

Working towards a restriction of PFAS under REACH

*A joint activity by Denmark, Norway, Sweden,
the Netherlands and Germany*



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport



Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin



Swedish Chemicals Agency



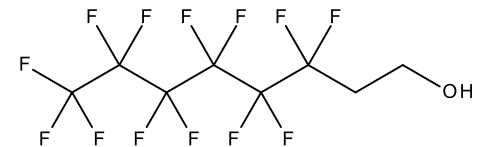
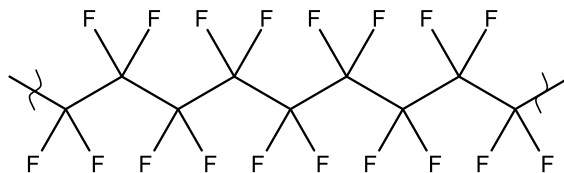
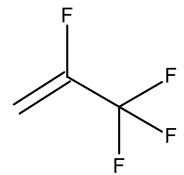
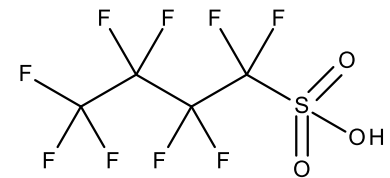
NORWEGIAN
ENVIRONMENT
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Ministry of Environment
and Food of Denmark
Environmental
Protection Agency

Per- and polyfluoroalkyl substances, PFAS

- Synthetic compounds, manufactured since 1950's
- Very diverse group of substances
- OECD (2018): 4700 PFAS
- Unique and useful properties from technical viewpoint
- However, also harmful properties – common for the whole group



Per- and polyfluoroalkyl substances, PFAS

- Main uses include:
 - Fire-fighting foam
 - Textile treatment
 - Food contact materials
- However, widespread use of PFAS, including in products





Worrying observations

PFAS in humans and biota

- Median for the sum of PFOS, PFOA, PFHxS, PFNA, PFDA and PFUnDA in serum or plasma - general populations (EFSA, 2020):
 - Adults: approx. 12 ng/mL
 - Children: approx. 8 ng/mL
- PFAS have the ability to disperse over long distances through air and water.
- Are detected far from any areas of manufacture or use, e.g., in arctic environments – making PFAS very much a global problem.

PFAS – Difficult to remove

- Many PFASs are highly soluble in water and have a low sorption potential, resulting in a preferred distribution to the aqueous phase
- Both legacy and novel PFASs detected in drinking water in non-EU countries. Limited monitoring in the EU.
- In Veneto, Italy, industrial activity contaminated drinking water with PFASs for 127.000 citizens
- These are often difficult to remove with conventional purification techniques
- May apply to: wastewater purification, drinking water production and removal of industrial emissions


Health effects

Health effects in humans that have been associated with exposure to certain PFAS are:

- Increased cholesterol levels
- Impact on infant birth weights
- Effects on the immune system
- Increased risk for cancer
- Thyroid hormone disruption

Health effects

- There is limited knowledge of the health effects of many PFAS
- However based on similarities between PFAS, there is good reason to consider all PFAS as a health hazard
- In addition, based on their similarities, combination effects of PFASs can be expected.



Substance properties responsible for the observations

Persistence

Concept

PFAS

Persistence

Mobility

Bioaccumulation

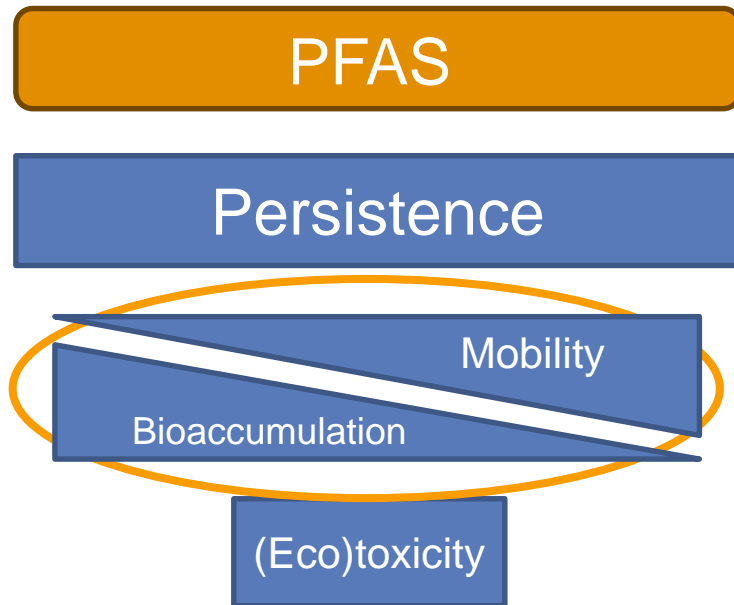
(Eco)toxicity

Persistence

- Covers all PFAS directly or indirectly as precursors can be transformed/ degraded to persistent PFAS
- Persistent due to strength of C-F bond
- PFAS remain in the environment for decades to centuries

Mobility

Concept



Bioaccumulation/ Mobility

- Small-molecule PFAS are in general either bioaccumulative (B) or mobile (M) depending on the substance properties, and altogether the whole partitioning range is covered
- In combination with extreme persistence the concerns for B and M become (to some extent) interchangeable

Toxicity/Ecotoxicity

Concept

PFAS

Persistence

Mobility

Bioaccumulation

(Eco)toxicity

(Eco)toxicity

- Information on (eco)toxicity is increasing for PFAS, but some PFAS will stand out as example
 - (Eco)toxicological effects related to these highly persistent chemicals will continue for decades to centuries following their continuous release to the environment
- Adverse effects are difficult to assess for long term cross generational exposure



From the substance properties
follow concern

ELEMENTS OF CONCERN

Properties

- Very high persistence
- High bioaccumulation potential
- High mobility
- Difficult removal
- Toxic effects in humans and the environment



- Continuous releases of PFASs will lead to continuously increasing levels in the environment that will last for decades and centuries (irreversible contamination)
- Increasing biota concentrations along the food-chain with highest PFAS-levels in top predators (e.g. polar bear)
- Potential for continuously increasing contamination of surface water, marine water and groundwater
- Societal concern for drinking water contamination
- High long-range transport potential via water and air will lead to contamination of remote regions and worldwide occurrence
- Continuous presence in water results in continuous bioavailability
- Growing probabilities of known and unknown effects, including those that would not be observed in standard tests
- Additive effects from combined exposure to multiple PFASs simultaneously
- Intergenerational effects, mother-to-offspring transfer

REACH Regulation and Restriction

- Aim is an EU-wide protection of human health and the environment
- Risks posed by chemicals which are not adequately controlled can be addressed via different RMMs
- Restriction can be a 'safety net' where risks cannot be addressed by other REACH processes or other EU legislation
 - only few limitations to scope
 - can address non-standard hazards / risks

Public Announcement concerning PFAS

Five European states call for evidence on broad PFAS restriction

ECHA/NR/20/13

The national authorities of Germany, the Netherlands, Norway, Sweden and Denmark invite interested parties to send in evidence and information on the use of per- and polyfluoroalkyl substances (PFAS) by 31 July 2020.

Helsinki, 11 May 2020 – The authorities of the five countries have agreed to prepare a joint REACH restriction proposal to limit the risks to the environment and human health from the manufacture and use of a wide range of PFAS.

<https://echa.europa.eu/-/five-european-states-call-for-evidence-on-broad-pfas-restriction>

Current Status – Preparatory Phase

- Call for Evidence (CfE) during Summer 2020 (about 570 responses received)
- Current pre-phase is planned to be finished with RMOA conclusion document
- PFAS considered to be substances that contain at least one aliphatic $\text{-CF}_2\text{-}$ or -CF_3 element
→ covers many substances and various structures

Preparatory Phase – Work on PFAS Uses

- Assessment of responses of CfE is taking place according to use with different Member States in lead for different uses:

NL: medical devices and pharmaceuticals; food contact materials; production of fluoropolymers; waste and recycling

DE: chrome plating; consumer mixtures; transport

SE: textiles, leather, apparel; cosmetics and personal care products

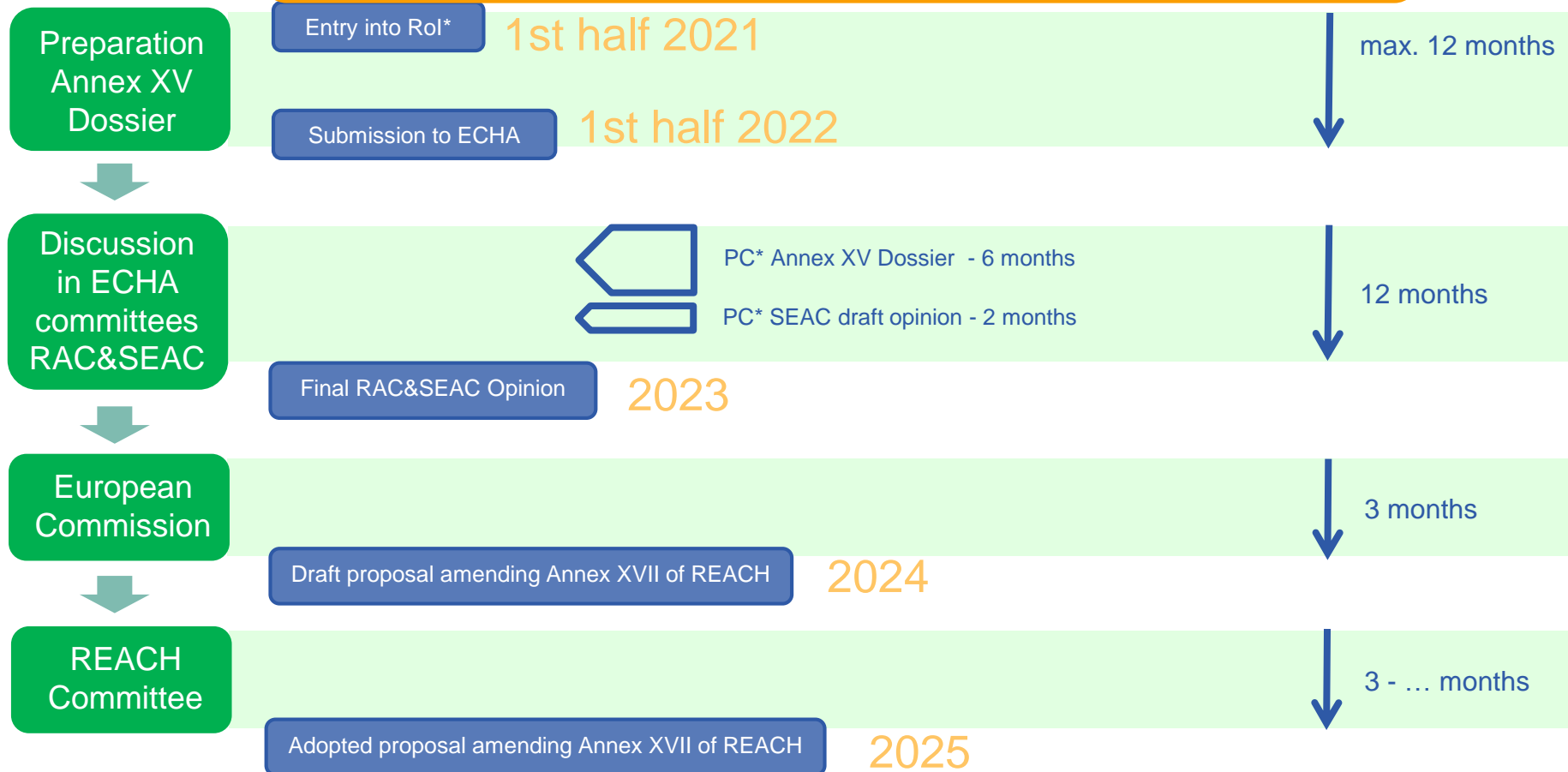
DK: lubricants and construction products; electronics, energy sector including semiconductors

NO: F-gases; ski waxes; applications within oil, gas and mining

Potential Timing PFAS Restriction



Currently PFAS restriction work is prior to RoI in a preparatory RMOA phase !



Thank you for your attention!

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