

Broad PFAS Restriction Proposal

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Preparation

May – July 2020
Call for evidence

July 2021 – Oct 2021
2nd stakeholder consultation

Oct 2021 – Jan 2023
Drafting of proposal

Stakeholder interviews, literature search, meetings



Jan 2020
First meeting

13 January 2023
Submission
of proposal

7 February 2023
Publication of
proposal

Hazard assessment

PFAS

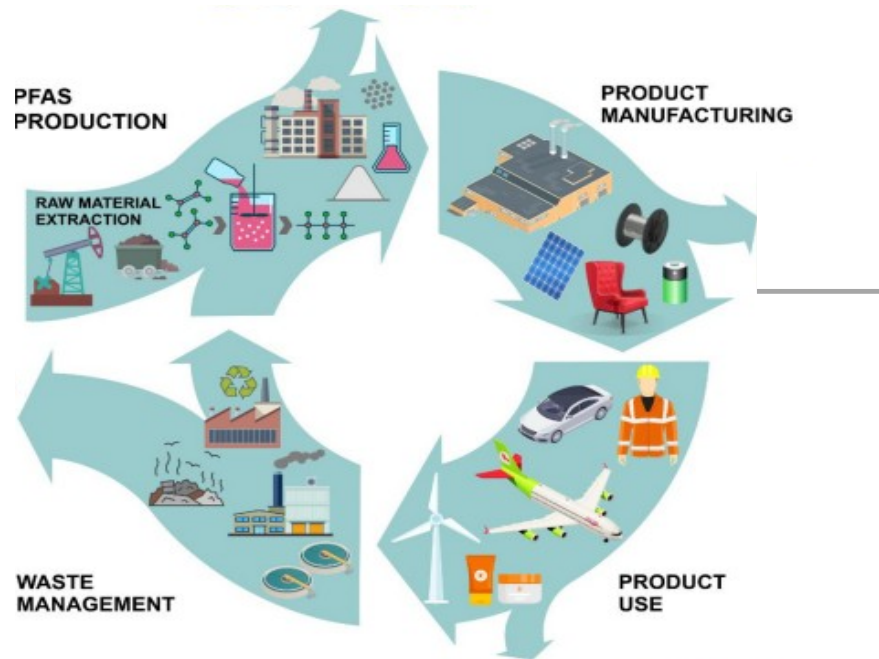
Persistence

Mobility

Bioaccumulation

Toxicity, Ecotoxicity, EA/ED,
Accumulation in plants, LRTP

75 000 tonnes/year of emissions in the EEA



Source:
https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD_PFAS.pdf



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Tonnages and emissions

Application	Tonnage range	Emission range % emitted in manufacturing and use phase	Emission contribution Contribution to total emission [%]
Applications of fluorinated gases	> 10 000	5 – 25	> 50
Textiles, upholstery, leather, apparel & carpets	> 10 000	5 – 25	10 – 50
Medical devices	> 10 000	5 – 25	5 – 10
Manufacture	> 10 000	0 – 5	1 – 5
Food contact materials and packaging	> 10 000	0 – 5	0 – 1
Transport	> 10 000	0 – 5	0 – 1
Construction products	1 000 – 10 000	25 – 75	1 – 5
Electronics and semiconductors	1 000 – 10 000	5 – 25	0 – 1
Lubricants	1 000 – 10 000	5 – 25	0 – 1
Petroleum and mining	1 000 – 10 000	0 – 5	0 – 1
Energy sector	1 000 – 10 000	0 – 5	0 – 1
Metal plating and manufacture of metal products	100 – 1 000	0 – 5	0 – 1
Cosmetics	10 – 100	> 95	0 – 1
Consumer mixtures	10 – 100	75 – 95	0 – 1
Ski wax	0 – 10	25 – 75	0 – 1



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Justification for EU wide measures

- Manufacture, import and uses in EU
- Global market with growing volumes
- Large variety of emission sources
- Ubiquitous presence and increasing levels in environmental media
- PFASs are mobile and cross borders
- EU internal market: level playing field

□ EU-wide risk reduction measures: Implement control efficiently and uniformly

The proposal - chemical definition

Column 1

Per- and polyfluoroalkyl substances (PFASs) defined as:

Any substance that contains at least one fully fluorinated methyl (CF_3 -) or methylene ($-\text{CF}_2-$) carbon atom (without any H/Cl/Br/I attached to it).

A substance that only contains the following structural elements is excluded from the scope of the restriction:

$\text{CF}_3\text{-X}$ or $\text{X-CF}_2\text{-X}'$,

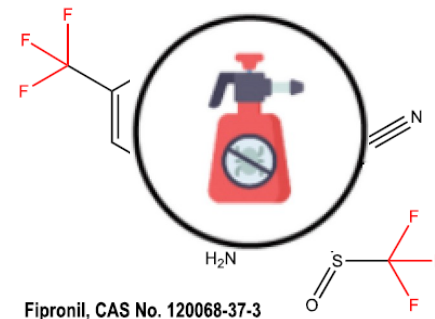
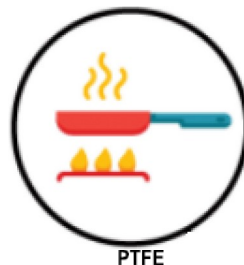
where $\text{X} = -\text{OR}$ or $-\text{NRR}'$ and

$\text{X}' = \text{methyl } (-\text{CH}_3)$, methylene ($-\text{CH}_2-$), an aromatic group, a carbonyl group ($-\text{C}(\text{O})-$), $-\text{OR}''$, $-\text{SR}''$ or $-\text{NR}''\text{R}'''$;

and where $\text{R/R}'/\text{R}''/\text{R}'''$ is a hydrogen ($-\text{H}$), methyl ($-\text{CH}_3$), methylene ($-\text{CH}_2-$), an aromatic group or a carbonyl group ($-\text{C}(\text{O})-$).

= OECD PFAS definition 2021

Over 10 000 substances covered. Some examples:



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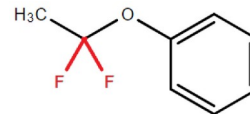
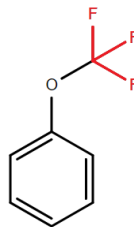
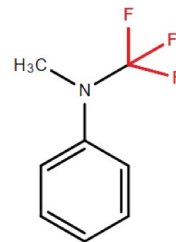
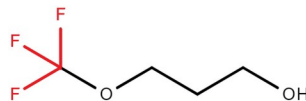
and where R/R'/R''/R'''' is a hydrogen ($-\text{H}$), methyl ($-\text{CH}_3$), methylene ($-\text{CH}_2-$), an aromatic group or a carbonyl group ($-\text{C}(\text{O})-$).

A few specific types of PFASs can be completely degraded in the environment. These are therefore excluded from the scope:

$\text{CF}_3\text{-O-}$ / $\text{CF}_3\text{-N<}$

$-\text{CF}_2\text{-O-}$ / $-\text{CF}_2\text{-N<}$

Examples:



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Proposed restriction

Ban on manufacture, use and placing on the market



- As substances on their own
 - As a constituent in
 - another substance
 - a mixture
 - an article
- } ≥ 25 ppb for any PFASs
} ≥ 250 ppb for sum of PFASs
} ≥ 50 ppm* for PFASs

* If total fluorine exceeds 50 mg F/kg the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFASs or non-PFASs.

Restriction Options assessed (RO)

RO1

Full ban of all uses

- Transition period: 18 months



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Restriction Options assessed (RO)

RO2

Ban with use-specific derogations

- Transition period: 18 months
- Duration of derogation:
 - 5-years
 - 12-years
- Time-unlimited derogations (specifically justified)
 - Active substances in biocidal products, plant protection products and pharmaceuticals
 - Refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives
 - Calibration of measurement instruments and as analytical reference materials



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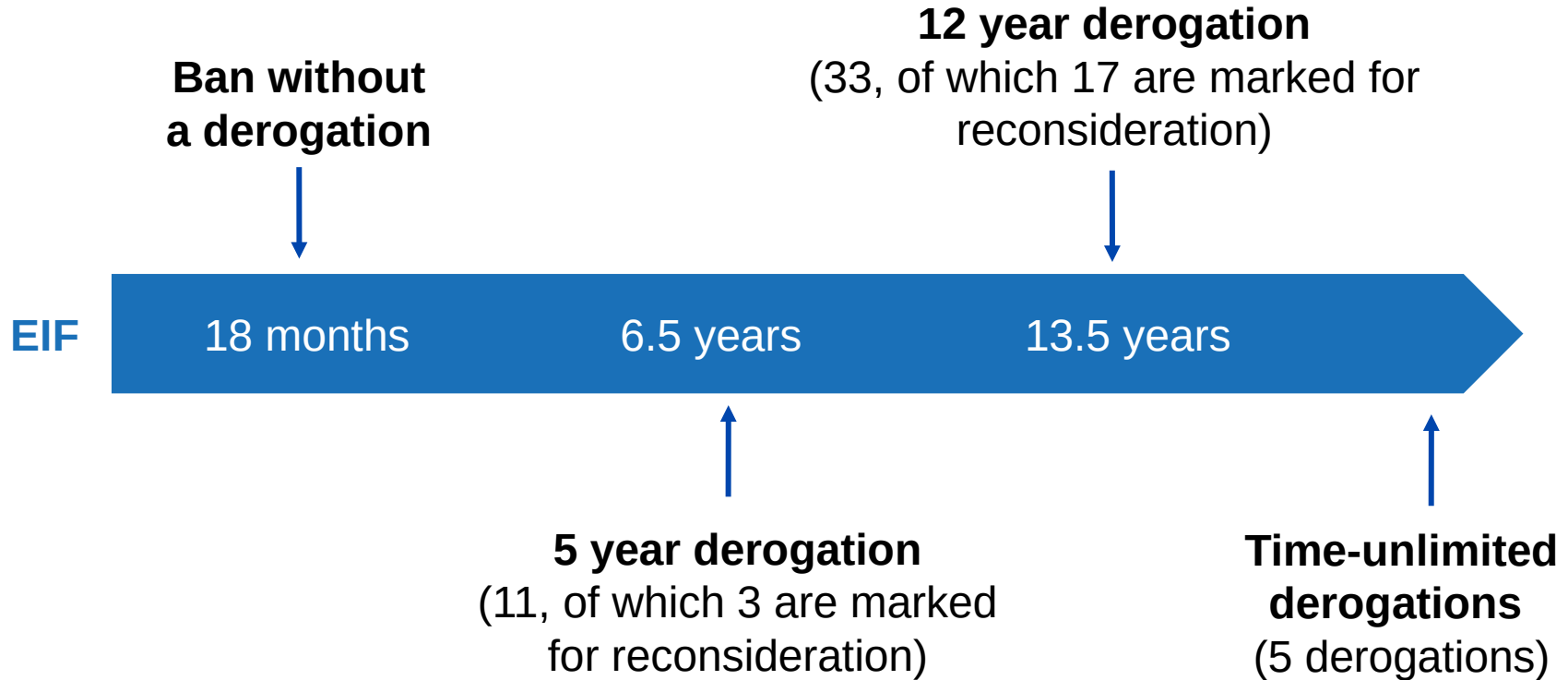


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Phase-out timelines



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Proposed restriction conditions - derogations

Two standard derogation timeframes chosen

Examples:

**Food contact materials
for industrial food and feed
production**

**Implantable medical
devices**

Alternatives under development
but not available at entry into
force

Identification, development
and certification of
alternatives needed

5 years

12 years

Proposed restriction: Reporting

Mandatory reporting in relation to majority of derogations

Who

- Active substances: Manufacturers, importers
- Uses of fluorinated gases & uses with 12 year derogation period:
 - Substance & articles: Manufacturers, importers
 - Mixtures: Formulators

What

- Information on the use (which derogation)
- Identity and quantity of substance placed on market



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Proposed restriction: Management plan

Requirement for a site-specific management plan in relation to fluoropolymers and perfluoropolyethers when making use of derogations



Who

- Manufacturers, importers and downstream users

What

- Identity of the substances and the products they are used in
- Justification for the use
- Conditions of use
- Safe disposal

Consequences for emissions 2025-2055

If no action is taken:

- Use of PFASs in the sectors investigated: 49 million tonnes
- Release of PFASs during manufacture and use: 4.5 million tonnes
- The difference is the PFASs that go to the waste stream. These emissions are not quantified.

Full ban of all uses with an 18-month transition period (RO1):

- Emissions (production and use): 0.2 million tonnes (during the transition period)
- Reduction by 96%

Ban with time-limited derogations (RO2):

- Emission reduction estimates are per derogation
- Emissions will be higher than in RO1
- Calculations are in progress

Conclusions and next steps

- Need for EU wide restriction for PFASs based on identified risks
- RO2 effective measure to reduce environmental emissions
 - Ban with use-specific derogations in combination with reporting requirements/management plan
 - Emission reduction still to be determined (RO1: 96%)
- Proposed restriction is an appropriate measure to address these risks within a reasonable timeframe

Next:

- Consultation is ongoing until 25 September
- Questions and outstanding issues

