

Link between the firefighting foam restriction and the wide PFAS restriction

FPP4EU

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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

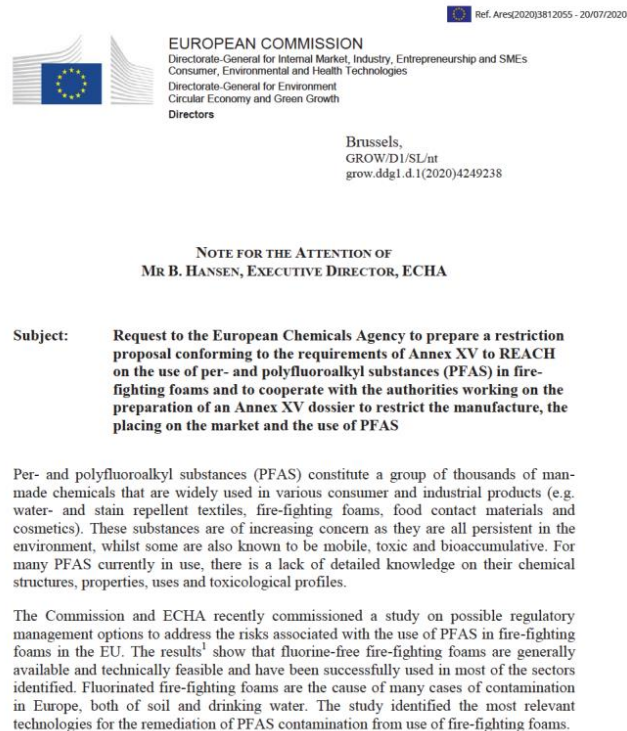
- Some PFAS already subject to [or pending] restrictions on manufacture/use under REACH or POPs regulation in EU (some also Stockholm Convention)
 - Perfluoroalkyl sulfonic acids (PFOS; [PFHxS])
 - Perfluoroalkyl carboxylic acids (PFOA; C9-C14 PFCAs; [PFHxA])
- Some identified as **SVHCs**
 - E.g. HFOP-DA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

Arrowhead approach

- Risk management has typically focused on 'arrowheads' with confirmed hazard properties and their 'precursors'
 - **Arrowheads** - terminal degradation product
 - typically PBT/vPvB properties e.g. PFOA, PFHxS, C9-C14 PFCAs
 - **'Precursors'** or **'related-substances'** transform to arrowhead
- A single restriction can cover many different substances as long as they contain the arrowhead moiety
- Effective but **slow** and can result in a cascade of **regrettable substitution**
 - PFOS → PFOA → PFHxA → ????

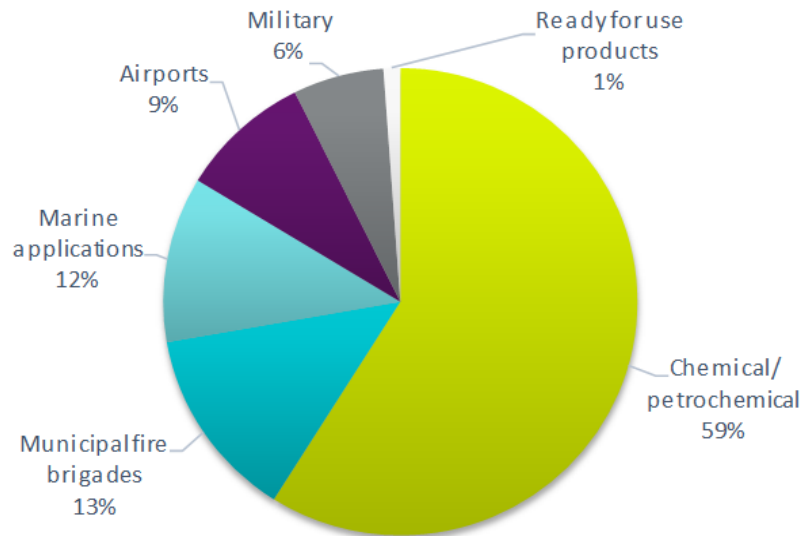
Mandate

- 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



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

A New OECD Definition for Per- and Polyfluoroalkyl Substances
Zhanyun Wang,* Andreas M. Buser, Ian T. Cousins, Silvia Dematto, Wiebke Drost, Olof Johansson, Koichi Ohno, Grace Patlewicz, Ann M. Richard, Glen W. Walker, Graham S. White, and Eeva Leinla

Cite This: Environ. Sci. Technol. 2021, 55, 15575–15578
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SCIENTIFIC OPINION
NON-PEER REVIEWED

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

Examples of PFASs that already meet the definition by Buck et al. (2011)*

perfluorooctanesulfonic acid (PFOS)
Chemical Abstracts Service Registry Number (CASRN) 1763-23-1

perfluorohexane
CASRN 355-42-0

perfluoromethane
CASRN 75-72-5

hexafluoropropylene (HFP)
CASRN 116-16-4

HFD-1234ac
CASRN 211-18-24-9

an example of polytetrafluoroethylene (PTFE)
CASRN 1062-80-6

an example of perfluoropolyethers (PFPEs)

an example of side-chain fluorinated polymers (SCFPs)

Examples of PFASs that are added under the new OECD definition*

perfluorocyclohexanesulfonic acid
CASRN 3706-05-9

perfluorooctanesulfonic acid
CASRN 75426-58-1

CASRN 13846-22-5

CASRN 271796-15-1

Figures
CASRN 120068-37-3

perfluorobenzene
CASRN 436-44-0

CASRN 34219-45-6

perfluorophenylbenzene
CASRN 378-78-3

* Blue moieties = fully fluorinated alkyl moieties that already meet the definition by Buck et al. (2011); green moieties = fully fluorinated alkenedyl moieties that are added under the new OECD definition; orange moieties = aromatic rings

Hazard/risk paradigm

PFASs
assessed as a
group

Persistence
is the common
property of the
group

Various
supporting
concerns

Properties

Very high persistence

Long-range transport potential

Mobility

Accumulation in plants

Bioaccumulation potential

Endocrine activity

Ecotoxicity

Effects to human health



Concerns related to combinations of properties

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

Difficulty to decontaminate raw water for drinking water, low effectiveness of end-of-pipe RMMs and difficulty to treat contaminated sites;

High potential for human exposure via food and drinking water;

Potential for intergenerational effects and delay of effects;

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

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

Global warming potential.

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
- Many 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
- Many PFASs are ubiquitous in environmental compartments and 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 ppm 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

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



Thank you!

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