



SWEDISH
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Comments from the Swedish Environmental Agency regarding the Reach Annex XV report – Proposal for restricting Per- and polyfluoroalkyl substances (PFAS)

The Swedish Environmental Protection Agency (SEPA) welcomes the Annex XV report on the restriction of per- and polyfluoroalkyl substances (PFAS) and supports to the proposed Annex XVII entry put forward by the authors of the Annex XV report.

The Swedish EPA is of the opinion that a broad restriction is the most rational and efficient way to manage this large group of substances given the high risks associated with its problematic properties and extensive use area. The challenges with recontamination in material recycling would be significantly alleviated through a broad restriction as compared to a targeted alternative. The Swedish EPA has taken notice of this being an issue of concern in the parallel restriction process of PFHxA and the possible contamination of PFHxA in for example food contact material (FCM) through recycling. This since non-FCM paper and cardboard are not covered by the targeted PFHxA-restriction being proposed by the commission. The Swedish EPA agrees also on the benefits of a restriction regarding controlling PFAS in imported articles.

The Swedish EPA 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 measures put forward within the chemical control system must aim at limiting emissions of all PFAS 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 in large population groups exceeds what is defined as a safe level, *i.e.*, exposures to multiple PFAS cannot, even to date, be avoided and combination effects are expected
- remediation of PFAS-polluted land and water 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 material and energy 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 will most likely be economically beneficial to society in the long run, although costly in the short term and related to negative consequences for individual companies.

The Swedish EPA supports the proposal and agrees with the conclusions in the report but would like to take the opportunity to put forward a few requests for improvement regarding the scope of the proposed restriction option (RO2).

Review of derogation times

There is a strong evidence base for a high risk of severe impacts on society in terms of negative effects on human health and environment due to the present and future PFAS emissions. Exposures (blood serum) are, as presented in the dossier, already above EFSA threshold values in substantial parts of the Swedish population, and the situation is likely similar across Europe. In addition, the costs of inaction are most likely underestimated due to for example non-inclusion of emissions from the waste treatment sector in the risk assessment model, and all in all it is highly uncertain if too much (or too little) time is provided under the proposed derogations. Thus, the time for action in the continued risk reduction work is critical irrespective of the restriction scope (RO1 or RO2), and the prevention of any unnecessary emission of PFAS is of importance.

Summarising the above:

- all emissions are a proxy to risk
- exposures are most likely underestimated, *i.e.* PFAS emissions /exposure from the PFAS stock in the environment and technosphere are not included
- there are high uncertainties in most steps of the restriction proposal assessment seen as a whole.

Since the Reach restriction *per se* is recognised as a powerful instrument to stimulate substitution, the Swedish EPA view the long derogation times of 13.5 years (and in some cases time-unlimited) as overly pessimistic in relation to innovation power. Moreover, predictions of this type that far into the future are highly uncertain by nature irrespective of the evidence base. Given these circumstances – uncertain ability of transition to alternatives combined with high risks with maintained PFAS emissions – the Swedish EPA therefore suggest that the proposal is amended with a review clause stating that the Commission shall carry out a review of the paragraphs mentioned in paragraph 7. The review shall consider new scientific information, including alternatives for the chemical products and articles referred to in the paragraphs mentioned in paragraph 7. Given the outcome of this review, the Commission shall propose amendments accordingly, e.g. by adjusting the time limit of the derogation. If derogation still

is deemed necessary by the commission, the review shall be repeated every three years.

Acceptance of proposal among stakeholders

To the understanding of the Swedish EPA, the basis for the estimation of, and justification for, the presented derogation times is the availability and applicability of alternatives to PFAS and the cost impact of a ban. If so, the proposal relies solely on a likelihood assessment of PFAS-substitution for any given use category present at the publication time of the proposal. This means that differentiation / weighting among derogations based on the specific use sectors' essentiality to society balancing the costs imposed by any emission due to the hazardous properties of PFAS is lacking. In relation to this, the Swedish EPA is of the opinion that the acceptance to the scope of proposed derogations would increase to all stakeholders if the justification for a specific derogation also were based on the use's benefits for society and not only availability of alternatives to PFAS. Derogation for uses based solely on business economic effects compared to derogations in uses that are essential to save human lives or the use's necessity to the green economy transition for example, would warrant relatively longer time limited exemptions from the ban if alternatives are non-existent or ineffective. For example, a derogation in refrigerants in air conditioning-systems in combustion engine vehicles with mechanical compressors, as compared to PFAS polymers in medical devices or rechargeable car batteries. Restriction options allowing for derogations despite identified significant risks, and thereby, shifting the cost burden arising from health and environmental impacts to future generations, could at least qualitatively be acceptable, in comparison to exemptions purely justified due to its cost efficiency.

Quantification of health/environmental risks related to the proposed concentration limits

The Swedish EPA is of the opinion that the proposal lacks a discussion on the proposed concentration limits in relation to the health based and subsequent environmental limit values in related EU-legislation, *e.g.*, the Drinking Water Directive, the Water Framework Directive, etc. The Swedish EPA agrees with the conclusion that the proposed concentration limits will reduce the release of PFASs to the environment significantly, and thus, the risks as compared to today's situation. However, it is the opinion of the Swedish EPA that the dossier should include further investigations and descriptions of the potential consequences of the proposed concentration levels. How they relate to, and harmonizes with, other relevant health-based criteria for PFASs in surface and drinking water for example. Since threshold values in environmental media are low, the Swedish EPA finds it essential to problematize the situation at which the use of products (mixtures and/or articles fulfilling the restriction concentration limits) could still cause levels in the environment to exceed critical levels and subsequent legally induced remediation or emission abatement requirements. Thus, there may be a need to elaborate further on how the potential post-restriction costs of remediation of contaminated soil and groundwater as well as treatment of contaminated drinking water may impact the

socioeconomic assessment of the proposal, and if needed, arrive at a new proposed threshold level.