

Risk management of PFASs at the European Chemicals Agency

PFAS Global 2022

24 March 2022



Restriction Process Coordinator
European Chemicals Agency



Overview

- PFASs as a **hot topic** for EU risk management
- Risk management of PFASs based on **'arrowheads'**
- Proposed REACH restriction for **all PFASs** in firefighting foams

PFAS concern

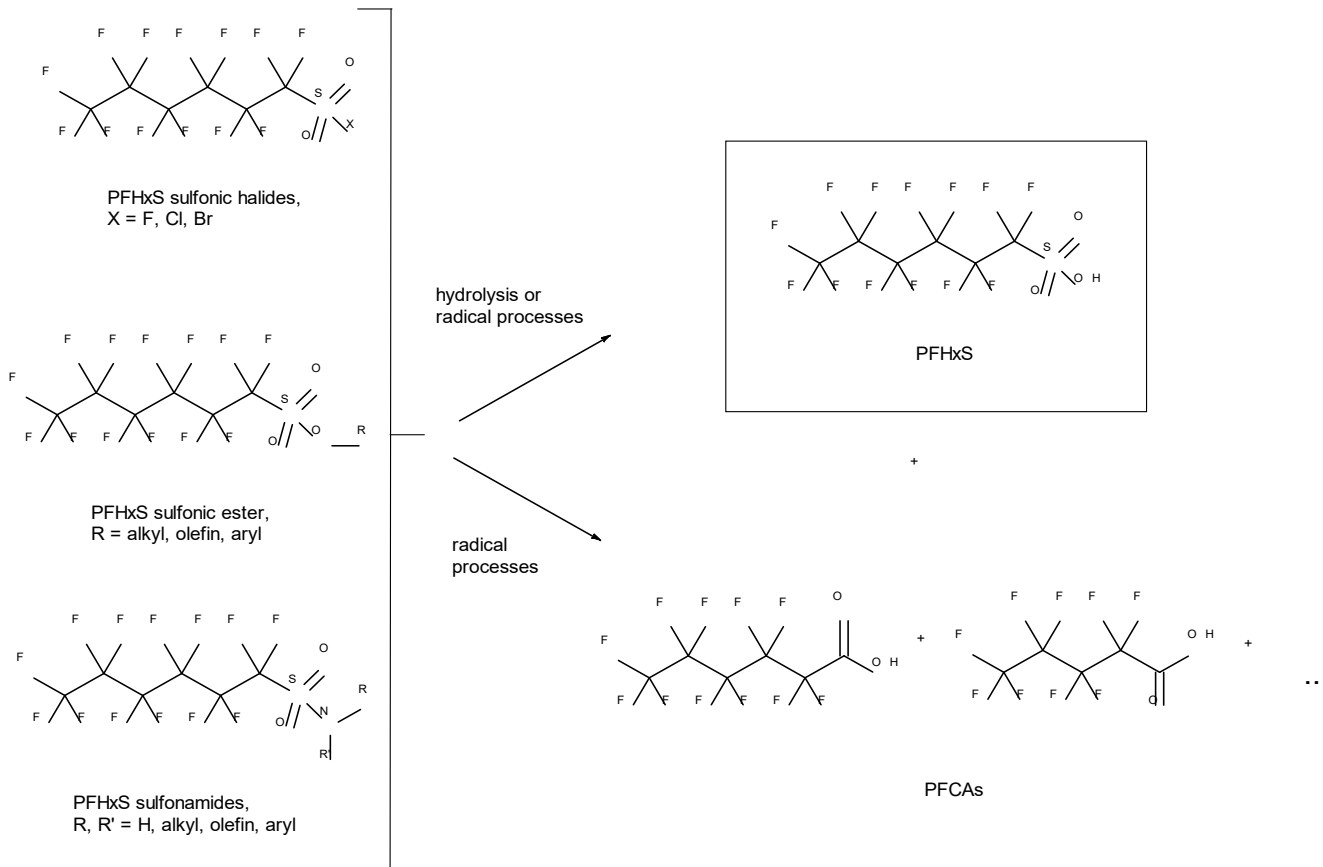
- PFAS contain (numerous) carbon-fluorine bonds
 - **Very stable** - resist (bio)degradation
- Some are highly soluble and mobile (i.e. surfactants)
 - can be readily transport once in the environment
 - frequently observed to contaminate groundwater, surface water and soil
- Some bioaccumulate
 - notably 'long chain' perfluoroalkyl substances
- Some met REACH criteria for persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative (vPvB)

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

Arrowheads and related substances

- 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 have lead to regrettable substitution
 - PFOS → PFOA → PFHxA → ????



PFASs in firefighting foams

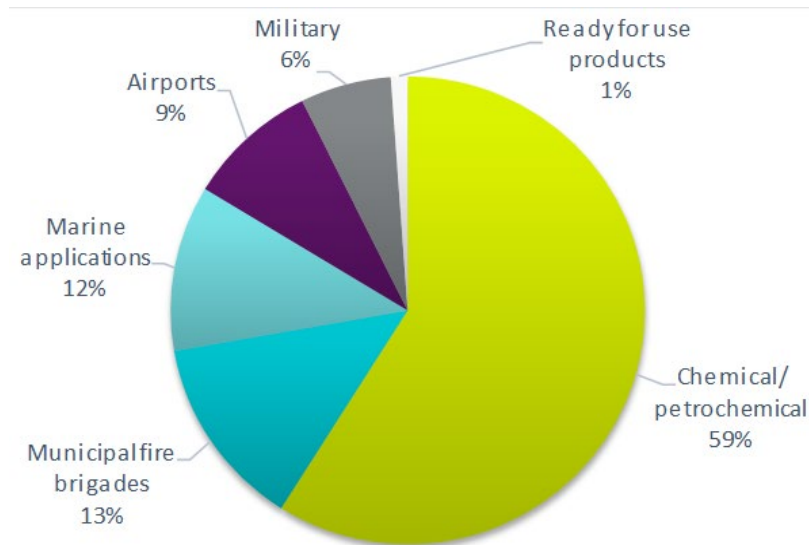


Image: ©iStock.com



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)



A New OECD Definition for Per- and Polyfluoroalkyl Substances

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

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NON-PEER
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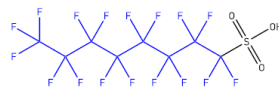


KEYWORDS: PFAS definition, cheminformatic tools, PFAS synthesis, PFAS universe, PFAS terminology

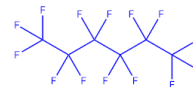
Per- and polyfluoroalkyl substances (PFASs) comprise a class of chemicals that has attracted much attention since the early 2000s, when the hazards and ubiquitous occurrence of two PFASs—perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS)—were reported. Early commu-

market. The list included substances that contain fully fluorinated carbon moieties, but do not meet the PFAS definition in Buck et al. (2011) due to a lack of a $-\text{CF}_3$ group in the molecule. Additionally, recent advancement of non-targeted analytical techniques enabled identification of more

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



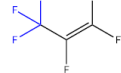
perfluorooctanesulfonic acid (PFOS)
Chemical Abstracts Service Registry Number (CASRN) 1763-23-1



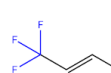
perfluorohexane
CASRN 355-42-0



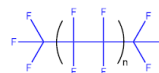
perfluoromethane
CASRN 75-73-0



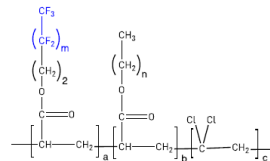
hexafluoropropylene (HFP)
CASRN 116-15-4



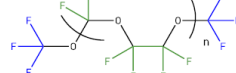
HFO-1234ze
CASRN 29118-24-9



an example of
polytetrafluoroethylene (PTFE)
CASRN 9002-84-0



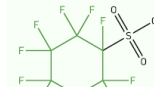
an example of side-chain
fluorinated polymers (SCFPs)



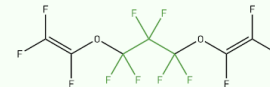
an example of perfluoropolyethers (PFPEs)

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

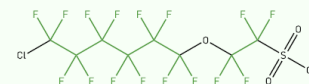
Examples of PFASs that are added under the new OECD definition*



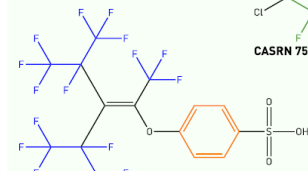
perfluorocyclohexanesulfonic acid
CASRN 2106-55-0



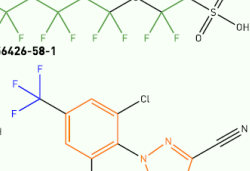
CASRN 13846-22-5



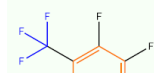
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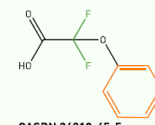
CASRN 271794-15-1



Fipronil
CASRN 120068-37-3



perfluorotoluene
CASRN 434-64-0

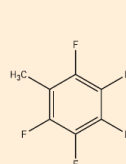


CASRN 24210-45-5

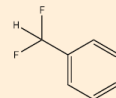


[perfluoropropyl]benzene
CASRN 378-98-3

Examples of substances that are NOT PFASs



CASRN 771-56-2



CASRN 455-31-2



trifluoromethane
CASRN 75-46-7



CASRN 75-63-9



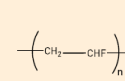
CASRN 75-63-8



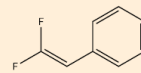
CASRN 2314-97-8



difluoromethane
CASRN 75-10-5



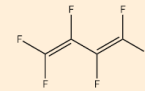
polyvinyl fluoride (PVF)



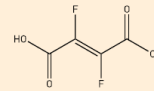
tetrafluoroethylene (TFE)
CASRN 116-14-3



hexafluorobutadiene
CASRN 685-63-2



CASRN 685-63-2



CASRN 685-64-3

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

Hazard assessment

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 conclusions

- Persistence combined with supporting concerns
 - Quantitative risk assessment is not reliable or practicable
 - Not possible to demonstrate safe use
 - Continued use would inevitably result in accumulation to levels causing adverse effects
 - Restriction applied as a 'safety net'
- 'Case-by-case' risk assessment according to Annex I (section 0.1) of REACH
 - Risks of PFASs are non-threshold
 - Releases are a proxy for uncontrolled risk
 - Risk management to minimise releases

Restriction option analysis

RO#	Description	Emission reduction profile and possible issues
1	Restriction on the placing on the market (use allowed until expiry date of stocks)	Progressive reduction of emissions
2	Restriction on the placing on the market and use (transitional periods per sector of use)	Defined substitution deadlines provide strong incentive for substitution
3	Restriction on the placing on the market, use and export (transitional periods per sector of use)	Exports also banned
4	Restriction on the placing on the market and use (transitional periods per sector of use) with a derogation mechanism for Seveso / defence	Slower reduction of emissions than the other ROs since the largest sector could request derogation for use. Risk management unlikely to be completely effective. Complex enforcement/practicality
5	Restriction for all uses (transitional periods per sector of use) unless risk management measures (RMMs) in place to minimise emissions	Allows substitution if technically and economically feasible and continued use of PFAS foams where not. Only applicable at limited sites being able to implement strictest RMMs. Risk management unlikely to be completely effective

Evaluation and decision making

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



Thank you!

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