



Ministry of Environment
of Denmark
Environmental
Protection Agency

PFAS restriction proposal and fluorinated gases

Køle- og varmepumpeforum 2023

23 March 2023
Toke Winther

PFASs = Per- and PolyFluoroAlkyL Substances



PFAS

> 10.000 substances*



Fluorinated
gases



- Refrigeration
- Heat pumps
- Aircondition
- Etc.



OECD (2021) PFAS definition: Substances that contain at least one –CF₂– or one –CF₃ group, without any H/Cl/Br/I attached to it (with some exceptions)

Restriction proposal - content

▪ **REACH = Registration, Evaluation, Authorisation and restriction of Chemicals**

▪ **Restriction proposal:**

- ✓ Chemical identity
- ✓ Hazards, risks, effects
- ✓ Applications
- ✓ Availability of alternatives
- ✓ Socioeconomic analysis – impact assessment



▪ **PFAS restriction proposal**



Preparation



Restriction process – next steps



Consultation in scientific committees

Including 6 months + 60 days stakeholder consultation

22 March 2023
Start of
consultation

5 April 2023
Online information
session

22 September 2023
End of 6 months
consultation

March 2024
Opinion of
Committees

2025
COM decision
Entry into Force

2026/2027
Restriction becomes
effective



Next steps – key messages (consultation)

- Dossier submitter cannot amend dossier on own initiative
- Information needs to be submitted to Public Consultation
- Information submitted on sector level is preferred (instead of individual submissions)
- **Well-substantiated scientific evidence is key:**
 - ✓ Alternatives, impacts (costs and benefits), missed uses, tonnages and emissions, R&D efforts, etc.
 - ✓ If available, quantitative information is preferred
- Guiding questions from ECHA committees
- Position papers and unsubstantiated claims are not useful
- Link to Public Consultation:
[https://comments.echa.europa.eu/comments cms/AnnexXVRestrictionDossier.aspx?RObjecId=0b0236e1885e69de](https://comments.echa.europa.eu/comments/cms/AnnexXVRestrictionDossier.aspx?RObjecId=0b0236e1885e69de)



PFAS - basis for restriction



Global focus

- **Exposure to PFAS in general has gained increasing attention**
 - ✓ EU chemicals strategy for sustainability
- **PFAS linked to pollution of the environment, including drinking water, food and feed**
- **Some PFASs already restricted in the EU (PFOS, PFOA, C9-C14 PFCAs)**
 - ✓ This proposal does not affect these existing restrictions
 - ✓ Decision making for restrictions on PFHxS and PFHxA is ongoing
- **Several restrictions in non-EU countries**
 - ✓ Certain US States (California, Washington, NY, etc.), Australia

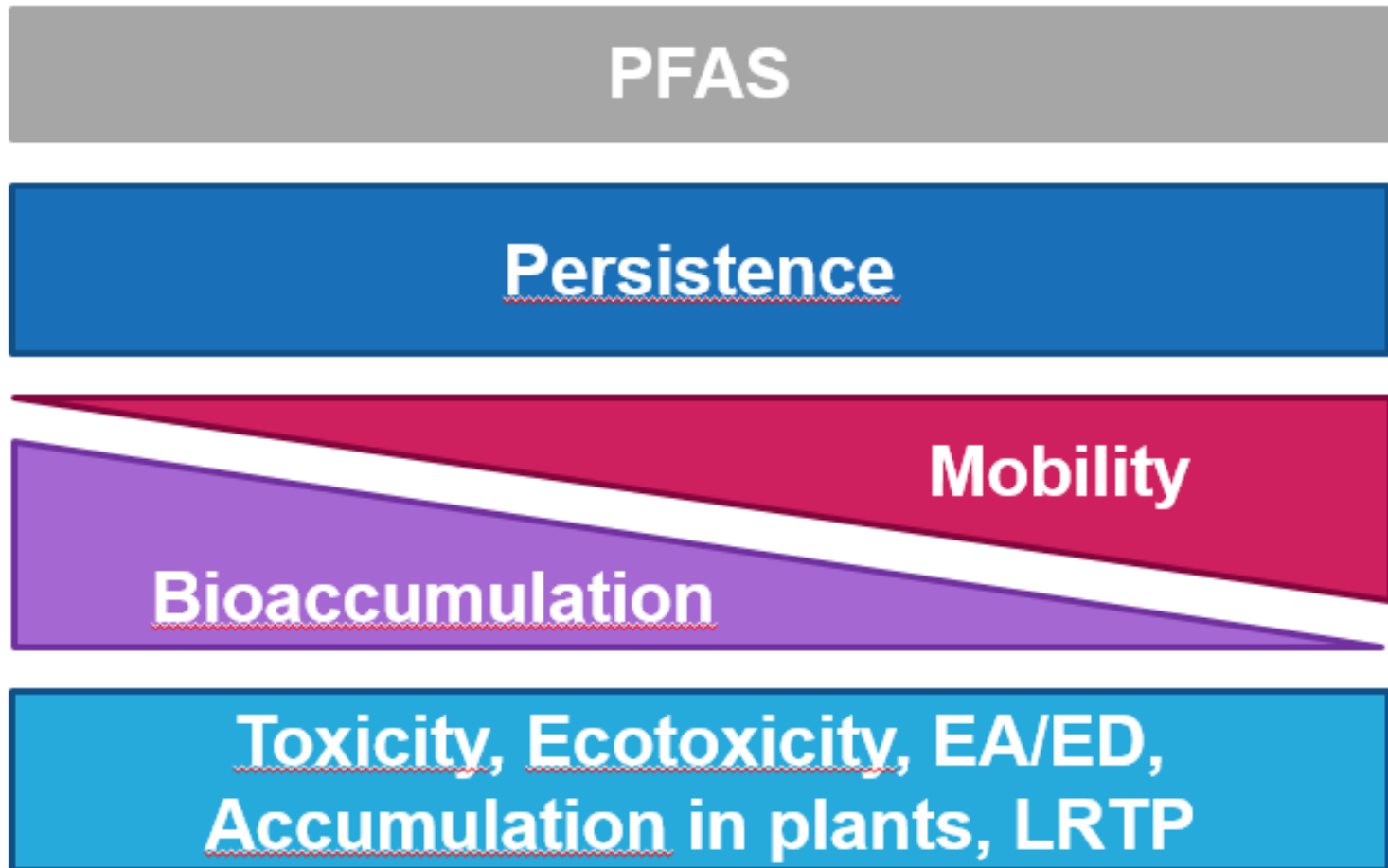


«Forever chemicals»

- All PFASs in scope of this restriction proposal are either persistent themselves or degrade to other persistent PFASs
- Persistence due to strength of the carbon-fluorine bond
- PFASs remain in environment for decades to centuries



Hazard Assessment



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

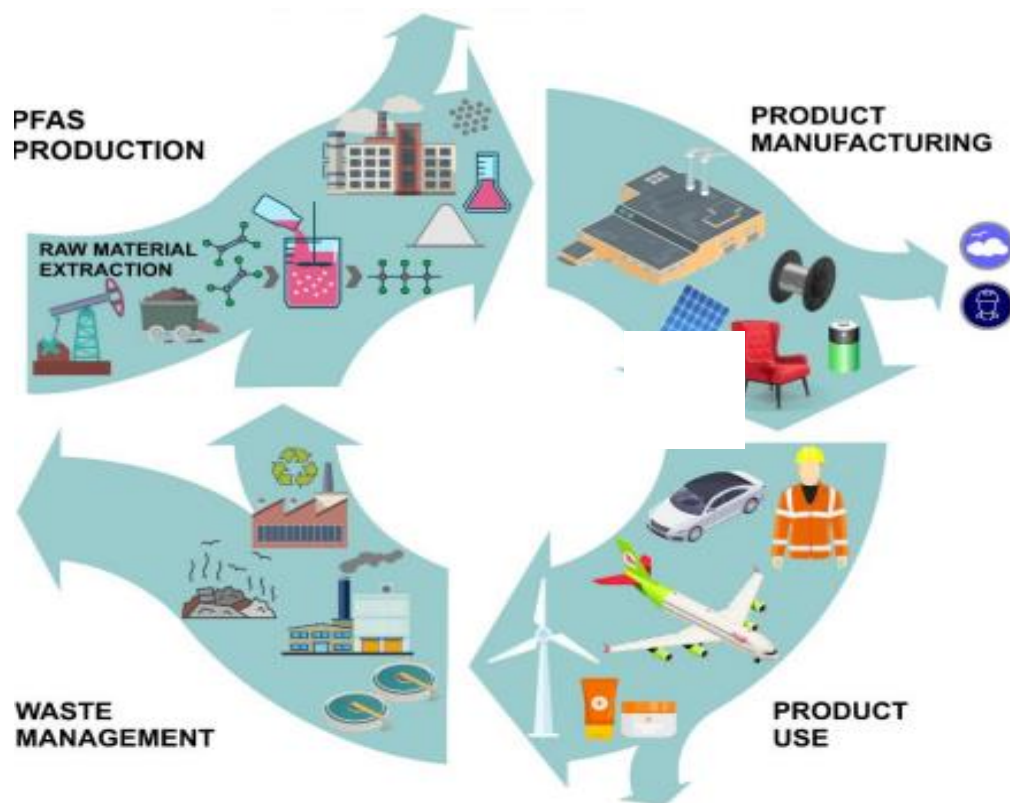
- Industrial processes
- Firefighting foams
- TULAC Food contact materials (incl. packaging)
- Metal plating/metal products
- Consumer mixtures
- Ski wax
- Transport
- Applications of fluorinated gases
- Electronics and semiconductors
- Energy sector
- Construction products
- Lubricants
- Petroleum and mining
- Medical devices
- Cosmetics
- Other uses



Emissions

75 000 tonnes of emissions in 2020

4.4 million tonnes of emissions over 30 years including an estimated increase of PFAS use



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



Analysis of alternatives

- **Alternatives already adopted in many sectors/uses**
- **For some sectors alternatives already identified but time needed to implement or alternatives not available in sufficient quantities (e.g. industrial food and feed production)**
- **In other sectors research and development still needed (e.g. medical devices)**



Risk characterisation

- Risks are not adequately controlled, and releases should be minimised...
- ... because of accumulation over time which leads to levels likely to cause effects for humans and environment
- Risks of PFASs are considered as non-threshold
- Releases are used as a proxy for risk
- Effectiveness of the proposed restriction is based on the effectiveness of emission reduction



Proposed restriction: Ban

Ban on manufacture, use and placing on the market



- As substances on their own
 - As a constituent
 - 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.

Annex XV report (page 4-8) para. 2

<https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49>



Restriction Options (RO's) assessed

RO1

Full ban of all uses

- Transition period: 18 months

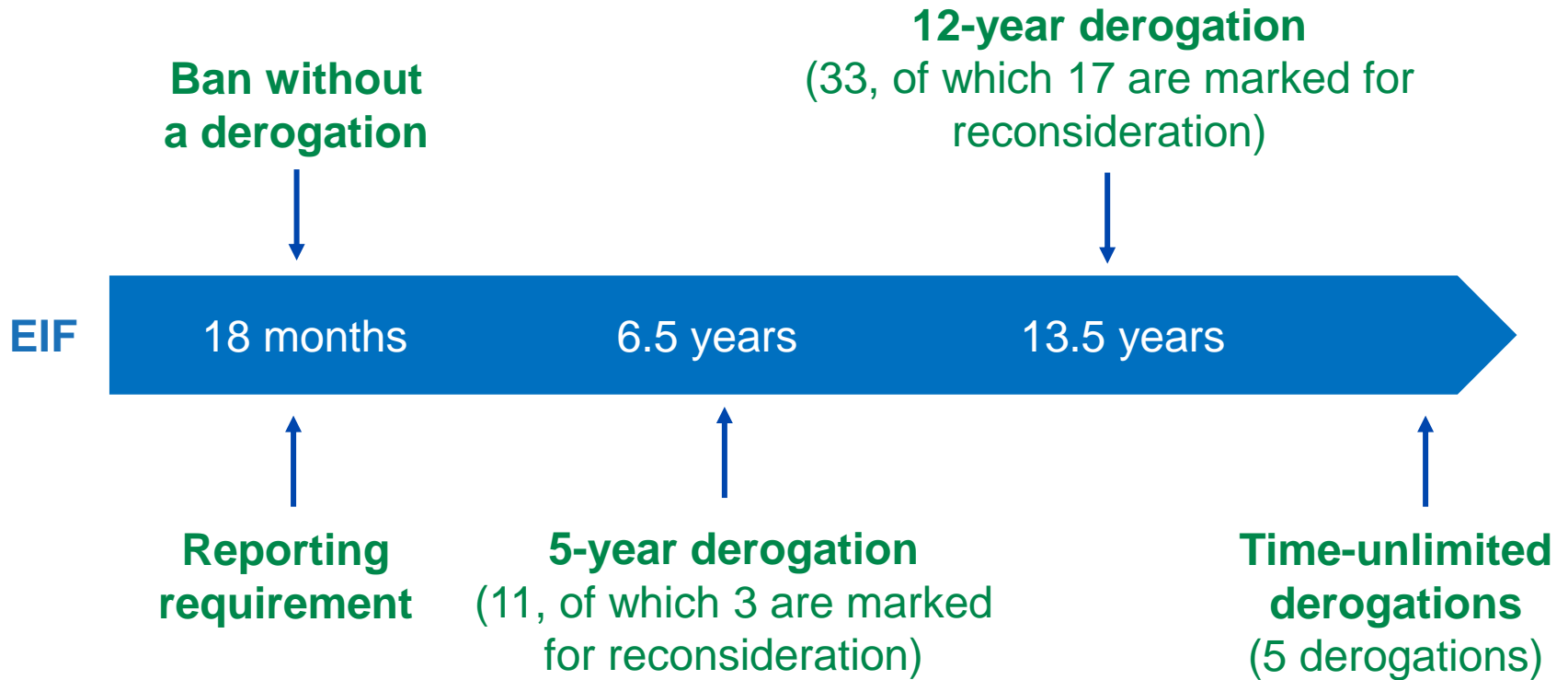
RO2

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)



Phase-out timelines



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



Annex XV report (page 4-8) para. 7

<https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49>



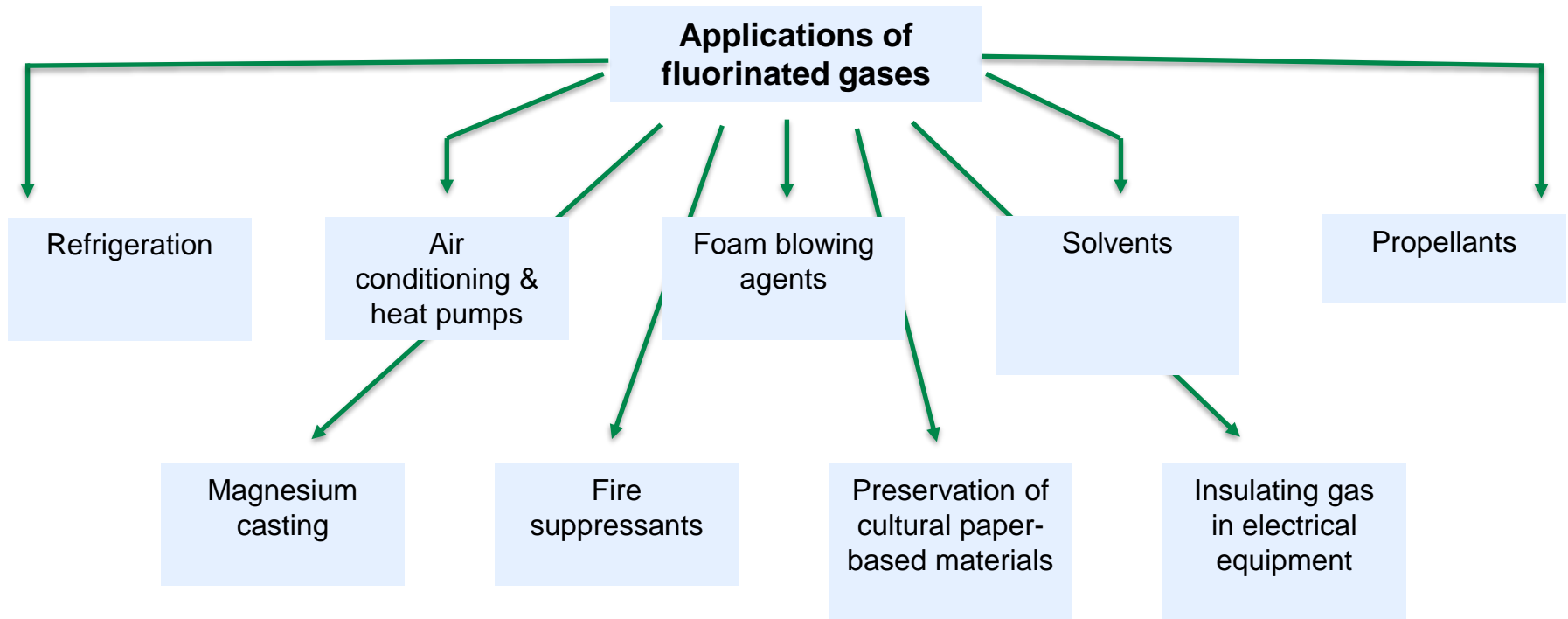


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Implications for fluorinated gases

23 March 2023
Toke Winther

Applications – fluorinated gases

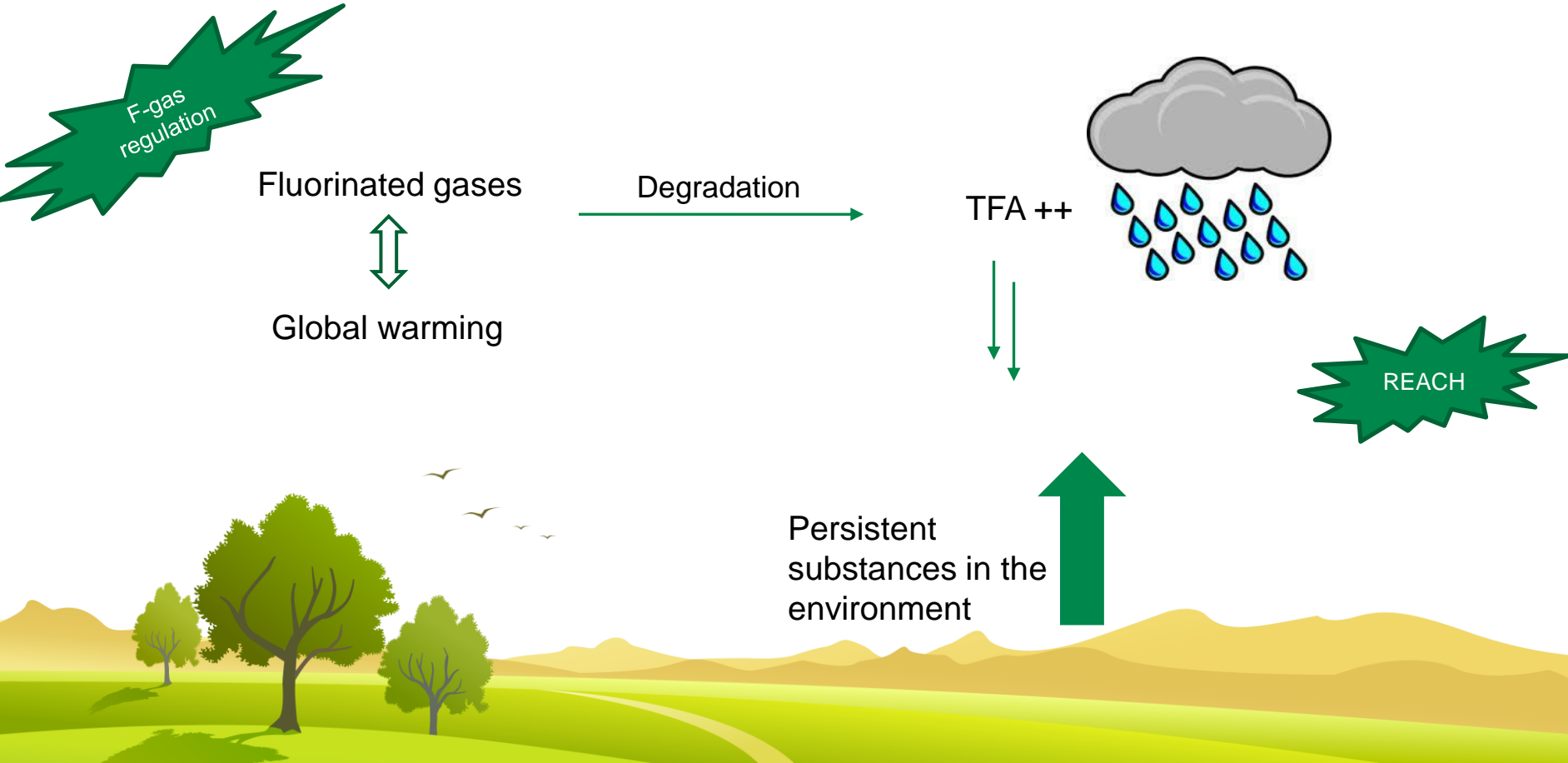


Tonnages and emissions

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

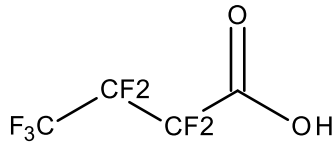


Concerns – fluorinated gases

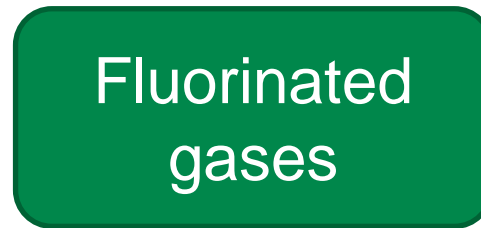
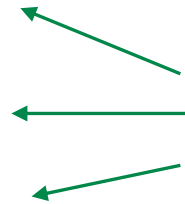


Atmospheric degradation of fluorinated gases

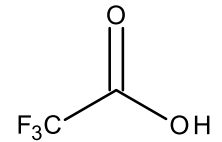
Other degradation products like e.g.



PFBA



e.g. HFC-134a, HFO-1234yf, HFE-7100 ...




TFA



TFA in beer and tea

Food Chemistry 351 (2021) 129304

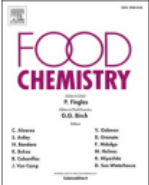


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Contents lists available at [ScienceDirect](https://www.sciencedirect.com)

Food Chemistry

journal homepage: www.elsevier.com/locate/foodchem




Short communication

Ultrashort-chain perfluoroalkyl substance trifluoroacetate (TFA) in beer and tea – An unintended aqueous extraction

Marco Scheurer, Karsten Nödler^{*}

TZW: DVGW-Technologiezentrum Wasser, Karlsruher Str. 84, 76139 Karlsruhe, Germany



ARTICLE INFO

Keywords:
Alcoholic and non-alcoholic beverages
Perfluoroalkyl substances
Polyfluoroalkyl substances
Aqueous extraction
Brewing process
Trifluoroacetate

ABSTRACT

Trifluoroacetate (TFA) is an ultrashort-chain perfluoroalkyl substance, which is ubiquitously present in the aqueous environment. Due to its high mobility, it accumulates in plant material. The study presented here shows for the first time that TFA is a widely spread contaminant in beer and tea / herbal infusions. In 104 beer samples from 23 countries, TFA was detected up to 51 µg/L with a median concentration of 6.1 µg/L. An indicative brewing test and a correlation approach with potassium (K) indicate that the main source of TFA in beer is most likely the applied malt. It could be proven that the impact of the applied water is negligible in terms of TFA, which was supported by the analysis of numerous tap water samples from different countries. The unintended extraction of TFA was also demonstrated for tea / herbal infusions with a median concentration of 2.4 µg/L.

<https://www.sciencedirect.com/science/article/pii/S0308814621003095>



TFA in groundwater

- TFA identified in 219 of 247 (89%) groundwater samples in DK. Max concentration 2.4 µg/L
- DK limit value for TFA in drinking water 9 µg/L



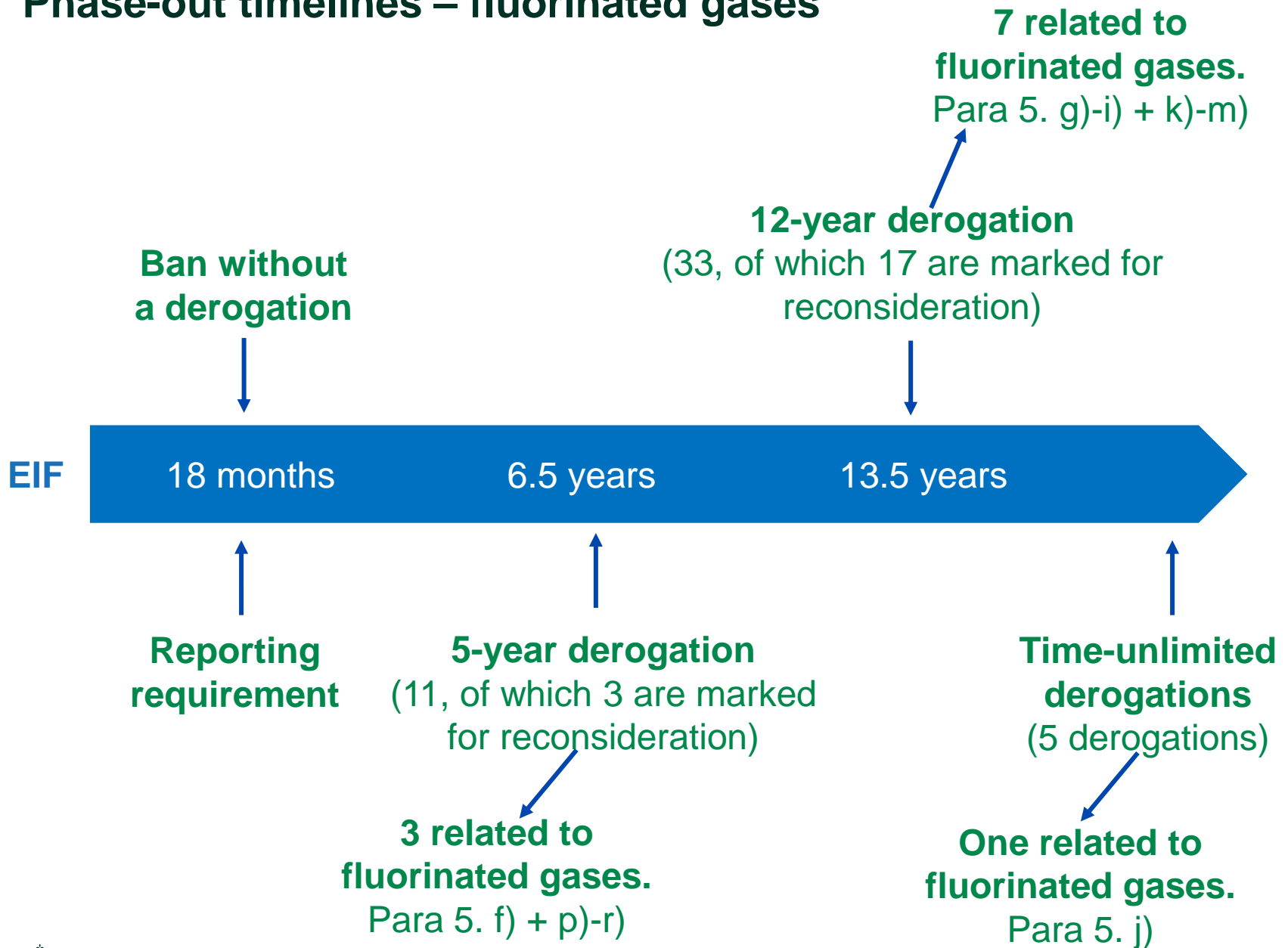


Chemical scope of the PFAS restriction (Fluorinated gases)

- **Wide scope – group regulation**
- **-CF₂- or -CF₃ (without any H/Cl/Br/I attached to it)**
- **Included: e.g HFC-125, HFC-134a, HFC-227ea, HFO-1234yf, HFO-1234ze, HFO-1336mzz,...**
- **Not included: HFC-23, HFC-32, HFC-152a, HCFC-141b, HFO-1132a**

Foto: Torgrim Asphjell, Miljødirektoratet

Phase-out timelines – fluorinated gases



(timelimited) derogations related to fluorinated gases

- **5 j. refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives;**
- **5 i. maintenance and refilling of existing HVACR equipment put on the market before [18 months after EiF] and for which no drop-in alternative exist until 13.5 years after EiF;**
- **5 f. refrigerants in low temperature refrigeration below -50 °C until 6.5 years after EiF;**





Per- and polyfluoroalkyl substances (PFAS)

EC / List no: - CAS no: -

CLP Annex VI Index number

Further substance information

Per- and polyfluoroalkyl substances (PFASs) defined as: 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).

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

CF₃-X or X-CF₂-X,

where X = -OR or -NRR' and X' = methyl (-CH₃), methylene (-CH₂-), an aromatic group, a carbonyl group (-C(O)-), -OR'' or -NR''R''',

and where R/R'/R''/R''' is a hydrogen (-H), methyl (-CH₃), methylene (-CH₂-), an aromatic group or a carbonyl group (-C(O)-).

- Germany
- Denmark
- Netherlands
- Norway
- Sweden

Submitter(s)

Details on the scope of restriction

Restriction on the manufacture, placing on the market and use of PFASs.

Reason for restriction

PFASs are, or ultimately transform into, persistent substances, leading to irreversible environmental exposure and accumulation. Due to their water solubility and mobility, contamination of surface, ground- and drinking water and soil has occurred in the EU as well as globally and will continue. It has been proven very difficult and extremely costly to remove PFASs when released to the environment. In addition, some PFASs have been documented as toxic and/or bioaccumulative substances, both with respect to human health as well as the environment. Without taking action, their concentrations will continue to increase, and their toxic and polluting effects will be difficult to reverse.

Remarks

Status

Submitted

Date of intention

15-Jul-2021

Expected date of submission

13-Jan-2023

Withdrawal date

Reason for withdrawal

Start of Call for Evidence consultation

19-Jul-2021

Deadline for comments on the Call for Evidence

17-Oct-2021

Start of second Call for Evidence consultation

Deadline for comments on the second Call for Evidence

Start of third Call for Evidence consultation

Deadline for comments on the third Call for Evidence

Restriction report (and annexes)

- Annex A
- Annex B
- Annex C
- Annex D
- Annex E
- Annex F
- Annex G
- Appendix E4
- Appendix G1
- Appendix G2
- Annex XV report

Information note on restriction report

• **Annex XV report** = «summary» (200 s)

- Restriction entry = page 4-8

• **Annex A (A.3.9)** = use

• **Annex B.9 (B.9.9)** = exposure

• **Annex E (E.2.8)** = alternatives and socio-economic analysis

Webinar 5. april, ECHA

<https://echa.europa.eu/-/restriction-of-per-and-polyfluoroalkyl-substances-pfass-under-reach>

<https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b>



Next steps – key messages

- **Public Consultation 22 March – 25 September 2023**
- **Well-substantiated scientific evidence as input is key**

