



ARNIKA, CHEM TRUST, CLIENTEARTH, EEB and IPEN comments to the REACH restriction: PFHxA, its salts and related substances

13/05/2020

The undersigning organisations support the dossier submitters conclusion that *“a restriction on PFHxA, its salts and related substances is the most appropriate way to limit the risks for human health and the environment on an EU level”*.

The restriction of PFHxA, its salts and related substances (precursors) is necessary:

- To prevent further build-up in the environment of very persistent PFHxA;
- To prevent further irreversible contamination of drinking water from this very persistent and mobile substance;
- To prevent large scale contamination of edible plants and vegetables from PFHxA;
- To minimise exposure of future generations to PFHxA;
- To put an end to the shift from C8 to C6 chemistry, a case of regrettable substitution. The restriction is also necessary to avoid PFHxA and related substances to become a substitute to PFOA, related substances and its salts when the restriction will come into force in July 2020.

We also support the grouping approach to the restriction which includes all PFHxA related substances. This approach is necessary to prevent PFHxA from being released in the environment as degradation products of related PFAS.

However, the undersigning organisations would like to provide some comments to strengthen the proposal.

Scope: The proposed concentration limits of 25 ppb and 1000 ppb in the Restriction Report mirror the final PFOA restriction decision by the Commission. However, it should be noted that the Dossier submitter of the PFOA restriction proposal put forward a threshold of 2 ppb for PFOA and PFOA related substances in order to ensure that these substances were not intentionally applied in these uses.

The final limit of 25 ppb that was finally adopted by the Commission was the result of the RAC and SEAC Committees who, following claims by industry stakeholders on the lack of availability of testing methods, changed in their opinion the scope of the PFOA restriction proposal. Testing methods have developed rapidly since the PFOA dossier was submitted and there are no constraints today for establishing a threshold of 2 ppb. To put this into perspective, the drinking water limits that have been established in the EU and the US for PFOS, PFOA and some other PFAS are in the 10- 100 ppt range. We believe that the restriction proposal and the RAC and SEAC opinions should include a transparent justification on the data and scientific justification for deriving this threshold.

Derogations: Efforts in the European Union today are increasing to limit PFAS to a few, essential uses. It is therefore vital that all efforts contribute to support that goal. This includes only allowing use of PFHxA for specific, narrowly defined essential 'need to have' rather than 'nice to have' uses where no alternatives exist. We believe that the current derogations and delayed application of the restriction include uses where feasible, cost-effective non-fluorinated alternatives are available. Much information about non-fluorinated alternatives for these uses have already been developed by the POPs Review Committee (POPRC) under the Stockholm Convention in the review of PFOS, PFOA and PFHxS, which are applicable also for PFHxA [1].

Also, there is no further elaboration as to why the uses for the proposed derogations are essential. Without such an analysis to clearly justify the derogations, the EU effort to phase out PFAS will be seriously hampered and the decision to allow continued emissions illegitimate. We note that for some derogations that there is only a small quantity used. However, as defended by the dossier submitter, any release is a proxy for unacceptable risk. The first step to assess whether a release may be acceptable is therefore to consider the function it serves. It is only when this function is confirmed to be necessary for the functioning of society or 'need to have' rather than 'nice to have' that a CEA should be done.

The onus is on the industry to bring robust and reliable information in order for DS to consider derogations. We consider that SEAC should request the DS to explain why it considered robust and reliable the information provided by stakeholders, both for this and any other proposed derogations or transitional period. SEAC should also request the DS a summary of the type of actor who answered.

See detailed comments to specific derogations below.

Hazard assessment: The hazard assessment provides a comprehensive overview of the elements of concerns related to PFHxA, its salts and precursors. The hazard assessment demonstrates convincingly the need to eliminate present and future emissions into the environment to reduce exposure and risks caused by PFHxA, its salts and precursors. At some points, the text would benefit from increased emphasis on the particular combination of the properties leading to the very high concern: the combination of extreme persistency, high mobility, and long range transport leading to the irreversible worldwide environmental pollution and contamination of drinking water. Suggestions to strengthen the text of the restriction proposal are provided in the comments below. Also, we would recommend updating the literature search to accommodate recent publications in the Annex XV report and Annexes. NGOs support the use of the Annex XV report to inform the Stockholm convention process on POPs.

Risk characterisation: The dossier submitter concludes that PFHxA should be considered a non-threshold substance for the purposes of risk assessment, similar to PBT/vPvB substances under the REACH regulation. We fully support this conclusion based on the evidence provided in the dossier. Further comments are provided below.

Cost and benefits: The dossier proposes a discount rate of 4% in the NPV for all costs, unless otherwise specified (there is currently no exception specified). A discount rate of 4%, however, appears too high for environmental costs, especially regarding the very high persistency of the substances in scope. In particular when dealing with persistent chemicals it is important to consider the benefits for future generations from a restriction. Therefore the discount rate of 4% should be reduced. See detailed comments below.

Also, any cost-benefit analysis should include the health-related costs of PFHxA exposure as well as costs for environmental remediation, which are both likely to be extensive.

Detailed comments

Regarding the proposed scope

Regarding the method for establishing the concentration limits

The dossier does not reveal how the value of 1000 ppb was derived, and in what way it would best serve the purpose of the restriction (addressing an unacceptable risk, Reach Art. 68(1), or indeed the higher-level conclusions of the Council of the EU of June 2019 (“to eliminate all non-essential uses of PFAS”).

Information in section 2.4 unspecifically calls the value of 1000 “feasible” and points to Annex G, the results of the stakeholder consultation. It uses a false alternatives fallacy (“*threshold of zero [...] most effective, [...] [but] not feasible and enforceable (e.g. due to detection limits)*”).

This casts doubt on whether this value was derived specifically for the chemicals under consideration in this restriction proposal or has been re-used from previous restrictions of other PFAS (Eg. PFOA, PFHxS). Considering that this value impacts the potential of the restriction to address the proven unacceptable risk, we urge RAC and the dossier submitter to reconsider.

Annex G reveals that the stakeholder consultation included “*companies as well as associations*” (Annex to the dossier, p. 214). This casts further doubt on the justification of this value:

- The stakeholder group did not include independent experts.
- Information in scientific and technical literature seems excluded.
- Information from the stakeholder consultation is not included. It is unclear whether the consulted stakeholders were asked “*whether a threshold of 1000 ppb is feasible*” (although it is not clear what “*feasible*” means) or to communicate effective concentrations of the substances in scope in products (esp. mixtures and articles).
- No *ad-hoc* analyses were carried out. With modern analytical tools, it would have been proportionate to determine relevant levels of PFASs in currently existing products, especially in those giving rise to high release potential.

We believe that the restriction proposal and the RAC and SEAC opinions should include a transparent justification on the data and scientific justification for deriving this threshold.

Regarding the outcome

The figure of 1000 ppb (i.e. 1 ppm) may appear low and therefore effective at first sight. However, the threshold must take the specific properties, uses and releases of PFHxA into account to avoid

a meaningless restriction that would not force a major shift towards safer alternatives in order to protect human health and the environment. When those elements are taken into account, the logical conclusion is that this limit should be significantly lower by several orders of magnitude.

Many applications, especially in articles, are surface treatments with high release potential. These surface treatments are applied as thin layers to thicker substrates and as such represent only a small part of the total mass. Even on light substrates such as an outdoor jacket, scientific results and a back-of-the-envelope calculation show that the value of 1000 ppb is too high to force companies to change their current practice by substituting or meaningfully reduce the use of the substances concerned. A more justifiable threshold based on available data and information would be 2 ppb. In any case, the final threshold should be derived on the basis of information consolidated by experts devoid of any conflict of interest, using a fully transparent approach.

Alternatively, a concentration threshold may be derived for the relevant layers of the treated materials. Surface treatments are by definition 1) non-uniformly distributed and 2) present in the outer layers of the material. Therefore a concentration threshold on the surface (e.g. the top 5 μm) would be more meaningful, while also simplifying material sampling and sample preparation.

A study by Gremmel et al. [2] analysed contents of fluorotelomer alcohol moieties (6:2, 8:2 and 10:2) in fifteen outdoor jackets (of which one being PPE). Fourteen of the jackets had total fluorotelomer concentrations well below 1000 ppb, ranging as low as ca. 10 ppb! As the value in the paper are expressed in $\mu\text{g}/\text{m}^2$, a more useful metric for surface treatments, we converted them to ppb, assuming a weight of 450 g per jacket and a surface area of 1.4 m^2 , based on real measurements. It should be noted that most of the jackets in the Gremmel study were coated with 8:2 chemistry rather than the 6:2 chemistry in scope here; this may make a subtle difference. More importantly, the discrepancy among the studied jackets, and between real values and this dossiers' assumptions, by more than two orders of magnitude demonstrates:

- That the 1000 ppb threshold is very likely wrongly derived (even a “most-plausible-case” scenario of an outdoor jacket, as a rather light item).
- That available scientific literature provides evidence to support a much lower threshold.
- That many manufacturers, at least 10 years ago, had poor process control and used either excessive amounts (up to 100-fold between the jackets with the highest and the lowest extractable FTOH concentrations in articles of the same function), or inefficient types of treatment. Regarding SEAC's prerogatives, this suggests that the cost of PFAS is likely so minor in the total cost of articles that manufacturers do not even try to optimise it – this situation is unlikely to have changed since then.

Furthermore, a recent study by I van der Veen et al. [3] showed that the concentration may increase during the use. Increased concentrations of several PFAS (including PFHxA) in textiles were observed after weathering. Concentrations of PFHxA increased after weathering in 8 out of

the 13 samples as much as two orders of magnitude, surpassing by far the proposed limit value of 25 ppb. The study highlights that the increase in concentrations of PFASs due to weather conditions might not only have an environmental impact, but also a health impact as the use in outdoor clothing may also form a direct exposure route to humans, since there is dermal contact with the textiles. In order to take into account the fact that the amount of PFHxA tested on the shelf might not reflect the value in real life a conservative threshold should be established.

Regarding the derogations

Photographic coatings applied to films

The dossier notes that “According to a stakeholder for some specific applications suitable non-fluorinated alternatives have not been found.” However, what these applications are is not clear and hence it is not possible to evaluate the alternatives. In addition, the dossier concludes that “Digital techniques will completely replace traditional photographic film within the coming years.” This is not an essential use and no derogation should be provided.

Fire-fighting foam: Fluorinated fire-fighting foam is one of the most dispersive uses there is, that has already irreversibly contaminated ground- and surface waters in most countries. This made the POPRC include warnings against replacing PFOA and PFHxS with fluorinated alternatives. This alone should be enough to prevent any derogations for PFHxA and related substances in firefighting foam.

The dossier makes a number of conclusions where it is unclear what the justifications are. For example:

- It assumes that short-chained PFAS alternatives have the same properties as PFOS/PFOA based foam and fulfill all fire safety requirements. However, this is a misconception based on the fact that C6 foams typically include a significant proportion of C8 PFAS. Hence, the properties the dossier assumes that C6 foam have are likely generated by the mixture of C8 and C6 PFAS in the foam. Indeed, pure C6 foam (free from any C8 substances) struggles to meet the same safety requirements as C8 foam. [4][5]
- It proposes derogations for certain uses in the petrochemical industry and for certain uses in defence applications but does not provide the information they based their conclusion that alternatives are not available. Also, it states that “Other armed forces report challenges regarding a complete transition due to missing alternatives in the defence sector”. It is important to note that if this conclusion is based on the US MilSpec that US bases in Europe have to adhere to, this specification includes an old requirement of fluorinated foam without taking the recent technological developments into account and should not serve as an indication that no fluorinated alternatives are available.

Finally, the Dossier Submitter intends to restrict the use of PFHxA-related substances in fire-fighting foams that are already placed on the market five years after entry into force of this restriction. This would mean that direct releases into the environment from use of these foams would continue for an additional five years, noting that environmental remediation of PFHxA is extremely costly.

This extremely long transitional period is not justified and the responsible approach would instead be to manage old stocks through recall approaches by the manufacturers.

Latex printing inks

It is unclear why the evaluation of this use does not take alternative techniques into account. It is also not clear why this would be considered an essential use. Finally, the derogation is based on an assumed lifespan of 7-10 years instead of considering that the existing fluorine-free alternative latex printing ink could be used in the same type of cartridges and be placed in the same type of printers.

Non-woven medical textiles: It should be noted that this is a broad derogation proposed without a time limit despite that the restriction dossier concludes that *“estimates that industry will not face higher cost when substituting from PFHxA-related substances to fluorine-free substances.”* The derogation is based on the need to have textiles that are both stain and oil repellent, but no details about what the essential uses that require both properties have been provided. Effective non-fluorinated alternatives (including alternative techniques) are available that provide these properties, although not any that provide both properties. Hence, more information should be provided to justify this derogation and the scope must be much better defined. Also, a time unlimited derogation provides no incentive for industry to replace PFHxA-related substances with safer, non-fluorinated alternatives. If a derogation is deemed necessary, this should be time limited.

Other derogations proposed under 5,7, 8 and 9

Derogations under paragraphs 7, 7 and 8 should include the reporting requirements included under paragraph 9.

The derogations proposed under paragraph 9 are all time unlimited and some are very broad. Without a deadline, there is no incentive to develop non-fluorinated alternatives. Also, without further definition, alternatives cannot effectively be evaluated. Since these are all used frequently by e.g. healthcare workers it is important to minimize exposure to PFHxA and other PFAS to prevent adverse effects to human health. A substitution plan should be required for these derogations as it is the case for art 6 derogations.

Derogation 11 for fluoroelastomers used in the automotive and aerospace industry

'The DS justifies the paragraph 11 derogation (150 ppm for fluoroelastomer) by weighing the cost of not being able to use APFHx [sic] for the manufacturing of fluoroelastomers against the estimated quantity of emissions. However the assessment done by the DS cannot justify such derogation.

First, the emissions taken into account are highly likely to be strongly underestimated:

- The emissions taken into account in the weighting seem to be limited to those released during service life of articles into water and soil and do not include the quantity emitted during production (see B.9.4). It is noted however that APFHx is used as processing aids from 10-100 t/a and that emissions, according to the information sent by one of the two manufacturers, is in the kg range.
- The DS recognises that the "estimated number of unreported releases could be much higher. The amount of articles imported into the EU containing fluoroelastomers or other products with APFHx as impurity is unknown".
- The assessment seems based on information sent by the two only EU manufacturers, without an evaluation of the accuracy, robustness and reliability of the data provided.

Second, the emissions are weighed against the potential loss of profits incurred in a non-use scenario:

- The assessment seems based on information sent by the two only EU manufacturers, without an evaluation of the accuracy, robustness and reliability of the data provided. The costs are likely strongly overestimated
- This approach does not follow the method SEAC set for itself to evaluate restriction reports and applications for authorisation for PBT and vPvB. It is true that it is not currently demonstrated in the dossier that PFHxA fulfil all criteria of a PBT, but their extreme persistence and the irreversibility of their effects as described by the DS justify a similar approach that requires to weigh the emissions, knowing that any release is a proxy for unacceptable risk, against factors such as the costs of remediation, the cost of damages or the cost of measures reducing the level of emissions. See SEAC/24/2014/04. Also, with the new evidence on toxicity that have emerged, there is likely a need to reassess the toxic properties of PFHxA.

Considering that the objective of the restriction is to minimise as much as possible any emission, in this situation the DS would have needed to:

- Require from the manufacturer reliable information on the cost of **reducing the emissions** during the manufacture and the service life of products rather than accept the emissions as they are.
- Examine whether the elements manufactured with fluoroelastomers play a 'need to have' or 'nice to have' function in the automotive and aerospace sector.
- The availability of alternatives has not been assessed for this application, neither in the report nor possibly by the manufacturer. PTFE can nowadays be polymerised without any

fluorinated surfactants, so it appears likely that APFHx could also be replaced by non-fluorinated substances.

- If a derogation were to be considered necessary after this analysis, set it with a threshold taking into account the possibility to reduce the emissions. In addition, set a derogation limited in time with a requirement for a substitution plan for the two manufacturers identified. It is recognised that alternatives by the DS are currently available but do not allow to achieve the performance sought for. The restriction needs to promote further innovation in this sector.

Regarding the labelling as a risk management option

The dossier considers in section 2.2 the option of labelling PFASs-containing substances (for the sake of clarity: this does not refer to CLP-type hazard labelling, but to attaching a label with a warning to the article or mixture). While the decision to opt for restriction instead is justified, this does not exclude labelling requirements as a tool for transparency and additional risk reduction, esp. when derogations are granted for some essential uses.

A big shortcoming in the current situation is the lack of transparency on the presence of intentionally added PFASs in mixtures and articles. Users have in many cases no possibility to make informed choices, or to properly dispose of used products containing PFASs.

This restriction would benefit from a requirement to label mixtures and articles with the proposed warning (or equivalent),

- Whenever they fall under a derogation in the restriction;
- Whenever they contain intentionally added PFASs below the threshold of the restriction;
- For all newly manufactured products as of a date well before the actual restriction enters into force.

Specific comments on section 1.1: *“The problem identified - Introduction”*

p11, para 1

- *“Some substances like PFOA and PFOS are hazardous to human and environment.”*
Understatement, long chain and short chain PFAS (C4 - C14) have been identified as substances of very high concern and included in the REACH candidate list. Suggestion to reflect in text that PFAS with carbon chains ranging from C4 - C14 are identified as substances of very high concern to human health and/or the environment.

p11, para 2

- *“PFHxA was also detected in groundwater.”* Add: *“and drinking water”*

Regarding the Hazard assessment (1.3)

General remark on hazard assessment

Short-chain PFAS have been used as regrettable substitutes for e.g. PFOS and PFOA since they have been put forward as less toxic. However, there is clear evidence that these, including PFHxA, cause adverse effects. It should also be noted that a recent study by Gomis et al. [6] showed that this perceived lower toxicity is in fact confounded by differences in their distribution and elimination kinetics. The conclusion of the study is that *“Since the manifestation of a toxic effect depends on the dose of the toxicant at the target site, PFASs that have a fast clearance and thus a low bioaccumulation potential can still be intrinsically toxic”* and that *“Whether toxic effects are triggered would depend on the level of exposure. Toxicity risks linked to persistent short-chain PFAAs is therefore not to be excluded since these chemicals are expected to accumulate in the environment with low reversibility and lead to highly elevated exposures.”*

- There are a range of studies showing adverse effects in Sprague Dawley Rats exposed to PFHxA. Many of the effects are similar to effects of exposure to other PFAS. A recent Technical Report from the National Toxicology Program (NTP) under the US Department of Health and Human Services [7] reviewed the available evidence and concluded that there is clear evidence for a range of adverse effects, including increased liver weights and bile acid concentration.
- Decreases in cholesterol concentrations.
- Decrease in total thyroxine (T4) and free T4 hormones.
- Mild increases in alkaline phosphatase activity (biomarkers of hepatocellular injury) and decrease in red blood cell mass.
- Olfactory epithelium degeneration, hyperplasia, and inflammation

There are also indications of adverse effects in Zebrafish. For example, a recent study showed significant effects on gene expression in larval zebrafish following developmental exposures to PFHxA, indicating the potential to interfere with normal development of the spinal cord [8].

There are also a range of studies indicating adverse effects in humans from exposure to PFHxA [9]. For example, it has been shown to share key characteristics of other carcinogens and induce oxidative stress; strongly inhibit human carbonic anhydrase isozyme hCA IX with low (nanomolar) dissociation constants; cause changes in the glycoprotein receptor CD44 (receptor for e.g. for hyaluronan, osteopontin and collagens) that is involved in cell adhesion and migration; and be negatively associated with testosterone level in adolescent males.

Additional comments to specific chapters of the hazard assessment

- p18, para 2: *“underpinned by what can be referred to as their ‘extreme’ persistence in the environment”.*
 Insert after *“extreme persistence”*: *“, high mobility and long range transport potential”* to reflect that it is the combination of extreme persistence and high mobility that lead to widespread occurrence in the environment, resulting in non-reversible environmental pollution.
- p19, 2nd last bullet point: *“PFHxA may cause adverse effects on human health such as developmental toxicity”.*
 Update text to reflect recent findings on endocrine disrupting effects (NTP, 2018).
- p19, last bullet point: *“Problems with PFHxA exposure do already occur today (e.g. contamination of soil in Rastatt, Germany and uptake of PFHxA in plants).”*
 Add sentence mentioning countries with occurrence in drinking water:
 PFHxA is already detected in drinking water across many countries, with detections most common in Sweden, Italy, Belgium, Netherlands, Norway and Germany.
 Although reported levels of PFHxA are still relatively low in the EU, the concentrations will inevitably increase if emissions to the environment continue.
- p20, 1st para: *“Structurally similar perfluorinated carboxylic acids with longer carbon chains, e.g. PFOA or C9-C14 PFCAs, were already identified as being (very) persistent fulfilling the persistency criteria of REACH Annex XIII”.*
 Suggestion to amend text to reflect that structurally similar PFASs with same and shorter carbon chain have been identified as well as being vP according to the criteria of REACH Annex XIII. (e.g. PFBS, PFHxS).
- p20: *“Removal from the environment, decontamination and purification”.*
 Add information on problems with purification of drinking water. With the current state of technology it can be concluded that removal of PFHxA from drinking water is not possible in full scale drinking water installations.
- p.21: *“Potential for long-range transport”.*
 Add references and specify remote locations where PFHxA is detected to reflect world wide distribution. Long range transport is confirmed by monitoring data. PFHxA is detected in remote areas such as in Arctic ocean, Alpine snow and air samples of the Norwegian polar region.
- p.24,25: *“PFHxA causes long-term and intergenerational exposure of humans and biota – even if releases have ceased. Future generations are exposed to PFHxA via human breast milk”.*
 Expand information: Placental transfer was demonstrated by prenatal developmental toxicity studies in rats and mice.

Regarding preliminary discussions on exposure and risk

Regarding the approach to risk assessment

We believe there is a major contradiction, resulting in several erroneous assumptions of releases of PFHxA. In section 1.3.6, p. 26, the report says (1) “*many precursors of 6:2 fluorotelomer alcohol (FTOH) degrade very quickly to the acid*” and (2) “*Using data gained by several authors, about 39 kg PFHxA are emitted by one tonne 6:2 FTOH (e.g. Liu 2010, Zhao 2013)*”. Statement (1) is almost correct (and replacing “*precursors of*” should be replaced by “*compounds containing*”), statement (2) is wrong in content and in reference:

- The two references cited do not make any mention of either the figure or the topic.
- As the said precursors degrade quickly, the mass balance must be checked: what happens to the bulk of the “*one tonne of 6:2 FTOH*”? This material will still consist mostly of perfluorinated C6 chains, all of which are of environmental relevance due to their persistency.
- The degradation of FTs to PFCAs with loss of two fluorine atoms can be inferred to be the major metabolic fate, not an exceptional one. The seminal paper by Dinglasan *et al.* [10] proves (on the example of 8:2 FT) that this is the case, although one side-pathway includes a slower step via an unsaturated fluorotelomer acid.
- Even if under relevant environmental conditions, FTs are degraded into several PFHxA-related compounds as suggested by the Annex on p. 24, these substances are closely related and certainly persistent substances. In the likely absence of data proving their (eco)toxicological innocuous and swift breakdown in the environment, they should be equated to the equivalent concentration of PFHxA.
- Authoritative references on microbial [10] and atmospheric [11] degradation should be referenced here and used as a basis for the analysis.

A result of this is that all emission calculations in this section and elsewhere may be underestimating the real situation. The restriction proposal would benefit from the reviewing of these calculations.

Additional comments on the exposure assessment:

- p. 26: “*therefore no direct release of the acid into the environment is expected*”. While it is true that PFHxA is only registered as a salt, this statement is misleading: a release of the conjugate base of any acid can equate to the release of the acid itself, given the reversibility of the protonation/deprotonation reaction – it may be useful to add here a value of the (very low) pKa of PFHxA. In all recent regulatory processes, acids and their conjugate bases have been regarded as (eco)toxicologically equivalent – this should also be clarified here.
- Annex, section B.9.5. regarding the textile assessment : the life-cycle stage of re-impregnation for personal protective equipment (listed among the derogations in the restriction proposal) is not being taken into account. We are concerned that the re-

impregnation process performed by professional launderers and consisting of adding impregnation agents to the laundry cycle could lead to emission in the environment via wastewater and would like to see emission estimations related to this stage.

- Annex, section B.9.6 regarding the paper assessment : emission from compostable moulded-fibre food packaging in the environment from compost is not being taken into account. These food container items (bowls, plates, clamshell box) have been increasingly present on the market as substitutes to single-use plastic containers. However product testing in the US [12] and in the UK [13] have demonstrated that they have high PFAS content. The total organic fluorine content of such items has been found to be 10 times higher than in some greaseproof paper packaging in the UK study. These items are marketed as compostable and could end-up in home compost or municipal compost facilities, contaminating the compost further used to fertilise soil. We would like the dossier submitter to consider this route of emission for the exposure assessment.

Regarding conclusions on the cost and benefits

Regarding the costs taken into account, we would like to highlight that the polluter-pays-principle is currently hardly ever applied, consequently the environmental cost of pollution caused mostly does not translate into financial cost for the polluter.

One may consider the polluters to be the manufacturers of the substances, industries transforming the substances in scope or the professionals and consumers using the different products and causing (knowingly or not) pollution. If such cost were not externalised to the environment, it would add considerable cost figures into the equation, by companies directly paying for the pollution they cause directly and indirectly (i.e. through articles that pollute in their service life where this is not communicated to the customer). Financial projections, e.g. in GAAP, are supposed to be made according to the prudence principle - the financial counterpart of the precautionary principle in public and environmental health. In our view, applying the prudence principle here would mean that externalities should be accounted for, as it cannot be taken for granted that the polluter-pays-principle will not be applied in the future.

Regarding discount rates, on p. 45, the dossier proposes a rate of "4% in the NPV for all costs, unless otherwise specified" (there is currently no exception specified). Given the very low risk-free interest rate and the moderate risk premium in many businesses, this rate appears realistic for current business decisions. However, regarding environmental cost, a discount rate of 4%, however, appears more difficult to justify, especially regarding the very high persistency of the substances in scope. The discount rate, as used in classical economics, translates uncertainty about the future. PFASs being "forever chemicals", the uncertainty about future effects is very low. Given their high persistence and non-threshold (eco)toxicology, an economical view would impose a discount rate of 0% or very close to 0%.

In particular when dealing with persistent chemicals it is important to consider the benefits for future generations from a restriction. Therefore the discount rate of 4% should be reduced. For more details see here: <https://chemtrust.org/wp-content/uploads/nef-discounting-future-damage-comp.pdf>

Also, it is important to take the cost of inaction into account. There are many case studies showing the cost of environmental remediation of various PFAS, and health costs can also be significant. While not only including PFHxA a recent report estimated that the total annual health-related costs (for three different levels of exposure) was at least EUR 2.8 to EUR 4.6 billion in the Nordic countries and EUR 52 to EUR 84 billion in the EEA countries. The range of costs for environmental remediation only for the five Nordic countries is estimated at EUR 46 million to 11 billion.

References

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