) PFAS compounds like PFOA and PFOS. Early studies of their endocrine activity indicate that they are likely to have similar effects as well. Their persistence and mobility will lead to irreversible contamination of water bodies as well as worldwide exposures, as was the case for previous PFAS compounds. Given the expected increase in the use of GenX as it replaced other PFAS processes worldwide, these compounds are clearly cause for an "equivalent level of concern" per Article 57(f).

Due to all the elements mentioned above, we believe that HFPO-DA qualifies for identification as an SVHC.

[4] doi: 10.1289/EHP4372