



CHEMTrust

Protecting humans and wildlife
from harmful chemicals

Submission

Call for evidence supporting an analysis of restriction options for PFAS under REACH

July 2020

1. General comments

CHEM Trust is very concerned about the global contamination of humans and wildlife with per- and polyfluorinated alkyl substances, PFAS, and have advocated for their stricter control for more than a decade. This group of substances is made up of the most persistent synthetic chemicals manufactured to date. Despite early warnings they can now be found in the blood and breastmilk of people and wildlife all around the worldⁱ. This means the current EU and global regulatory approaches need to be accelerated and strengthened to address the pervasive contamination with PFAS.

We therefore welcome the current initiative led by the national authorities of Germany, the Netherlands, Norway, Sweden and Denmark to propose a restriction of the whole PFAS groupⁱⁱ. Indeed, **only a stringent group restriction could put an end to the never-ending cycle of regrettable substitution within the PFAS group** which has been observed in the past decades and prevent further build-up of these harmful chemicals in the environment. Since the phasing out of some of the long-chain PFAS, short-chain PFAS have been used increasingly as substitutes and subsequently their concentration in the environment are increasingⁱⁱⁱ.

It's a matter of urgency

Already in 2005, during an EU-wide family biomonitoring survey, WWF had found that all participating children had PFOS in their blood, and many of them PFOA^{iv}.

Since then, only those two PFAS out of the 4,700 PFAS substances on the market have been restricted globally via the Stockholm Convention (PFOS in 2009 and PFOA in 2019) and a handful more are restricted at the European level. However, research has shown that many more PFAS, long-chain as well as short-chain, have found their way even to remote regions^v.

Increasing concerns from human biomonitoring data in Europe

A recent German Environmental Survey^{vi}, carried out between 2014 and 2017 on children and adolescents, shows that there is still considerable exposure of the young generation to the phased-out chemicals PFOS and PFOA (PFOS was found in 100% of the participants and PFOA in 86%). Moreover, 20% of the participants had levels of PFOA

exceeding the Human Biomonitoring value (HBM-I), indicating an exposure at which negative health effects cannot be excluded with sufficient certainty (including reduced birth weight and developmental toxic effects, reduced fertility, reduced antibody formation after vaccination, increased cholesterol concentrations and type II diabetes).

The youngest age-group of the participants were born after the restriction of most uses of PFOS in the EU. The presence of the chemical in their blood demonstrates how exposure to PFAS continues even after emissions have ceased due to their extreme persistence. And this illustrates why **every year of delay in the regulation of these highly persistent chemicals means an increasing burden for future generations.**

Increasing concerns about mobility

Research has shown that although short-chain PFAS are less bioaccumulative than their long-chain counterparts, their extreme persistence associated with a high mobility in the water compartment means that continuous emissions will lead to increasing environmental exposure^{vii}. These new generations of PFAS have been less studied and less is known about their potential adverse health effects compared to the older generation. However, they are increasingly recognised of concern, with HFPO-DA and PFBS identified as substances of very high concern under REACH in 2019^{viii}.

Increasing concerns about toxicity at lower levels than previously thought safe

Experience with the most studied PFAS (eg. PFOA and PFOS) shows that with increasing knowledge, the evidence for harm increases. For instance, looking at the evolution of the estimated tolerable daily intake for PFOA by the European Food Safety Authority, the value firstly estimated at 1500 ng/kg bw/day in 2008^x has been lowered by over 1700 folds in 2018 to 0.86 ng/kg bw/day^x. This means that **what was once considered a safe level of exposure is now considered unsafe.**

Increasing concerns about cumulative exposure

Gathering the similar amount of hazard data for all 4,700 PFAS as for PFOA or PFOS would take decades. **Allowing these potentially harmful chemicals to build up in the environment waiting for the data to be generated would be contrary to the precautionary principle.** Moreover, because of the known co-exposures to multiple PFAS at the same time, potential combination effects cannot be excluded. Considering that the existing body burden of PFOS and PFOA already frequently exceeds estimated safety thresholds (see example above), adverse effects from combined exposures to structurally similar substances may already occur. Therefore, it should be of utmost priority to prevent adding more PFAS to the existing burden.

Increasing concern about unmonitored PFAS

Research suggests that the real total PFAS exposure might be currently underestimated. It is increasingly reported that a significant fraction of either total organic fluorine (TOF) or extractable organofluorine (EOF) occurring in the environment is not accounted for by the PFAS suite routinely monitored^{xi}. This is suggesting that many more PFAS than the ones routinely monitored and currently regulated are present in the environment. Therefore, only a blanket ban on the whole PFAS family could account for all possible PFAS emissions.

Restricting PFAS as a group is the necessary step for protection

Considering the irreversible nature of the PFAS contamination and the extreme persistence of these chemicals, potential adverse effects related to PFAS exposure could last for generations. That is why all PFAS emissions should be minimised as much as possible now by restricting all non-essential uses of PFAS to prevent further build-up of these substances in the environment, so future generations won't be exposed to potentially harmful levels of PFAS mixtures.

2. Key recommendations

CHEM Trust will follow the upcoming restriction proposal under REACH and support the process to find a way that delivers the best protection for health and environment. Here are our key recommendations:

The scope of the restriction

The restriction should cover all PFAS substances containing at least one aliphatic -CF₂- or -CF₃ element to:

1. Stop regrettable substitution within this family of highly persistent chemicals;
2. Account for all potential PFAS emissions, including from PFAS currently undetected due to analytical limitations;
3. Account for any potential precursor of highly persistent PFAS chemicals;
4. Encompass the uses of PFAS in the whole supply chain.

Principles for derogations

For the PFAS currently restricted under REACH such as PFOA many derogations have been granted which are not justified by the absence of alternatives^{xii}. Keeping in mind that every year of derogation granted for a product and/or use means additional emission, further build-up in the environment and therefore increasing exposure for generations to come:

- There should be as few exemptions as possible and derogations should be granted exclusively to products and/or uses essential to society for which no alternatives are yet available.
- The products and/or uses that will benefit from a derogation should be defined very specifically to avoid potential loopholes.
- All derogations should be time limited with frequent reassessment of available alternatives.

Essential uses

The definition will be critical in succeeding to limit emissions of these highly persistent substances to the strict minimum in order to minimise future generations' exposure and

prevent further irreversible contamination. We refer to the definition proposed by Cousins et al., 2019^{xiii}:

“Uses considered essential because they are necessary for health or safety or other highly important purposes and for which alternatives are not yet established.”

With the important caveat that *“This essentiality should not be considered permanent; rather, a constant pressure is needed to search for alternatives”*

Concentration limits

The concentration limits for the presence of PFAS impurities in mixtures and articles that will be proposed should be fit for the purpose of limiting emissions to the strict minimum. CHEM Trust, together with other NGOs, have criticised concentration limits in previous REACH restriction proposals on other PFAS chemicals as being too high^{xiv}.

Therefore, for the general PFAS restriction, concentration limits should:

- Be as low as possible according to the most advanced analytical developments in PFAS analysis to avoid intentional use.
- Be reassessed regularly and, if needed, improved according to the latest analytical developments.
- Have a unit of measurement adapted to different PFAS uses. Many PFAS uses correspond to surface treatment or coating, therefore a limit given in terms of ppm would not be fit for purpose in many applications. In addition to a weight or volume concentration limit, a surface concentration limit should also be defined.

Conclusion

CHEM Trust views the PFAS group restriction as the only way to ensure a high level of protection for human health and the environment from exposure to these highly persistent chemicals and to put an end to a never-ending spiral of regrettable substitutions.

ⁱ CHEM Trust, 2019. PFAS – the ‘forever chemicals’, Invisible threats from persistent chemicals. https://chemtrust.org/wp-content/uploads/PFAS_Brief_CHEMTrust_2019.pdf

ⁱⁱ ECHA, May 2020. Five European states call for evidence on broad PFAS restriction. <https://echa.europa.eu/de/-/five-european-states-call-for-evidence-on-broad-pfas-restriction>

ⁱⁱⁱ OECD, 2015. Working Towards a Global Emission Inventory of PFASs: Focus on PFCAs-Status Quo and the Way Forward. OECD/UNEP Global PFC Group. Environment, Health and Safety, Environment Directorate, OECD Publishing, Paris, France. 85p. <https://www.oecd.org/chemicalsafety/risk-management/Working%20Towards%20a%20Global%20Emission%20Inventory%20of%20PFASs.pdf>

^{iv} WWF, 2005. Generations X. Results of WWF’s European Family Biomonitoring Survey. https://chemtrust.org/wp-content/uploads/Generationsx_wwf_2005.pdf

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- ^v Del Vento et al., 2012. Volatile per- and polyfluoroalkyl compounds in the remote atmosphere of the western Antarctic Peninsula: an indirect source of perfluoroalkyl acids to Antarctic waters? *Atmospheric Pollution Research*, 3, 4, 450-455. <https://doi.org/10.5094/APR.2012.051>
- ^{vi} Duffek et al., 2020. Per- and polyfluoroalkyl substances in blood plasma – Results of the German Environmental Survey for children and adolescents 2014–2017 (GerES V). *International Journal of Hygiene and Environmental Health*, 228, 113549. <https://doi.org/10.1016/j.ijheh.2020.113549>
- ^{vii} Crookes, M. J. & Fisk, P., Peter Fisk Associates, 2018. Evaluation of using mobility of chemicals in the environment to fulfil bioaccumulation criteria of the Stockholm Convention. https://ec.europa.eu/environment/chemicals/reach/pdf/40424CRea010.i2%20Task%20F%20Assessment%20of%20mobility%20as%20a%20criteria%20for%20POPs_Final_updated.pdf
- ^{viii} CHEM Trust, 2019. Identification of HFPO-DA and PFBS as substances of very high concern (SVHC). CHEM Trust's comments to the consultations. https://chemtrust.org/wp-content/uploads/CHEM-Trust_PFAS-consultations-responses_November-2019_updated-Jan2020.pdf
- ^{ix} EFSA, 2008. Perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and their salts. Scientific Opinion of the Panel on Contaminants in the Food chain. <https://www.efsa.europa.eu/en/efsajournal/pub/653>
- ^x EFSA, 2018. Risk to human health related to the presence of perfluorooctane sulfonic acid and perfluorooctanoic acid in food. <https://www.efsa.europa.eu/en/efsajournal/pub/5194>
- ^{xi} Spaan et al 2019. Fluorine Mass Balance and Suspect Screening in Marine Mammals from the Northern Hemisphere. *Environmental Science & Technology*, 54, 7, 4046–4058. <https://doi.org/10.1021/acs.est.9b06773>
- ^{xii} Joint NGO comments, 2019. Detailed comments on the draft amendment of the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds. <https://chemtrust.org/wp-content/uploads/NGO-Comments-on-EU-Draft-PFOA-Law-.pdf>
- ^{xiii} Cousins et al., 2019: The concept of essential use for determining when uses of PFASs can be phased out. *Environmental science: Processes & Impacts*, 11, 1803-1815. <https://doi.org/10.1039/C9EM00163H>
- ^{xiv} Joint NGO comments, May 2020. CHEM TRUST, EEB and IPEN comments to SEAC draft opinion on an Annex XV dossier proposing restrictions on Perfluorohexane sulfonic acid (PFHxS) including its salts and related substances. https://chemtrust.org/wp-content/uploads/PFHxS_SEAC_PC_EEB_Chemtrust_IPEN_May2020.pdf
- Joint NGO comments, May 2020. ARNIKA, CHEM TRUST, CLIENTEARTH, EEB and IPEN comments to the REACH restriction: PFHxA, its salts and related substances. https://chemtrust.org/wp-content/uploads/NGO_input_PFHxA_restriction_13May2020.pdf