

Proposed restriction of PFAS in firefighting foams

RAC-

XXX

ECHA: XXX



Outline

- Background
- SID and hazard
- Restriction proposal
- Risk assessment
- Impact assessment
- Conclusions

Global focus PFAS in firefighting foams

- Exposure to PFAS in general has gained increasing attention for several years
- Use of PFAS in firefighting foams is linked to pollution of the environment, including drinking water. Several use restrictions have been put in place in certain non-EU countries, e.g. in certain US States (California, Washington, NY, etc.), other initiatives in Australia, also some targeting the defence sector.
- Green Deal: EU's chemicals strategy and EC Staff Working Document on PFAS

Regulatory actions in the EU

- 2019-2020: Preliminary studies by ECHA/Commission on use of PFAS fire-fighting foams and their alternatives
- July 2020: Commission requested ECHA to prepare a restriction proposal for **all PFAS** in firefighting foams, in cooperation with the five authorities preparing the 'universal' PFAS restriction
 - Action from the Chemical Strategy for Sustainability
- 2020-21: RAC and SEAC evaluated the proposed restriction on PFHxA
 - Fire-fighting foams one of the uses assessed
 - completed in December 2021

PFAS in firefighting foams: function

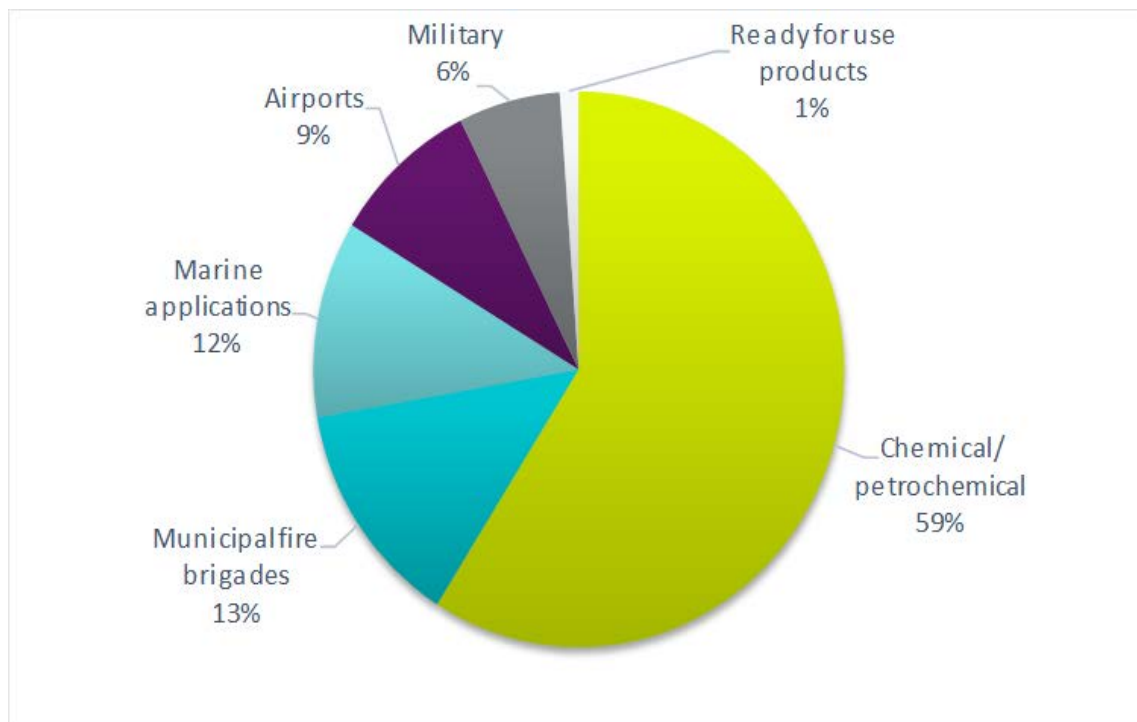
- Primary function as a surfactant
- Form a film over the surface of a burning liquid
- Particularly relevant and effective for industrial fires with flammable liquids (Class B fires)

Image: ©iStock.com



Sectors of use

- Around 18 000 tonnes of PFAS fire-fighting foams are sold in the EU each year
- Equivalent to around 500 tonnes of PFAS



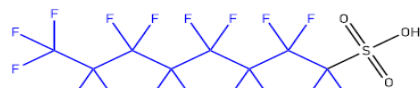
- Oil/(petro)chemical sector is the largest user
- Most sectors have examples of users that have substituted to F-free foams (typically training)

Per- and polyfluoroalkyl substances (PFASs) defined as:

- any substance that contains at least one fully fluorinated methyl (CF_3) or methylene (CF_2) carbon atom (without any H/Cl/Br/I attached to it).
- This restriction proposal covers all substances containing PFASs as defined above as a constituent (including as impurity or additive) as well as in mixtures.
- This definition is equal to the OECD definition, derived in 2021

- A recent study by the OECD/UNEP Global PFC Group identified 4 730 CAS-numbers associated with individual PFASs or PFASs mixtures (OECD/UNEP, 2018).
- A comparison of REACH registered and/or CLP notified PFASs in 2019 with the OCED/UNEP list revealed that there may be more than 9 000 different individual PFASs.
 - 6 257 were notified only to the ECHA classification and labelling database
 - there were 508 substances with active registrations, 257 of these were full and the remainder intermediate.
- The US EPA have assembled a consolidated 'master list' of 6 330 PFASs by combining information from several existing lists (U.S. EPA, 2020).

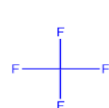
Examples of PFASs that already meet the definition by Buck et al. (2011)*



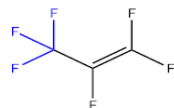
perfluorooctanesulfonic acid (PFOS)
Chemical Abstracts Service Registry Number (CASRN) 1763-23-1



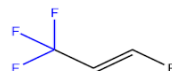
perfluorohexane
CASRN 355-42-0



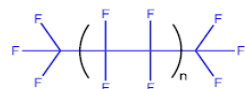
perfluoromethane
CASRN 75-73-0



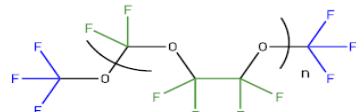
hexafluoropropylene (HFP)
CASRN 116-15-4



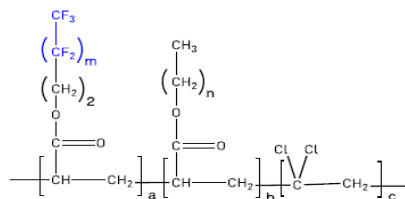
HFO-1234ze
CASRN 29118-24-9



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



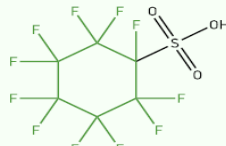
an example of perfluoropolyethers (PFPEs)



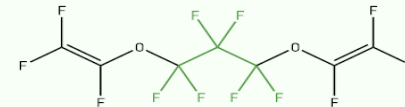
an example of side-chain
fluorinated polymers (SCFPs)

* **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

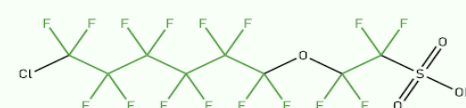
Examples of PFASs that are added under the new OECD definition*



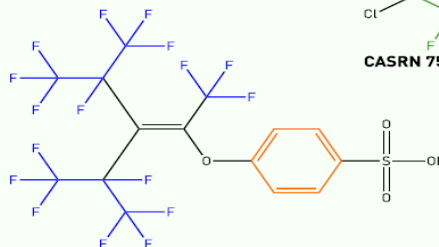
perfluorocyclohexanesulfonic acid
CASRN 2106-55-0



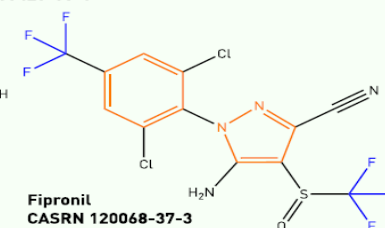
CASRN 13846-22-5



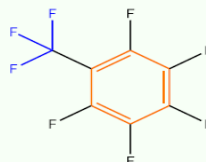
CASRN 756426-58-1



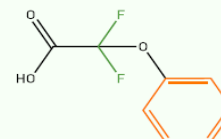
CASRN 271794-15-1



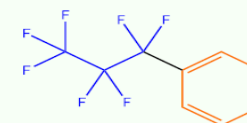
Fipronil
CASRN 120068-37-3



perfluorotoluene
CASRN 434-64-0

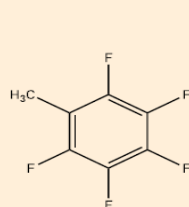


CASRN 24210-45-5

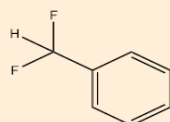


(perfluoropropyl)benzene
CASRN 378-98-3

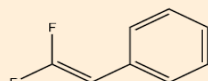
Examples of substances that are NOT PFASs



CASRN 771-56-2



CASRN 455-31-2



CASRN 405-42-5



trifluoromethane
CASRN 75-46-7



CASRN 75-72-9



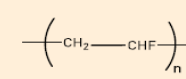
CASRN 75-63-8



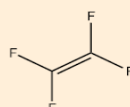
CASRN 2314-97-8



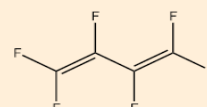
difluoromethane
CASRN 75-10-5



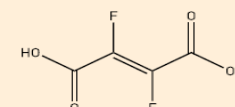
polyvinyl fluoride (PVF)



tetrafluoroethylene (TFE)
CASRN 116-14-3

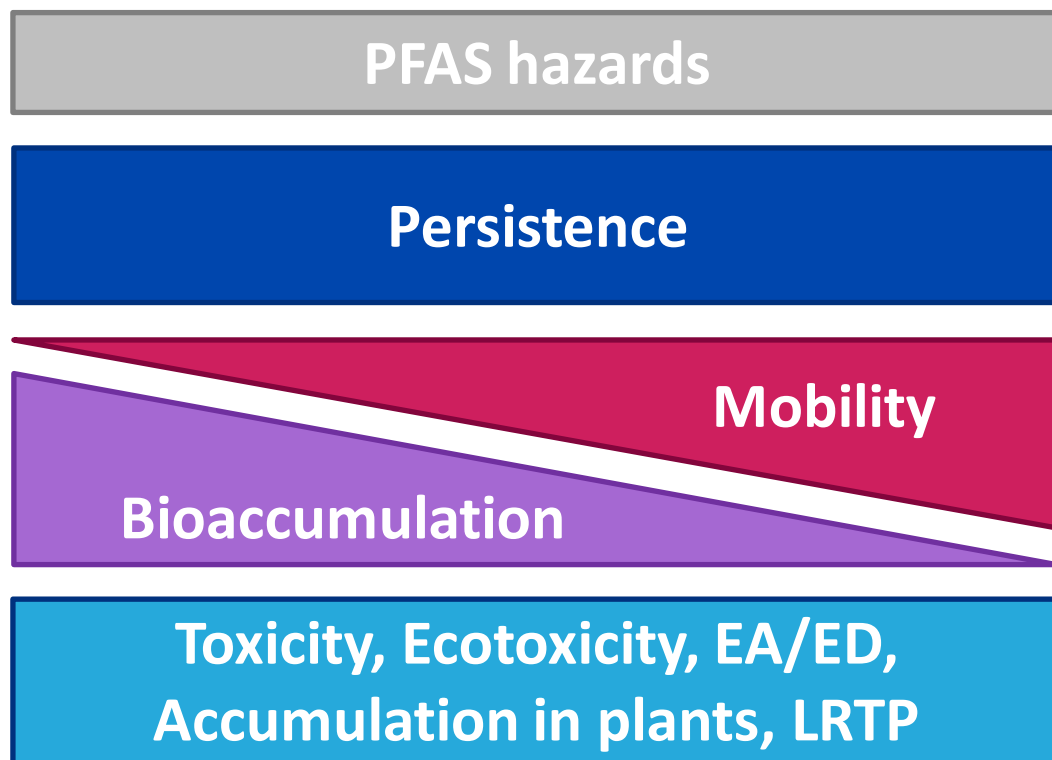


hexafluorobutadiene
CASRN 685-63-2



CASRN 685-64-3

- PFASs are considered as a group.
- The grouping is based on structural similarity (common perfluorinated moieties) that triggers equivalent hazards and risks among the substances covered, primarily related to the very persistent property of the perfluorinated part(s) of PFASs molecules.
- The grouping is also justified by the desire to avoid regrettable substitution and prevention of future exposures of those PFASs which are not currently in use.



Hazard assessment

Properties

Very high persistence

Long-range transport potential

Mobility

Accumulation to 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.

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- 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.

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 it is 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.

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
- Shorter-chained more mobile PFASs typically accumulate in above-ground plant parts, longer-chained PFASs accumulate in roots and show lower translocation factors to the above-ground plant parts.
- This is influenced by the higher water solubility, mobility, lower molecular size and lower hydrophobicity of the short-chain PFASs
- *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.*

Hazard assessment

Bioaccumulation

- C11-C14 PFCAs and C6-PFSA have been shown to fulfil the vB-criterion and C8-C10-PFCA the B criterion
- PFASs, particularly the PFAAs as arrowheads, accumulate more in air-breathing organisms as compared to gill breathing organisms
- 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 (primarily PFBA, PFBS, PFHpA, PFHxA, PFHxS, PFOS, FOSA, 6:2 FTOH , F- 53B, 6:2 Cl- PFESA, TFA, and C9-C11 PFCAs) 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.

Hazard assessment

Ecotoxicity

Endocrine Activity/Endocrine Disruption

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 heterogeneous 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 PFSA)s e.g. effects on behaviour, growth, reproduction, metabolism, organs (mainly liver) & immune system have been observed

EA/ED:

- *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 & precursors): 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. harmonized 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 soon for STOT RE 2)

Hazard assessment

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Mobility

Accumulation to 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.

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

- **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.

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.

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

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

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.
- Mixtures, delayed or yet undetected effects complicates the derivation of safe levels

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))

Analysis of alternatives

- Alternatives already adopted in many sectors and for training or testing
- Alternatives mostly tested in small-scale standard tests with a limited number of flammable liquids
- Performance testing against large fires or for certain flammable liquids (oil/chemical industry) advancing but not yet completed
- Performance of application system and technique is as relevant as the foam itself (properties/behaviour of alternatives is different from PFAS-foams)



Restriction options assessed

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 Proposed RO
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

No derogations proposed

All ROs include mandatory best practice additional RMMs during transitional periods

Transitional period per type/sector of use

Length based on:

- availability of suitable alternatives and time required to implement the transition (testing at user's site, installation/equipment adaptation and firefighting methods adaptation)
- capacity of containment of releases
- no compromise in fire safety

Sector/type of use or placing on the market	Transitional period from the entry into force
Seveso establishments	10 years
Other industries	5 years
Civilian aviation	5 years
Defence	5 years
Municipal fire services	18 months
Ready-to-use applications	5 years
Marine applications	3 years
Training and testing	18 months
Export	10 years

Additional conditions

From 6 months after entry into force:

- PFAS foams only allowed for **Class B fires**
- Set up and implement **PFAS firefighting foams management plan** aiming at **minimising the emissions** of PFAS in the environment as far as technically and practically possible
- collected PFAS-containing waste and foam concentrates needing disposal shall be handled for **adequate treatment**, minimising releases of PFAS to environmental compartments as far as technically and practically possible and shall exclude municipal wastewater treatment, irrespective of any pre-treatment
- **Label** of all containers of PFAS foam concentrates and PFAS waste

Concentration threshold

- 1000 ppb of PFAS in proposed
- Well below the typical PFAS concentration in foam concentrate (2.5%)
- High enough to allow detection and quantification by analytical methods
- No EU analytical standard yet but several methods exist and have been used in the context of firefighting foams
- Not too low to avoid excessive costs in equipment cleaning/replacement while having marginal impact on emissions reduction

Risk assessment

- PBT/vPvB approach, i.e. focus on emissions
- Two model PFAS used as surrogates for the whole tonnage
- Emissions to environment estimated for each use and life-cycle stage
 - Different transitional periods for restriction modelled

Approach to exposure assessment

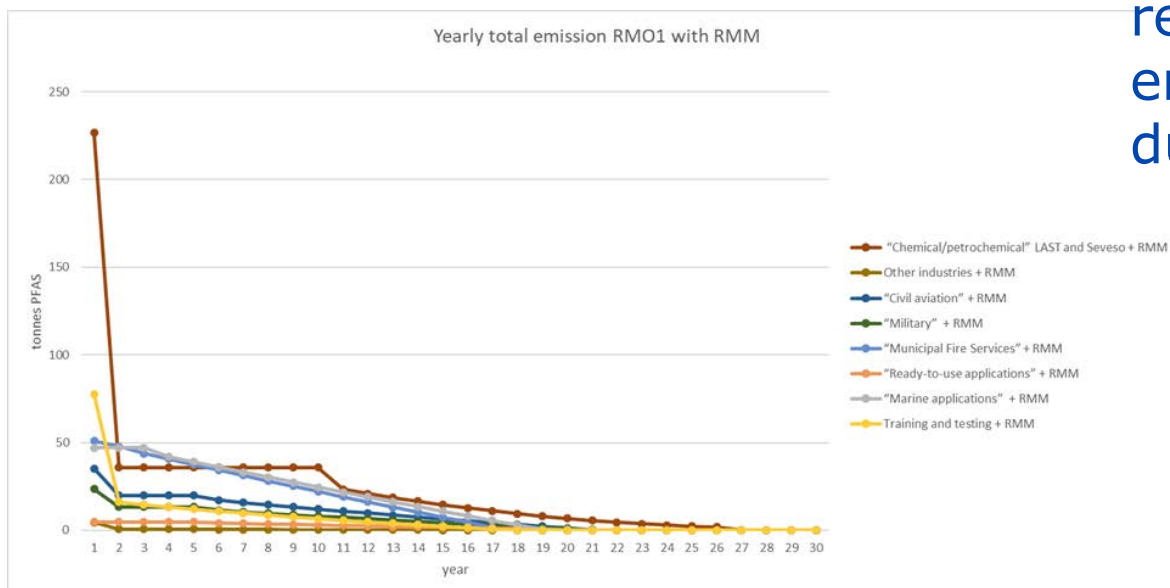
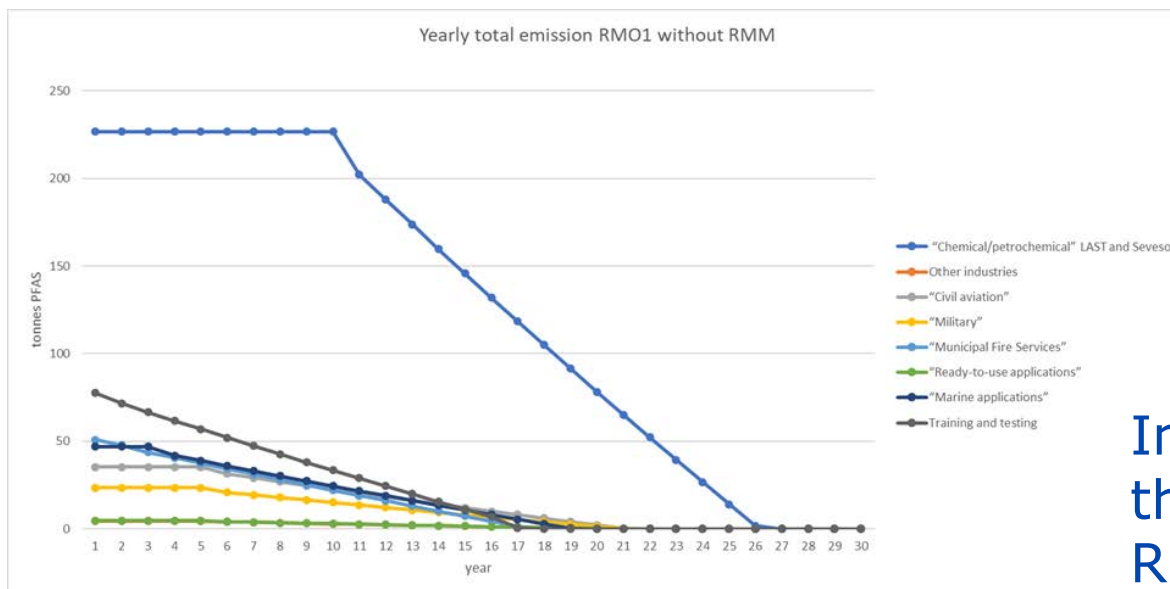
- Focus on emissions (PBT/vPvB approach)
- Two model PFAS used as surrogates for the whole tonnage
- Emissions to environment estimated for each use and life-cycle stage, Excel spreadsheets
- Provides the emission pattern over time for the 5 ROs
- Modelled “with” and “without” additional RMMs to identify the impact of the proposed RMMs
- Input parameters based on literature, industry feedback and expert judgement (e.g. in absence of clear information from industry on treatment of collected PFAS waste it has been assumed that the collected waste is sent to WWTP with zero effectiveness on PFAS)
- Several input parameters modifiable in the Excel sheet

Emission reduction and C/E per RO

Baseline: 14.1 kt of emissions over 30 years

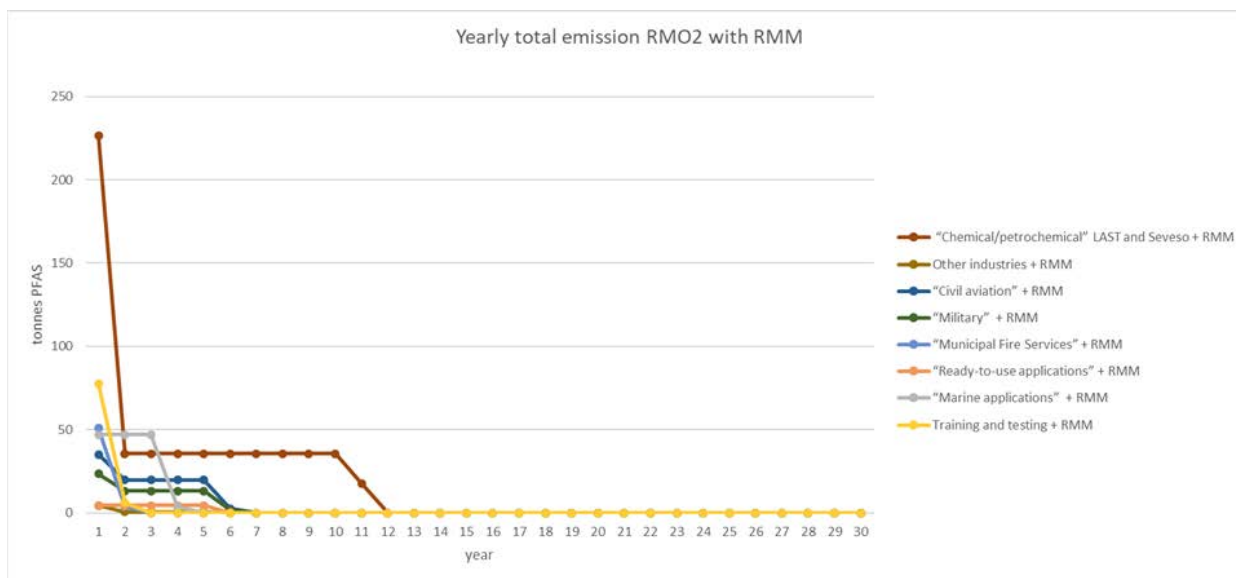
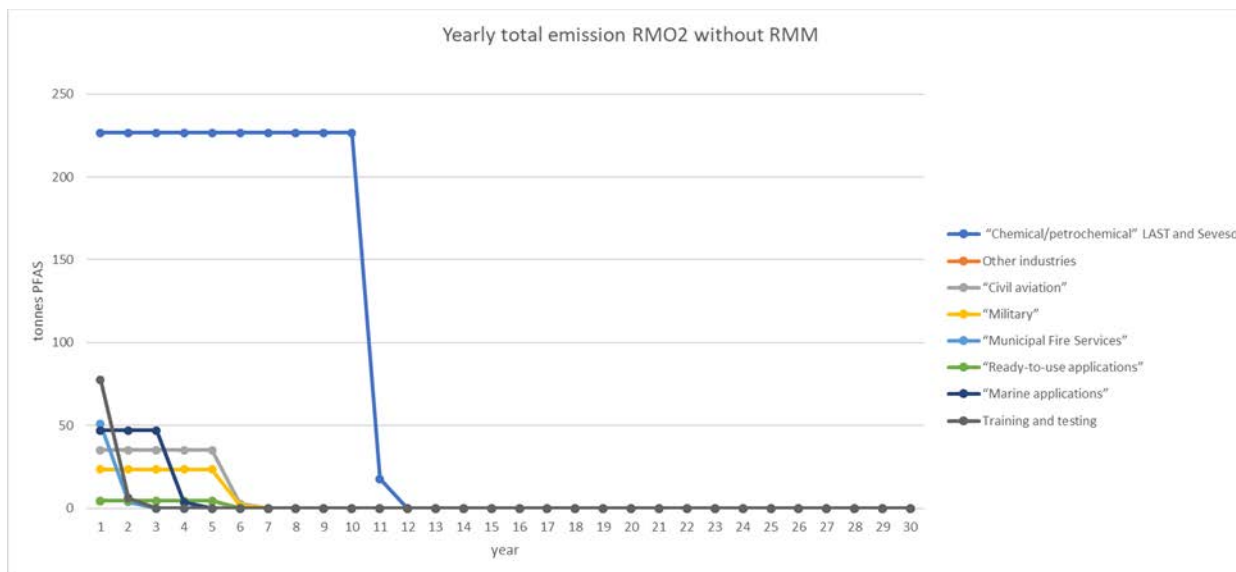
Restriction option		Emission reduction (kilotonnes in 30 years)	Cost to society (€billion in 30 years)	Cost-effectiveness (€/kg avoided emission)
1	Restriction on the placing on the market but use continued to be allowed until expiry date of the stocks	11.8	5.9	500
2	Restriction on the placing on the market and use after use/sector-specific transitional periods	13.0	6.8	520
3 ^[1]	Restriction on the export, placing on the market and use after use/sector-specific transitional periods	13.2	6.8	520
4	Restriction on the placing on the market and use after use/sector-specific transitional periods, with a derogation mechanism via a permit system to which only Seveso establishments and defence sites would be eligible	12.6	5.2	415
5	Restriction on the placing on the market and use for all uses after sector or use-specific transitional periods, unless adequate risk management measures are in place to capture all the emissions to the environment	12.5	15.0	1 200

Emission reduction pattern: example of RO1 with and without RMMs



Importance of the additional RMMs to reduce the emissions during the TPs

Emission reduction pattern: example of RO2 with and without RMMs



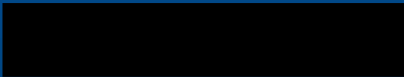
Impact assessment

- tbc

Conclusions and next steps

- The RO proposed is estimated to lead to a reduction of emissions of PFAS in the environment of about 13.2kt over 30 years.
- Combination of a progressive phase-out adapted to each type/sector of use and the application of additional risk management measures during the TPs
- The proposed restriction is an appropriate measure to address these risks within a reasonable timeframe:
 - Effective and proportionate
 - Practical and monitorable
- Public consultation between XX and YYY 2022

Thank you!

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