Link between the [redacted] restriction and the wide PFAS restriction

FPP4EU

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[redacted]
Restriction Process Coordinator
European Chemicals Agency

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Overview

- PFAS risk management in the EU
- Justification for grouping PFASs
- Links to wide restriction
  - Hazard/risk paradigm
  - Practicality
  - Some frequently asked questions
- Next steps

Existing regulation of PFASs in EU

- Some PFAS already subject to [or pending] restrictions on manufacture/use under REACH or POPs regulation in EU (some also Stockholm Convention)
  - Perfluoroalkyl sulfonic acids (PFOS; [PFHxS])
  - Perfluoroalkyl carboxylic acids (PFOA; C9-C14 PFCAs; [PFHxA])
- Some identified as **SVHCs**
  - E.g. HFOP-DA (GenX), PFBS, PFHxS
- Some undergoing REACH **substance evaluation** or have a **harmonised classification** under CLP regulation

Arrowhead approach

- Risk management has typically focused on specific 'arrowheads' and their 'precursors'
  - **Arrowheads** are 'terminal' degradation products with hazardous properties (typically PBT/vPvB)
    - e.g. PFOA, PFHxS, C9-C14 PFCAs, PFHxA
  - **'Precursors'** or **'related-substances'** transform to arrowhead
- A single restriction can cover many different substances as long as they can degrade/transform to the arrowhead
- Effective but **slow** and cascade of **regrettable substitution**
  - PFOS → PFOA → PFHxA → ????

Mandate

- Request 20 July 2020
- Assess **PFASs as a group**
- Build on previous studies on availability of alternatives
- Cooperate with authorities working on PFAS restriction
- Submission January 2022

Ref. Ares(2020)3812055 - 20/07/2020

EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Consumer, Environmental and Health Technologies
Directorate-General for Environment
Circular Economy and Green Growth
Directors

Brussels,
GROW/D1/SL/nt
grow.ddg1.d.1(2020)4249238

NOTE FOR THE ATTENTION OF
MR B. HANSEN, EXECUTIVE DIRECTOR, ECHA

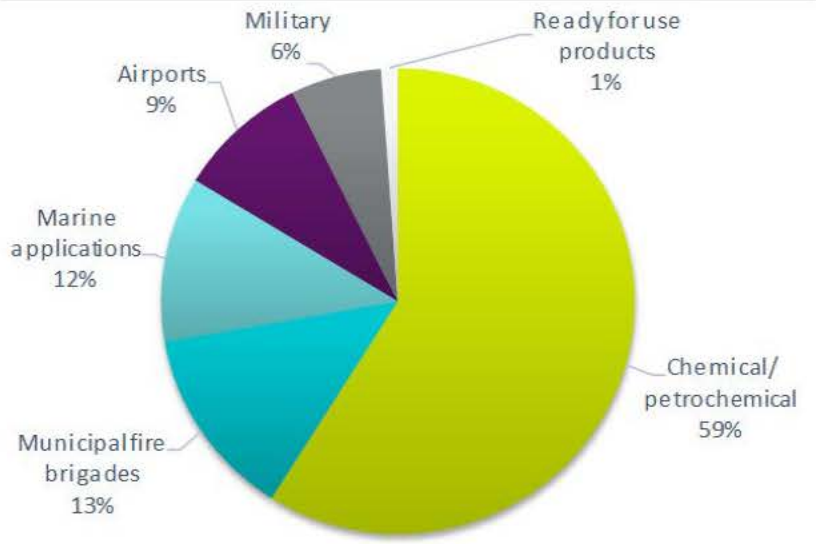
Subject: **Request to the European Chemicals Agency to prepare a restriction proposal conforming to the requirements of Annex XV to REACH on the use of per- and polyfluoroalkyl substances (PFAS) in fire-fighting foams and to cooperate with the authorities working on the preparation of an Annex XV dossier to restrict the manufacture, the placing on the market and the use of PFAS**

Per- and polyfluoroalkyl substances (PFAS) constitute a group of thousands of man-made chemicals that are widely used in various consumer and industrial products (e.g. water- and stain repellent textiles, fire-fighting foams, food contact materials and cosmetics). These substances are of increasing concern as they are all persistent in the environment, whilst some are also known to be mobile, toxic and bioaccumulative. For many PFAS currently in use, there is a lack of detailed knowledge on their chemical structures, properties, uses and toxicological profiles.

The Commission and ECHA recently commissioned a study on possible regulatory management options to address the risks associated with the use of PFAS in fire-fighting foams in the EU. The results[1] show that fluorine-free fire-fighting foams are generally available and technically feasible and have been successfully used in most of the sectors identified. Fluorinated fire-fighting foams are the cause of many cases of contamination in Europe, both of soil and drinking water. The study identified the most relevant technologies for the remediation of PFAS contamination from use of fire-fighting foams.

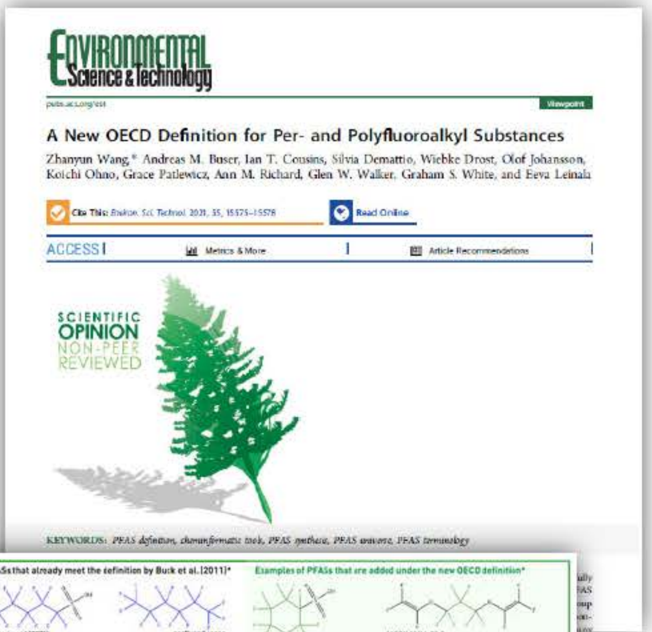
PFASs in firefighting foams

- Around 18 000 tonnes of PFAS firefighting foams sold in the EU each year
- 500 tonnes of PFAS
- Oil/(petro-)chemical sector is the largest user
- Most sectors have examples of users that have substituted to fluorine-free foams (typically training)



PFASs as a group

- Boundaries by OECD definition (2021)
- Structural similarity
  - Perfluorinated moieties
- Any substance that contains at least one fully fluorinated methyl (CF3) or methylene (CF2) carbon atom (without any H/Cl/Br/I attached to it)
- **Single hazard/risk paradigm**
  - Developed by DE, NL, DK, SE, NO
  - Ice-breaker in firefighting foams
  - Includes fluoropolymers/F-gases
- Avoid regrettable substitution


Environmental Science & Technology
pubs.acs.org/est
Viewpoint

A New OECD Definition for Per- and Polyfluoroalkyl Substances

Zhanyun Wang,* Andreas M. Buser, Ian T. Cousins, Silvia Demattio, Wiebke Drost, Olof Johansson, Koichi Ohno, Grace Patlewicz, Ann M. Richard, Glen W. Walker, Graham S. White, and Eeva Leinala

Cite This: Environ. Sci. Technol. 2021, 55, 15575−15578

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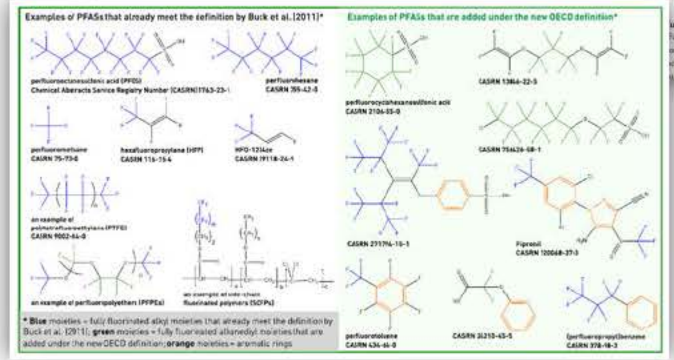
SCIENTIFIC OPINION NON-PEER REVIEWED

KEYWORDS: PFAS definition, cheminformatic tools, PFAS synthesis, PFAS universe, PFAS terminology



https://pubs.acs.org/doi/pdf/10.1021/acs.est.1c06896

Hazard/risk paradigm

PFASs assessed as a group

Persistence is the common property of the group

Various supporting concerns

Properties	**Concerns related to combinations of properties**
Very high persistence	High potential for ubiquitous, increasing and irreversible exposures of the environment and humans;
Long-range transport potential	Difficulty to decontaminate raw water for drinking water, low effectiveness of end-of-pipe RMMs and difficulty to treat contaminated sites;
Mobility	High potential for human exposure via food and drinking water;
Accumulation in plants	Potential for intergenerational effects and delay of effects;
Bioaccumulation potential	Potential for causing serious effects although those would not be observed in standard tests;
Endocrine activity	Estimation of future exposure levels and safe concentration limits is highly uncertain;
Ecotoxicity	Global warming potential.
Effects to human health	

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Hazard/risk paradigm

Properties

Very high persistence

Long-range transport potential

Mobility

Accumulation in plants

Bioaccumulation potential

Endocrine activity

Ecotoxicity

Effects to human health

- PFASs are among the most stable organic compounds
  - Resist (bio) degradation because of the stable C-F bond
- PFASs can be transported by air, water and matrices to which they are adsorbed or absorbed
  - e.g., dust, sediments, migratory animals and polymer particles
- PFASs are found in all environmental compartments as well as in biota (e.g. mammals, birds, fish)
- Plants accumulate many PFASs beyond expected levels
- Exposures may be higher than observed by monitoring
- For well studied PFASs effects on behaviour, growth, reproduction, metabolism, organs & immune system observed
- *In silico*, *in vitro* and *in vivo* data provide indications of interactions of various PFASs with the endocrine system
- Harmonised class. for PFOS, PFOA, PFNA, and PFDA (+ salts): carcinogenicity (Carc. 2), reproductive toxicity (Repr. 1B), effects on or via lactation (Lact.), specific target organ toxicity - repeated exposure (STOT RE 1).

Hazard/risk paradigm

- Persistence combined with supporting concerns
  - Quantitative risk assessment is not reliable or practicable
  - Not possible to demonstrate safe use (no reliable DNEL/PNEC)
    - Similar to PBT/vPvB
  - Continued use would inevitably result in accumulation to levels causing adverse effects
- 'Case-by-case' risk assessment according to Annex I (section 0.1) of REACH
  - Risks of PFASs are considered as non-threshold and not adequately controlled
  - Releases are a proxy for uncontrolled risk
  - Risk management to minimise releases

Practicality

- Concentration limit of 1 ppb PFASs
- Expressed as 'total organic fluorine'
- Presence and concentration of non-PFAS organofluorine substances shall be included on the product packaging
- Practical enforcement despite structural variability

Common questions

Common questions (1)

- Scope (which substances are in/out?)
  - Is analysis of degradation products (arrowheads) needed before a substance is **within** scope?
    - No, the scope is set by the OECD definition
  - Is substance-specific information on hazards or case-by case assessment of risks needed?
    - No, the hazard / risk conclusion is applicable to the whole group, irrespective of substance-specific information (no threshold)
  - Evidence to consider PFAS as non-persistent (OECD?)
    - RAC/SEAC and DS will assess justifications case-by-case
  - Will scope be based on PFASs used in firefighting foams?
    - No, intention is to prevent regrettable substitution – whole lifecycle

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Common questions (2)

- Existing OCs and RMMs
  - Is existing legislation sufficient to address the identified risks (e.g. IED / OSH / F-gas)
    - No, Annex XV report concludes existing measures are not sufficient to control the identified risk
    - DS notes that regulatory baseline is dynamic
    - Commission would need to reconcile any overlaps
  - What measures could be put in place?
    - Risk management objective is **minimisation of risk**
    - Restriction can apply to a minimised risk – if proportionate; is restriction disproportionate?

Common questions (3)

- Exports
  - Restriction applies use (e.g., formulation)
    - Justified based on risks at this lifecycle stage (releases)
    - Restriction prevents formulation for export
    - Socio-economic analysis refers to impacts on exports
    - DS will revise text after the consultation to prevent misinterpretation

Next steps

Next steps

- Proposal being evaluated by ECHA's committees for:
  - Risk Assessment (RAC)
  - Socio-Economic Analysis (SEAC)
- Six-month consultation of interested parties
  - **Stakeholder information session 5 April**
  - **Q&A published on ECHA website 15 June**
- Evaluation documented in 'opinions'
- Commission and Member States decide on implementing the restriction in REACH Committee
- Scrutiny by Council and European Parliament

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Thank you!

[redacted]

Backup slides

Hazard assessment

Persistence

- PFASs are among the most stable organic compounds. Common for all the PFASs is that they have perfluoroalkyl moieties present. These moieties resist environmental and metabolic degradation due to the very stable C-F bonds.
- PFASs can be divided with regard to the hazard assessment into "precursors" and "arrowheads".
- The precursors are known or expected - based on modelling - to degrade on a timescale from hours to years to the arrowheads, such as PFCAs, PFECAs and PFSAs.
- After gradual degradation of the non-fluorinated part, the degradation stops when only perfluorinated carbons, and in some cases other moieties at their highest oxidation state and with high persistence, are left in the substance.
- Lifetimes of the arrowhead PFASs in the environment exceed the criteria for very persistent substances. For example, PFAAs are key arrowheads in the environment, and if PFAAs degrade, they do it so slowly that it is not observable in standard tests.

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Hazard assessment

Long range transport potential (LRTP) and Mobility

- PFASs can be transported by air, water and matrices to which they are adsorbed or absorbed, such as dust, sediments, migratory animals, or through matrices in which they are included as additive, e.g. polymers. Calculated characteristic travel distances (CTD) of FTOHs and PFCAs reach thousands of kilometres in air and water.
- Short-chain PFAAs and many long-chain PFAAs can be considered mobile in water. Degradation of precursor - PFASs in the environment to PFAAs also render the precursors mobile in water at some point of time.
- For those PFASs, which are volatile, distribution in the environment occurs mainly via air.

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Hazard assessment

Accumulation in plants

- Plants accumulate many PFASs to levels which exceed the expected levels based on equilibrium partitioning indicating potential of PFASs to transfer from contaminated soil to plants.
- Consumption of plant material, e.g. grains and vegetables either as roots or above ground plant parts, function as a source of PFASs to humans and animals.

Bioaccumulation

- C11-C14 PFCAs and C6-PFSA have been shown to fulfil the vB-criterion and C8-C10-PFCA the B criterion
- Binding to albumin and transporter proteins, leads to an efficient distribution of PFASs into different tissues, enhance passage across brain, placental barriers, and transfer via milk.
- PFASs are found in all environmental compartments in mammals, birds, fish or other vertebrates throughout Europe and globally
- The actual exposures of PFASs, may be expected to be higher than the one observed in the monitoring programs – only a subset of PFASs currently monitored.

Hazard assessment

Ecotoxicity

- evidence for a subset of PFASs suggests that adverse effects occur but the large amount of different substances in the group of PFASs with heterogenous properties (e.g. due to different functional groups) makes the assessment of their ecotoxicity very complex.
- For a few well studied PFASs (mainly long chain PFCAs and PFSAs) e.g. effects on behaviour, growth, reproduction, metabolism, organs (mainly liver) & immune system have been observed

Endocrine Activity/Endocrine Disruption:

- *in silico*, *in vitro* and *in vivo* data provide indications of interactions of various PFASs with the endocrine system of environmental species
- adverse effects - some occurring cross generational – with potential relevance on population level have been observed

Hazard assessment

Human health effects

- Epidemiological evidence: association between increased serum levels of various PFCAs and PFSAs (arrowheads) and
  - ↓ vaccine antibody response, ↑ propensity of infections
  - ↑ serum cholesterol,
  - ↑ serum alanine transferase (ALT),
  - ↓ birth weight
- Animal data for various PFASs from different groups (arrowheads & prescursors): Toxicological effects
  - Liver (hepatocellular hypertrophy, ↑ ALT)
  - Immune system (↓ lymphoid organ weight)
  - Thyroid (↓ thyroid hormones)
  - Kidney (↑ kidney weight)
  - Reproduction (litter loss, neo-/postnatal mortality, ↓ offspring body weight, ↓ reproductive organ weight)
- E.g. harmonised class. for PFOS, PFOA, PFNA, and PFDA (+ salts)
  - carcinogenicity (Carc. 2)
  - reproductive toxicity (Repr. 1B, PFHpA to be added soon)
  - effects on or via lactation (Lact.)
  - specific target organ toxicity - repeated exposure (STOT RE 1, except for PFDA, PFHpA to be added soon; 6:2 FTOH to be added soonfor STOT RE 2)

Hazard assessment

High potential for ubiquitous, increasing and irreversible exposure of the environment and humans

- Environmental concentrations increase as a result of releases until reaching a steady state at a far point of time in the future.
- The environmental stock of the arrowhead PFASs formed is expected to prevail in the environment for decades if not centuries.
- Persistence in combination with mobility in the aquatic environment → none of the environmental compartments act as a potential removal pathway (i.e. a sink).
- Due to persistence even less mobile PFASs have time to be distributed in and between environmental compartments. (PFASs therefore reach effectively all media, including groundwater aquifers which function as drinking water reservoirs.)
- Even the most remote sites of the globe and most vulnerable environments cannot be protected from PFAS exposures.
- Monitoring data show PFASs are ubiquitously present.

Hazard assessment

Difficulty to decontaminate raw water and to reduce emissions with site-specific risk management

- Very high persistence of PFASs and mobility and for many PFASs also of surface activity trigger specific challenges to wastewater treatment and decontamination of, e.g., raw water used for drinking water and contaminated sites.
- Conventional and advanced methods not able to remove PFASs effectively or come with a high process cost due to their persistence and inertness to chemical and thermal reaction.
- Removal or remediation might only be feasible for contamination hotspots in few specific cases, but not for the majority of the environment, such as large aquifers, surface waters and the world's oceans.

Hazard assessment

High potential for human exposure via food and drinking water

- Accumulation of many PFASs in edible plants, the bioaccumulation potential observed for some PFASs and the very high persistence and mobility mean human exposure via food can be expected by many routes
- Drinking water is a source of PFAS exposures due to the difficulty to decontaminate raw water prepared for drinking water.
- Models demonstrate that mobile and persistent PFASs will ultimately reach over time - unless emissions are ceased - such high levels in organisms that will affect both ecosystems and human health widely
- Bioaccumulation and mobility can be seen as properties facilitating exposure and enhancing the likelihood of adverse effects in particular when combined with the very persistent property.

Hazard assessment

Potential for intergenerational effects and delay of effects

- Transfer via nursing/breast feeding and via placenta to the offspring
- Aforementioned increasing and irreversible exposures continuing over decades or even centuries increase the likelihood for intergenerational effects
- Increasing stock pollution → likelihood of effects to be observed at a later stage. At such point of time the effects would be very difficult to reverse.
- Increasing lines of evidence for effects of well-studied PFASs occurring at lower levels than previously anticipated AND increasing findings of hazardous properties of less studied PFASs

→ a threat of irreversible damage for future generations

Hazard assessment

Potential for causing serious effects although those would not be observed in standard tests

- Arrowhead PFASs constitute a diverse mixture of exposure whereas all the released PFASs in combination with the arrowhead PFASs form a very complex cocktail in the environment.
- Very long, multigenerational exposures cannot be appropriately addressed by standard tests.

Hazard assessment

Estimation of future exposure levels and safe concentration limits is highly uncertain

- Concentrations add up from past present and future.
- Currently no appropriate tools exist to estimate exposures reliably far in future. This is further complicated for PFASs by the degradation of the precursors to the arrowhead PFAS.
- Delayed or yet undetected effects complicates the derivation of safe levels.
- **Combined effects of the complex PFAS mixture**
  - The prediction of safe levels is more challenging, if not impossible, due to the complex mixture of used PFASs actually prevailing in the environment over long-term.
  - Given similar effect patterns for many PFASs in animal studies, such as effects on liver, thyroid hormone system, and immune system, additive effects may be considered as realistic worst-case estimation.

Hazard assessment

Global warming potential

- Persistent and volatile and will partition to the atmosphere where they will stay for a very long time.
- These PFASs may have a considerable global warming potential which could contribute to the greenhouse effect and global warming.
- Some of the strongest greenhouse gases known are PFASs(hydrofluorocarbons (HFCs), hydrofluoroolefins (HFOs) and hydrofluoroethers (HFEs)).