

2023-09-25

Case number

HaV 03031-2023

European Chemicals Agency

Telakkakatu 6 P.O. Box 400 FI-00121

Helsinki Finland

## Comments from the Swedish Agency for Marine and Water Management on the restriction report – Proposal for restricting per- and polyfluoroalkyl substances (PFAS)

The Swedish Agency for Marine and Water Management welcomes the Annex XV report on the restriction of per- and polyfluoroalkyl substances (PFAS) and supports the proposed Annex XVII entry.

The agency shares the rationale behind the proposed scope of the restriction, i.e. simultaneously restricting all use (with some derogations) of an entire group of substances. The main reasons why the PFAS restriction proposal must aim at limiting emissions of all PFASs to a minimum are:

- Risks of PFAS-emissions are of non-threshold nature, i.e., the intrinsic properties of PFAS, foremost their persistence and mobility in combination with negative effects on human health and environment, will inevitably lead to rising exposure levels and negative effects.
- PFAS exposures to humans via the aquatic environment already exceeds what is defined as a safe level<sup>1,2</sup>, i.e., exposures to multiple PFAS cannot, even to date, be avoided and combination effects are expected.
- Remediation of PFAS-polluted water and land is technically challenging or in some instances not even possible as well as extremely costly to society, not only in monetary terms but also regarding depletion of resources.
- There are alternatives to PFAS in many applications, and restriction per se is a very strong incentive to stimulate further development of alternatives;
- A complete PFAS ban is proportionate to the risk and will be economically beneficial to society in the long run.

The Swedish Agency for Marine and Water Management want to emphasise the dignity of the problem with PFAS pollution from a water management perspective and, highlight the substantial costs arising from PFAS pollution of the aquatic environment - which also underlines the importance of limiting the derogations under RO2 as much as possible.

## Aquatic environmental monitoring and risk characterisation for human health via the aquatic environment

Environmental monitoring data has shown that PFASs are ubiquitously found in the environment. PFASs are detected in samples of water, sediment and biota from both freshwater and marine environments<sup>3-12</sup>. Most PFASs are mobile in water and/or accumulate in biota, and both lead to unavoidable exposure of humans and the environment.

Reliable analytical methods for PFASs are necessary to dimension the problem and to follow the outcome of regulatory measures. The concentrations of PFASs in the environment are increasing but the composition of different PFASs is changing which suggests that regulated PFASs are replaced by new PFASs. Studies on extractable organic fluorine (EOF) and Adsorbable Organic Fluorine (AOF) in environmental samples and mass balance analysis show that significant fractions of organofluorine are unknown and therefore not captured by monitoring using only targeted PFAS analysis<sup>13</sup>. The ongoing efforts to develop and standardize the determination of total PFASs are important for regulatory implementation<sup>2</sup>.

The Swedish Agency for Marine and Water Management supports the conclusion that PFASs should be treated as non-threshold substances for the purpose of risk assessment in a similar manner to PBT/vPvB substances. Environmental concentration limits such as the parametric values in the drinking water directive<sup>2</sup> and proposed environmental quality standards in the priority substance directive<sup>1</sup> can however be useful to evaluate the proposed concentration limits in the restriction report and help provide cost estimates for the socio-economic analysis.

## Analysis of the proposed concentration limits

The Swedish Agency for Marine and Water Management is of the opinion that environmental quality standards can provide useful information for an evaluation of the proposed concentration limits in the Annex XV restriction report. The parametric values in the drinking water directive and the proposed environmental quality standards in the priority substance directive are low due to the potential harmful effects on human health. An analysis of whether the use of products (mixtures and/or articles fulfilling the restriction concentration limits) could still cause levels in the environment to exceed environmental quality standards and subsequent legally induced remediation or emission abatement requirements is relevant. This analysis is lacking in the restriction report.

## Socio-economic analysis

The restriction report estimates the emissions of PFASs to be about 4.5 million tonnes during the manufacture and usage phase, over a 30-year period, if no action is taken. The emission during the waste phase is not accounted for in the estimate and the Swedish Agency for Marine and Water Management want to emphasise that the emissions during the waste phase are significant

and consequently are the overall emission estimates most likely severely underestimated. Recent data collected from Swedish landfills showed for example that PFASs were detected in all land fill leachates in concentrations up to 200 µg/l (mean value 5.5 µg/l for the sum of 11 PFASs)<sup>14</sup>.

The impact assessment report (SWD(2022) 540 final)<sup>15</sup> of the proposal to amend the water framework directive and its daughter directives, provides a summary of some of the substantial economic benefits from avoiding PFAS ending up in European waters. For example, the avoided costs of PFAS removal in waste water are considerable: at least €9.13 billion annually. Estimates of the potential to avoid cost for reverse osmosis, specifically, to prepare drinking water to all 195 million EU households are also considerable: €39.1 billion annually. Also, not having to use reverse osmosis to produce drinking water will result in 20% savings of water extraction volumes compared to a situation in which the technique would be required. Non-health-based costs for environmental PFAS remediation totals EUR 821 million to EUR 170 billion (EEA/EU), with plausible best estimate EUR 10–20 billion. The overall annual health-related costs, following from exposure, have been estimated to be at least EUR 52 to EUR 84 billion in the EEA countries. However, the restriction report concludes that the impact of continued use of, and increased human exposure to PFAS, on human health that can be prevented through the proposed restriction options cannot be quantified due to limited, or missing data.

Taken together, the Swedish Agency for Marine and Water Management supports the conclusion that both restriction options are proportionate to the risk. Furthermore, emissions from PFASs in products and waste will continue for many years after the restriction is in place and there is an urgent need for action. The agency therefore wants to stress the need to limit derogations as much as possible.

## References

1. 2022/0344 (COD), Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2000/60/EC establishing a framework for Community action in the field of water policy, Directive 2006/118/EC on the protection of groundwater against pollution and deterioration and Directive 2008/105/EC on environmental quality standards in the field of water policy.
2. EU, 2021. Directive (EU) 2020/2184 of the European parliament and of the council of 16 December 2020 on the quality of water intended for human consumption. Official J Europ Union, L435 (DWD).
3. Database of environment levels of e.g. PFAS in Sweden: <https://www.sgu.se/produkter-och-tjanster/nationella-datavardskap/datavardskap-for-miljogifter/rapporterad-data-till-datavardskap-for-miljogifter/>
4. Naturvårdsverket 2016. Högfluorerade ämnen (PFAS) och bekämpningsmedel. En sammantagen bild av förekomsten i miljön. Redovisning av ett regeringsuppdrag. Rapport 6709.
5. SGU, 2019. Miljögifter i urbant grundvatten. SGU-rapport 2019:02. Available at: <http://resource.sgu.se/produkter/sgurapp/s1902-rapport.pdf>
6. Faxneld, S., Soerensen, A.L. 2021. The Swedish National Monitoring Programme for Contaminants in Freshwater Biota (until 2019 year's data). Report 3:2021. Swedish Museum of Natural History, Stockholm Sweden. Available at: <https://www.diva-portal.org/smash/get/diva2:1671404/FULLTEXT02.pdf>
7. Kärrman A, Fredriksson, F., Yuen, C.N.T., Yeung, L.W.Y. 2022. Screening of per- and polyfluoroalkyl substances (PFAS) in sediment and water close to paper industries. Rapport till Naturvårdsverket.

- Överenskommelse NV-06307-20. Available at: <https://www.diva-portal.org/smash/get/diva2:1720031/FULLTEXT01.pdf>
8. SGU, 2022. Contaminants in Swedish offshore sediments 2003–2021. SGU-rapport 2022:08, Available at: <http://www.diva-portal.org/smash/get/diva2:1666574/FULLTEXT02.pdf>
  9. SGU, 2022. Sedimentundersökningar i svenska kustområden 2021. SGU-rapport 2022:16. Available at: <https://resource.sgu.se/dokument/publikation/sgurapport/sgurapport202216rapport/s2216-rapport.pdf>
  10. Soerensen, A.L., Faxneld, S, 2023. Per- and polyfluoroalkyl substances (PFAS) within the Swedish Monitoring Program for Contaminants in Marine Biota. 6:2023, Swedish Museum of Natural History, Stockholm, Sweden. Available at: <https://www.diva-portal.org/smash/get/diva2:1791115/FULLTEXT01.pdf>
  11. SGU, 2023. Undersökning av limniska sediment. Konsultrapport inom regeringsuppdraget RUFFS. Available at: <https://resource.sgu.se/dokument/publikation/konsultrapport/konsultrapport07rapport/undersokning-av-limniska-sediment.pdf>
  12. Hees, P., Sundelin, T., Karlsson, P., 2023. Ultrashort PFAS in Swedish and Norwegian Drinking Water. Report from Eurofins, Available at: [https://cdnmedia.eurofins.com/european-east/media/2867434/eurofins\\_ultrashort\\_pfas\\_drink\\_water\\_23.pdf](https://cdnmedia.eurofins.com/european-east/media/2867434/eurofins_ultrashort_pfas_drink_water_23.pdf)
  13. The Toxicological Council, 2019. Toxikologiska rådets årsrapport 2019. Available at: <https://www.kemi.se/download/18.7729c77717443579210a29b/1599728229432/toxikologiska-radets-rapport-1-19.pdf>
  14. Miljösamverkan Sverige, 2022. PFAS vid deponier. Handlägggarstöd med fokus på PFAS i lakvatten. Report available at: <https://www.miljosamverkansverige.se/wp-content/uploads/2022-01-27-Rapport-PFAS-vid-deponier.pdf>. Data available at: <https://www.miljosamverkansverige.se/miljoskydd/pfas-vid-deponier/>
  15. EU, 2022. SWD(2022) 540 final. The impact assessment report accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directive 2000/60/EC establishing a framework for Community action in the field of water policy, Directive 2006/118/EC on the protection of groundwater against pollution and deterioration and Directive 2008/105/EC on environmental quality standards in the field of water policy. Available at: [https://environment.ec.europa.eu/system/files/2022-10/Staff%20Working%20Document%20-%20Impact%20Assessment%20Report%20accompanying%20the%20Proposal\\_0.pdf](https://environment.ec.europa.eu/system/files/2022-10/Staff%20Working%20Document%20-%20Impact%20Assessment%20Report%20accompanying%20the%20Proposal_0.pdf)