Regulation of PFAS in European Union, its evolution and the management of PFAS compounds under the Stockholm Convention

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PFASs are found everywhere

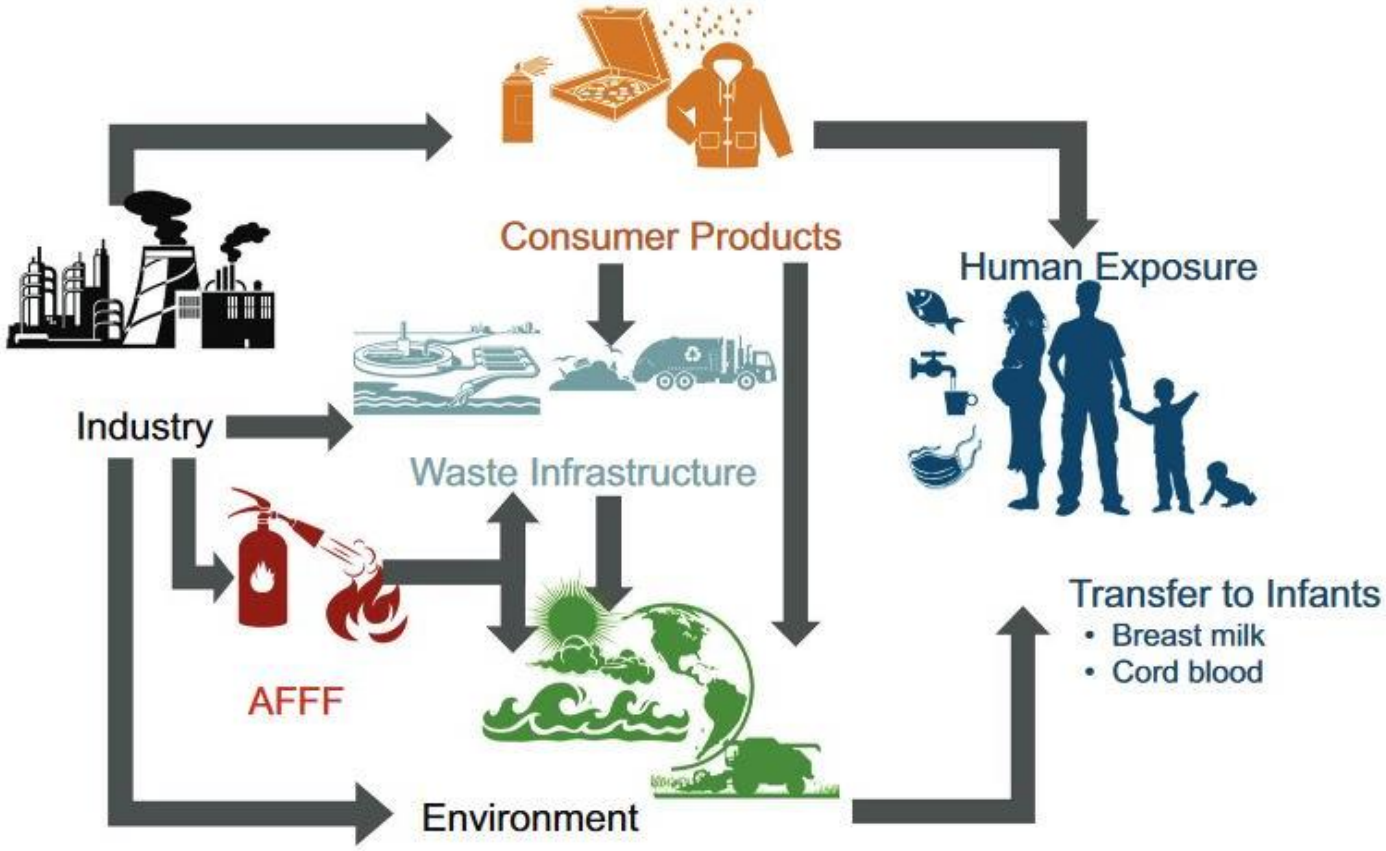
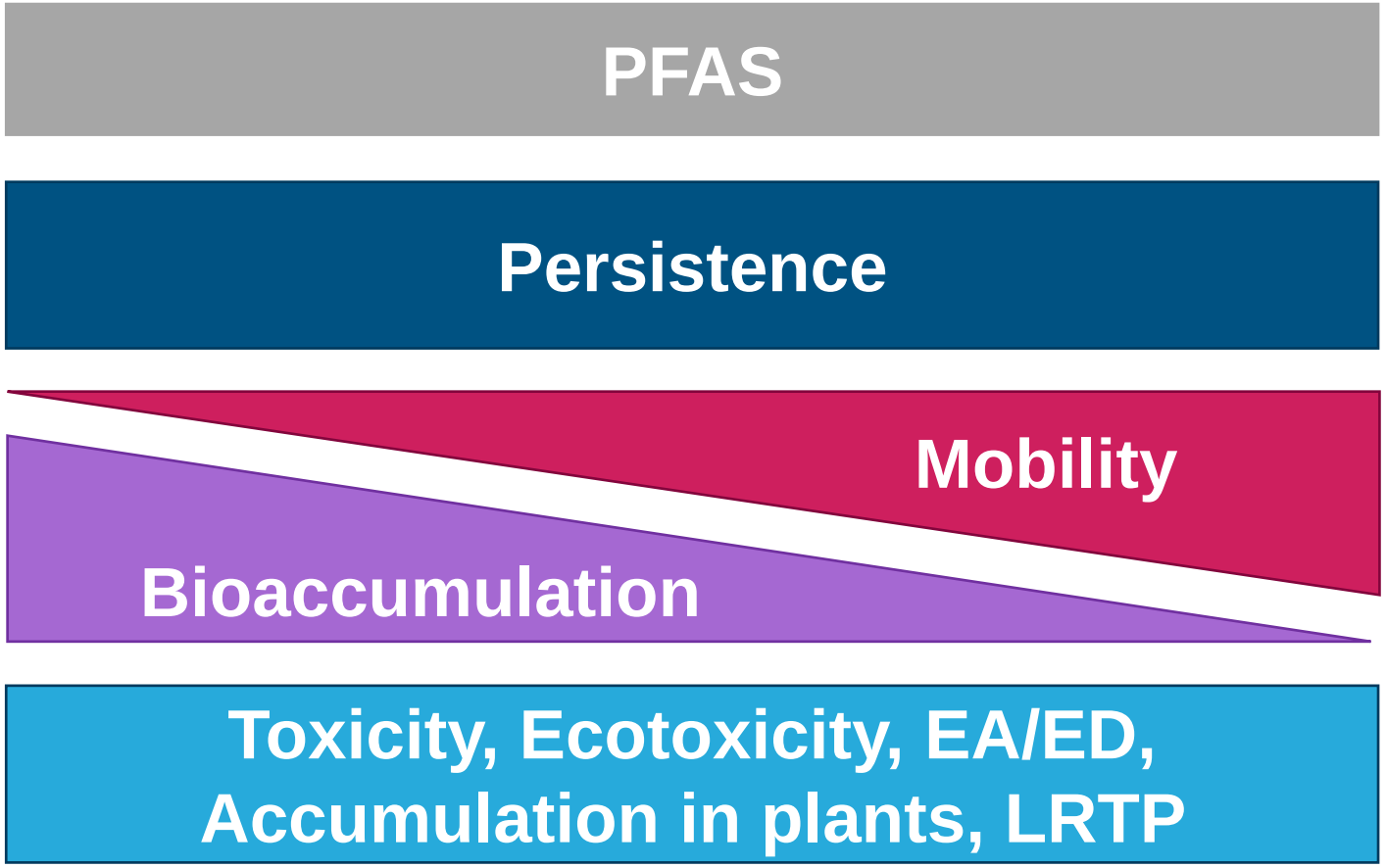


Illustration from Sunderland *et al.*, **2019**, J. Exposure Sci. Environ. Epidemiol., *29*, 131-147.

Hazard assessment



Hazards → concerns

Properties

- **Very high persistence**
- Long-range transport potential
- Mobility
- Accumulation in plants
- Bioaccumulation potential
- (Eco)toxicity
- Endocrine activity

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.

Function of PFASs

Combination of useful properties from technical viewpoint

- Water, oil and dirt repellency
- Durability under extreme conditions:
  - temperature, pressure, radiation, chemicals
- Electrical and thermal insulation
- Surfactants, refrigerants...

→ Used in high tonnages in many different sectors

Sectors/uses of PFASs

Rainwear

Non-stick coating

Cosmetics

Medical equipment

- Industrial processes
- Firefighting foams
- Textiles
- Food contact materials (incl. packaging)
- Metal plating/metal products
- Consumer mixtures
- Ski wax
- Transport

- Applications of fluorinated gases
- Electronics and semiconductors
- Energy sector
- Construction products
- Lubricants
- Petroleum and mining
- Medical devices
- Cosmetics
- Other uses

PFAS – Restrictions in REACH and SC/POPs

Substance (group)	Legislation	Applicable from
PFOS	Stockholm Convention/ POPs regulation	2006
PFOA	Stockholm Convention/ POPs regulation	2020
PFHxS	Stockholm Convention/ POPs regulation	2021
C9-C14 PFCAs	REACH	2021
TFDAs in spray products	REACH	2021
PFHxA	*REACH, not yet adopted*	*TBD*
PFAS in fire-fighting foam	*REACH, not yet adopted*	*TBD*
Universal PFAS restriction	*REACH, in opinion development phase*	*TBD*

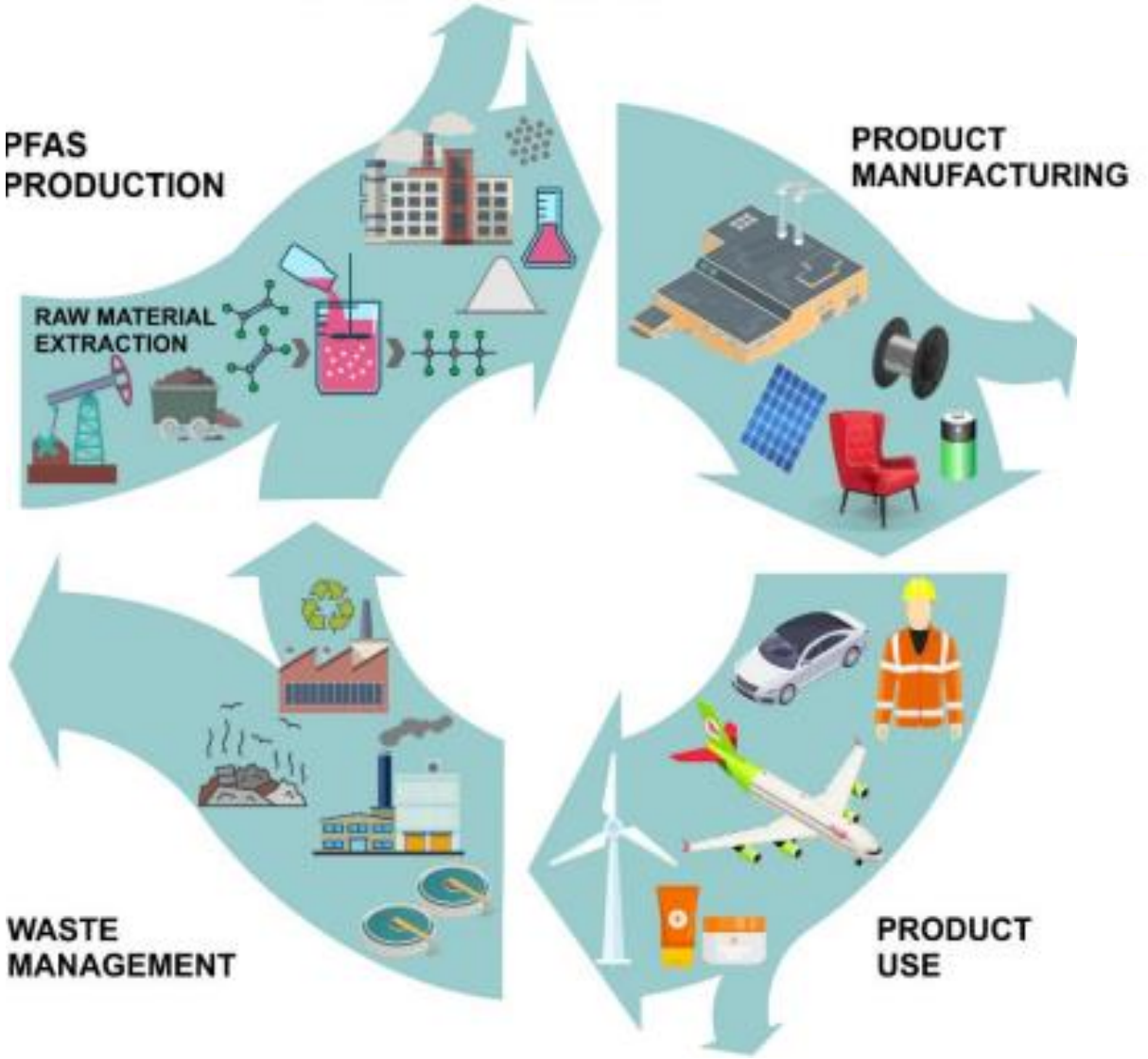
Universal PFAS restriction proposal (UPFAS)

- Submitted 13 January 2023
- Include all PFASs and uses (except for fire-fighting foam)
- Time-limited derogations for specific uses

The broadest restriction proposal in EU history

Over 10 000 PFASs

75 000 tonnes/year of emissions in the EEA



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

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

Chemical Scope

PFAS Definition (OECD (2021)):

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).

Exceptions:

A substance that only contains the following structural elements is **excluded from the scope** of the restriction: **CF_3-X or X-CF_2-X'**,

where X = -OR or -NRR' and X' = methyl (-CH_3), methylene (-CH_2-), an aromatic group, a carbonyl group (-C(O)-), -OR'', -SR'' or –NR''R'''; and where R/R'/R''/R''' is a hydrogen (-H), methyl (-CH_3), methylene (-CH_2-), an aromatic group or a carbonyl group (-C(O)-).

Includes persistent PFASs and their precursors
Includes polymeric PFASs

Restriction Options assessed

RO1

Full ban of all uses

- Transition period: 18 months

RO2

Ban with use-specific derogations

- Transition period: 18 months
- Duration of derogation:
  - 5-years (based on set criteria relating to alternatives)
  - 12-years (based on set criteria relating to alternatives)
  - Time-unlimited derogations (specifically justified)

Restriction proposal

Manufacture, use and placing on the market

- as substances on their own

Placing on the market

- as **constituent** in
  - Substances
  - Mixtures
  - Articles

Above certain concentration levels

Proposed restriction conditions - derogations

Two standard derogation timeframes chosen
Examples:

Food contact materials for industrial food and feed production

Alternatives under development but not available at entry into force

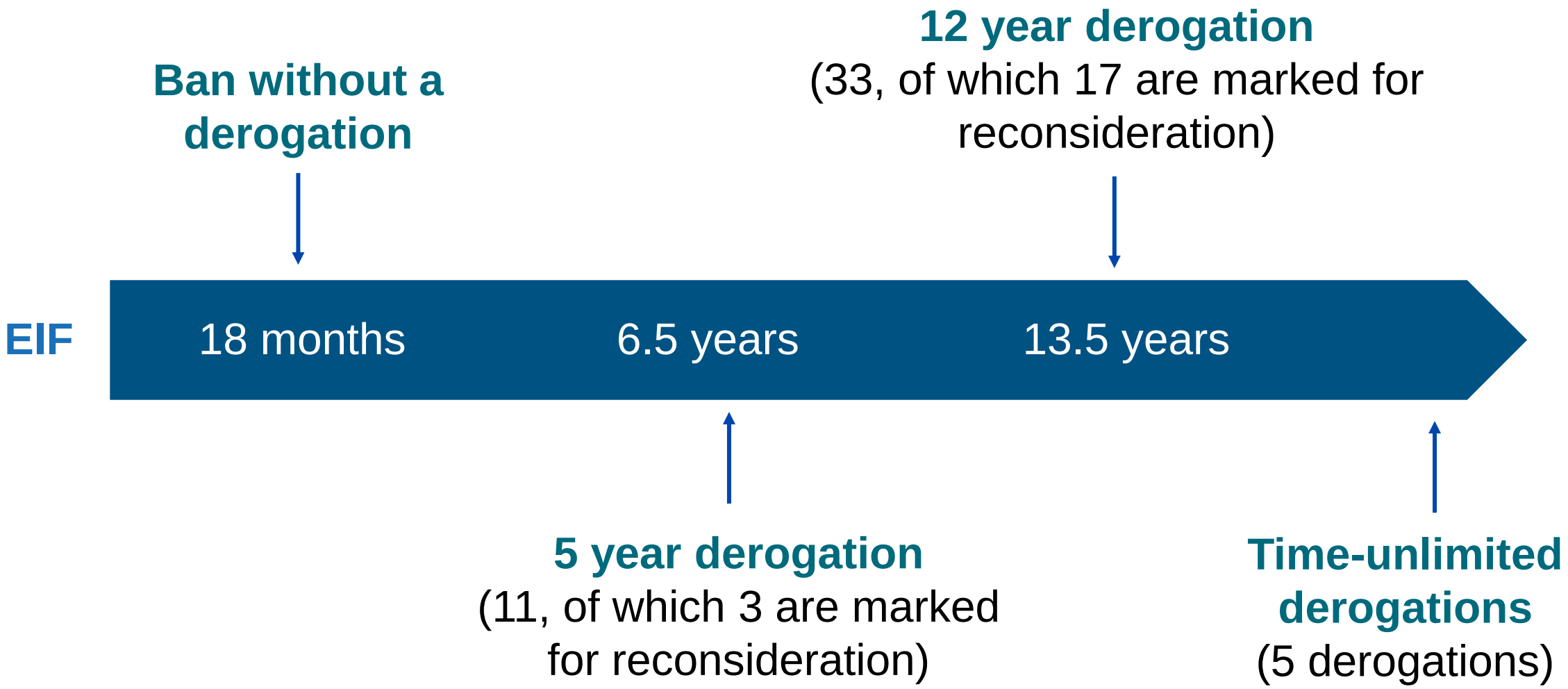
5 years

Implantable medical devices

Identification, development and certification of alternatives needed

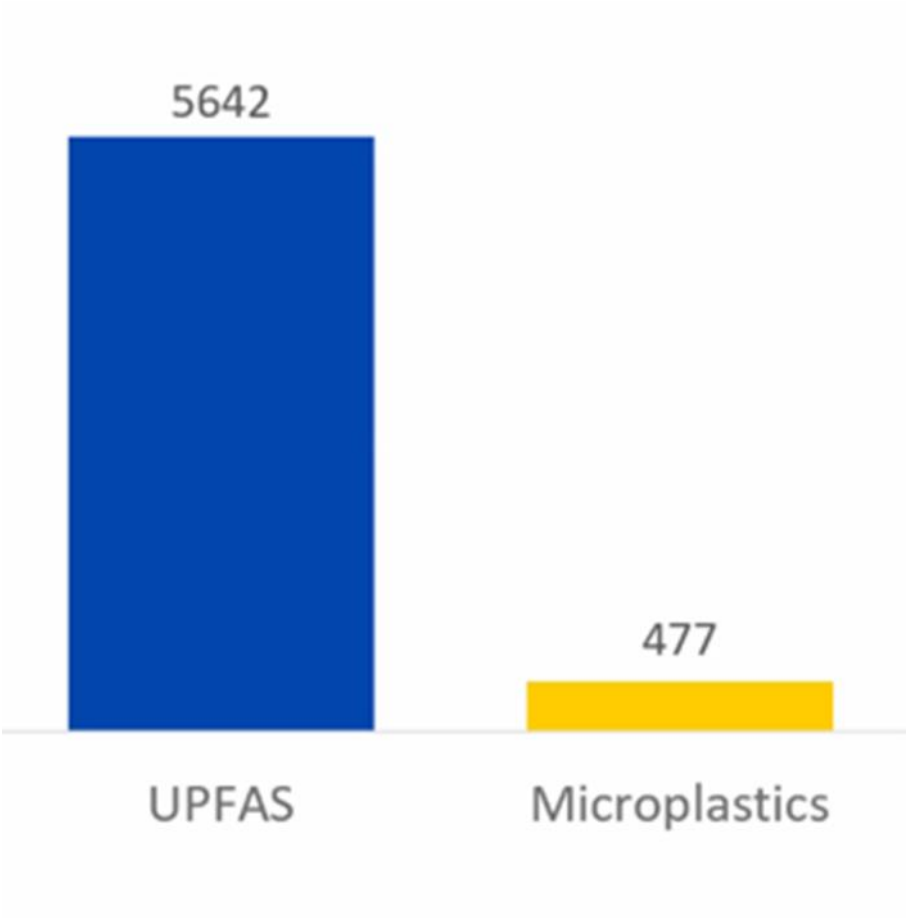
12 years

Phase-out timelines

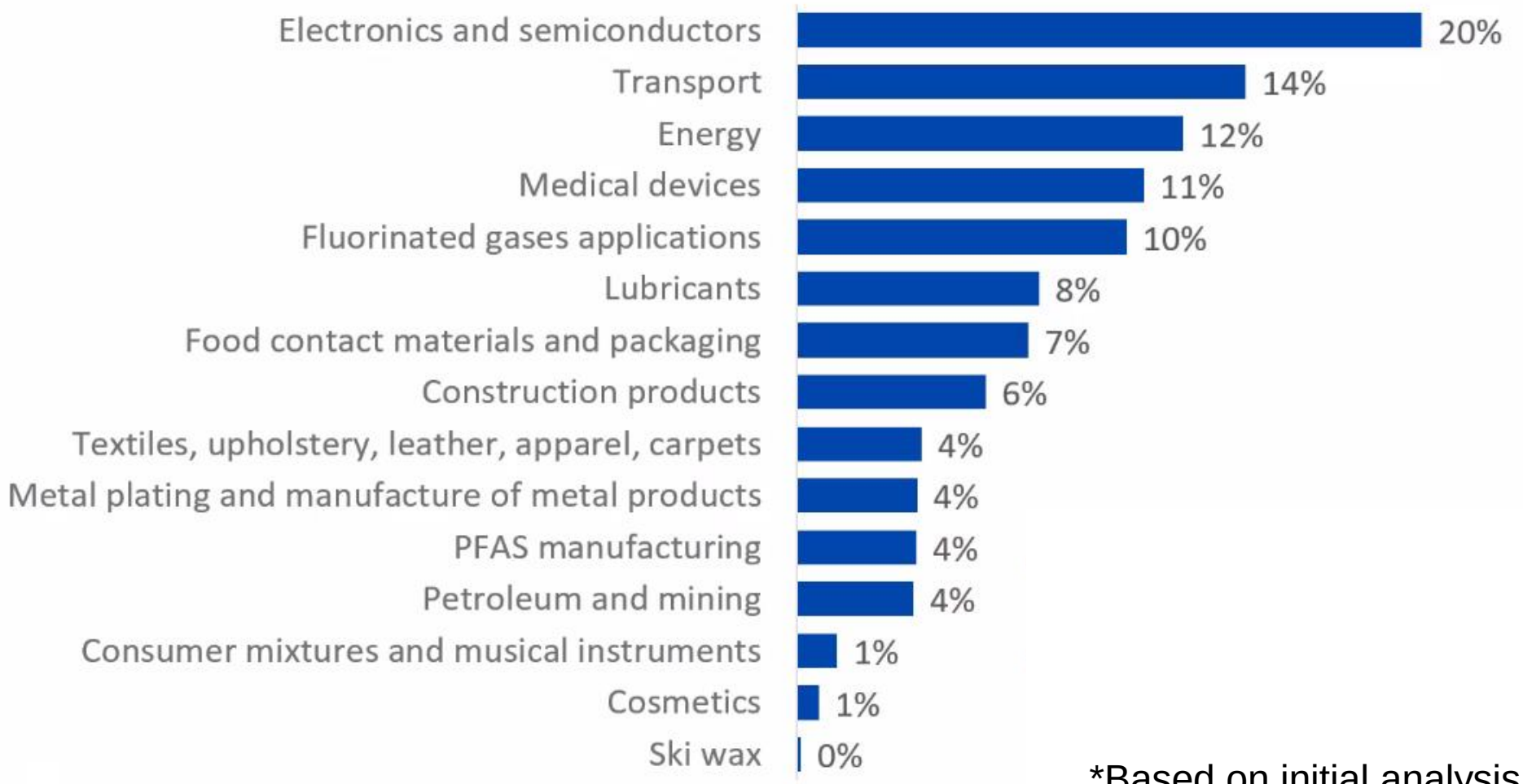


Public consultation

- 6-month consultation ended on 25 September
- Over 5,600 comments received
- From over 4,400 organisations, companies and the general public
- About 6,400 attachments,
- A total of over 100,000 pages



Comments per sector*



*Based on initial analysis of all comments

The process forward

- 6-month public consultation - may lead to an update of the proposal, e.g. new or revision of derogations (ended)

- Evaluation of the proposed restriction
  - Drafting of opinions by scientific committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC)

- Decision by the EU Commission together with the EU member states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