Update on the PFAS Restriction Proposal

VIG meeting
12 december 2024

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RIVM

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

baua: Bundesanstalt für Arbeitsschutz und Arbeitsmedizin

KEMI Swedish Chemicals Agency

Norwegian Environment Agency

Ministry of Environment of Denmark
Environmental Protection Agency

Content

- REACH
- Motivation/Need for regulation
- Next steps Dossier Submitters (DS) and ECHA
- Discussions in scientific committees/timelines

REACH- Largest chemical substances regulation in EU

- Applicable to all chemical substances with an owner

- Objectives:
  - Safe use for human and the environment
  - Innovation and alternatives
  - Level playing field (WTO)

Tasks and responsibilities for companies and authorities

- Reversed burden of proof

REACH-Players on the field

- European Commission (COM)
- ECHA (European Chemicals Agency)
- Manufacturers/Importers/Downstream Users
- National authorities (Competent Authority, Member States)
  - **Bureau REACH** (at RIVM) as delegated Competent Authority for REACH & CLP
  - REACH and CLP helpdesk:

  Official NL helpdesk

  https://www.chemischestoffengoedgeregeld.nl/
- › Enforcement on national level

Restriction proposal - content

- **REACH = Registration, Evaluation, Authorisation and restriction of CHemicals**

- **Restriction proposal:**
  - ✓ Chemical identity
  - ✓ Hazards, risks, effects
  - ✓ Applications
  - ✓ Availability of alternatives
  - ✓ Socio-economic analysis – impact assessment

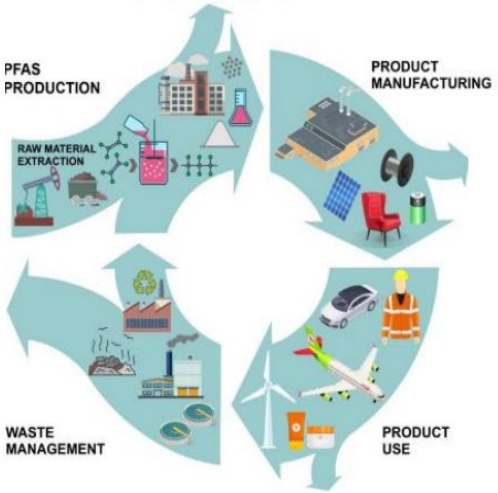
Motivation restriction proposal

- Green deal 2019
- CSS 2020
- NL political commitment
- 4 other countries agreed to collaborate with NL; DE, DK, NO, SE

Need for regulation

Hazardous Properties

- Persistence
- Mobility
- Bioaccumulation
- (Eco)toxicity, other properties



Emissions

75 000 tons
of emissions in 2020

4.5 Mio. tons
of emissions over 30 years

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

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Need for regulation

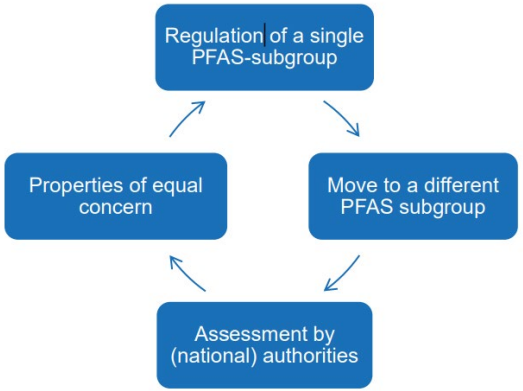
- Adverse effects on environment and human health
- PFASs are used in high tonnages in a variety of applications
- Emissions occur in all life cycle stages
- Monitoring data: ubiquitous presence of PFASs in the environment and in humans
- PFASs have very high persistence
- PFASs are difficult to remove once released into the environment, “forever chemicals“

- Uncontrolled risk from use of PFASs in EEA
- Need for EU-wide regulatory measure(s)

Regrettable substitution-grouping approach

Previous regulatory approach for PFAS

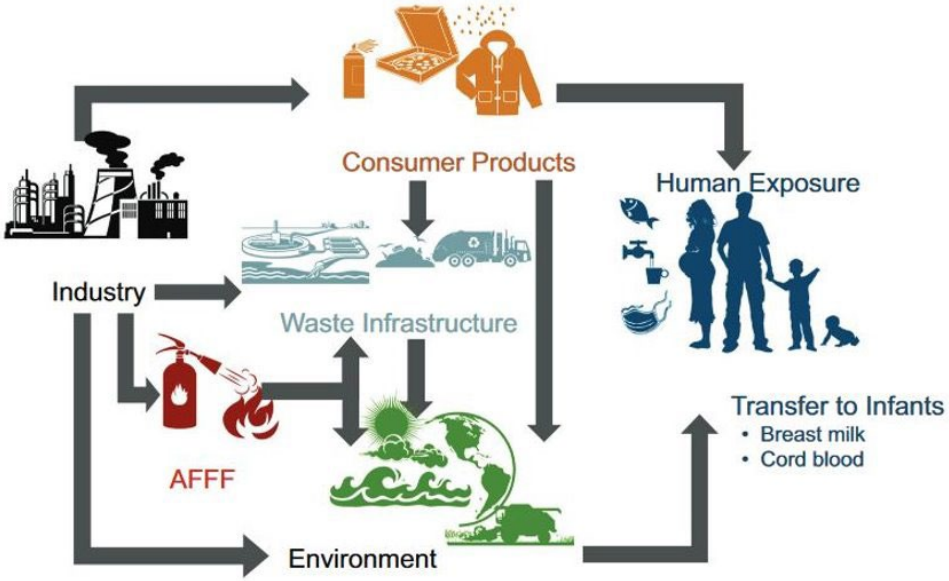
- **Small groups (various PFCAs)**



Further emissions into the environment over decades
- High overhead for authorities
- Uncertainty for stakeholders

Approach
- ✓ Regulating all PFAS in one group
- ✓ Precautionary principle

Emissions → Exposure



Emissions from all life cycle stages (production PFAS, production products, use phase, waste stage):

75000 tonnes (2020)

Source
https://bgc.seas.harvard.edu/assets/sunderland_jeseerev_2018wsi.pdf

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Emission reduction potential

Baseline:

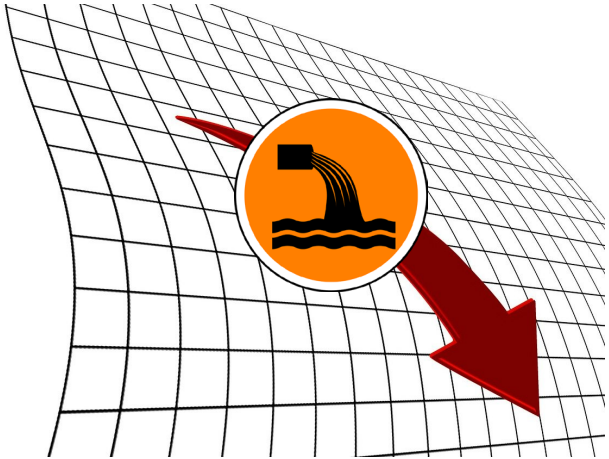
- 4.5 Mio tons of emissions (over 30 years)

RO1 (full ban):

- Ca. 4.3 Mio tons of avoided emissions (96%)

RO2 (restriction with use-specific derogations):

- Less effective/Quantification is work in progress



Medicines, active substances

Proposal

Derogation (time unlimited):

a. active substances in biocidal products within the scope of Regulation (EU) 528/2012

b. active substances in plant protection products within the scope of Regulation (EC) 1107/2009

c. active substances in human and veterinary medicinal products within the scope of Regulation (EC) No 726/2004, Regulation (EU) 2019/6 and Directive 2001/83/EC

Examples of new sectors

- Other medical applications (e.g. excipients and packaging for medicines)

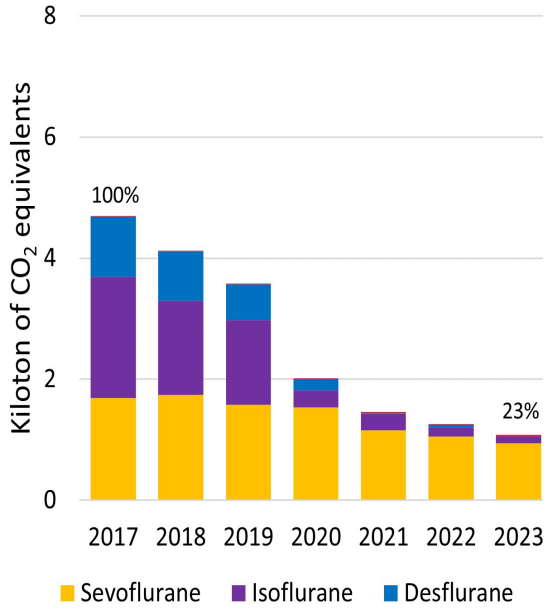
  Part of medicines authorisation that are not covered by the active substance derogation, e.g. propellants as excipients in pMDIs.

- Sealing applications: fluoropolymer uses in consumer and industrial applications, including seals, pipe lining, gaskets, valve parts, etc.

Alternatives- medical application

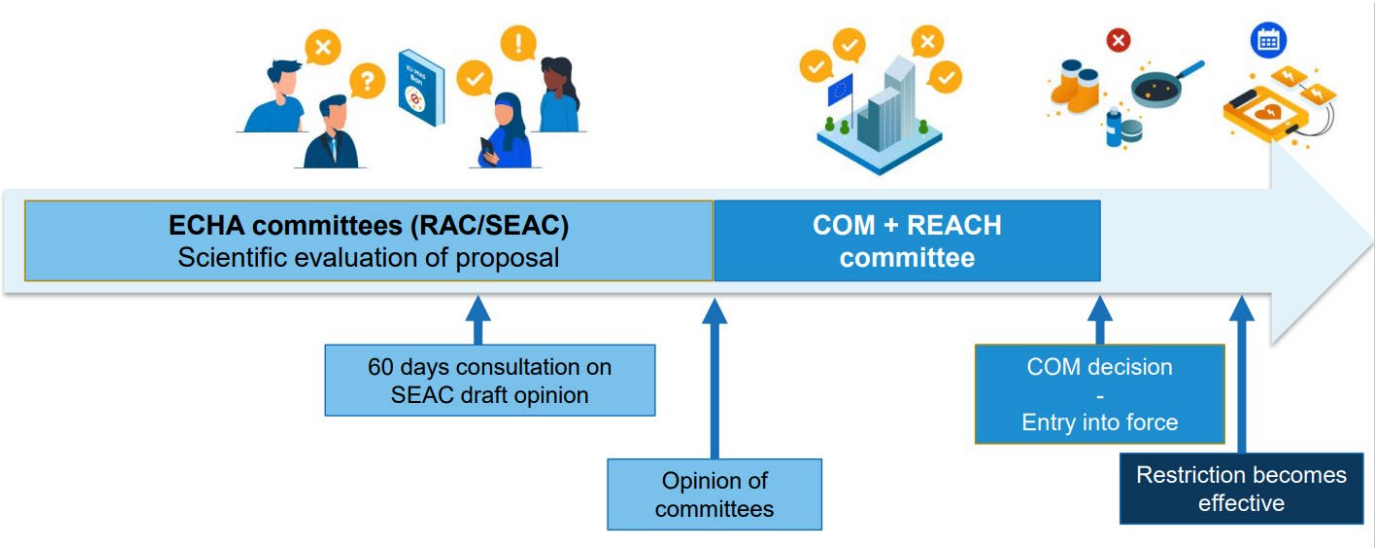
- Significant emission reduction fluorinated gases in medical application (NVA/Amsterdam UMC),
  paper in press
- Use in anesthetics (=active substance)
- Patient safety to be similar

(intravenous vs. inhalation)

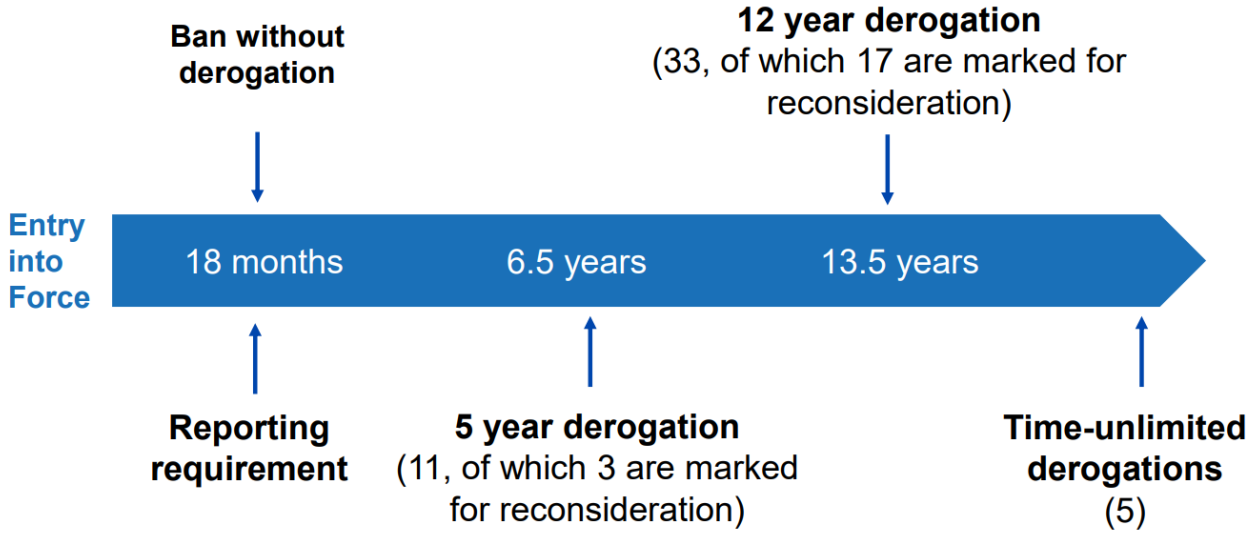


The process so far

Timeline


ECHA committees (RAC/SEAC)
Scientific evaluation of proposal
COM + REACH committee
60 days consultation on SEAC draft opinion
Opinion of committees
COM decision - Entry into force
Restriction becomes effective

Phase-out timelines



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Current discussions in RAC/SEAC

- Stay up to date: https://echa.europa.eu/de/-/highlights-from-june-2024-rac-and-seac-meetings

- Meeting minutes are being published

Meetings of the RAC - ECHA (europa.eu)

Meetings of the SEAC - ECHA (europa.eu)

Conclusions

- Dossier presents a proposal made by competent authorities
- Focus currently: Assessment of comments/alternatives
- Revision of dossier → BD is basis for opinions from RAC/SEAC
- Aim: Minimisation of emissions

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