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Universal PFAS restriction proposal

FOD VVVL – DG EM – DPPC - MRBC

REACH restriction process

- Limit or ban the **manufacture, placing on the market (including imports) or use of a substance**
- A restriction may apply to any **substance on its own, in a mixture or in an article**, including those that do not require registration
- Restriction dossier should include **hazard, risk and socio-economic analysis** (including alternative assessment)
- **EU-wide unacceptable risk** has to be proven

I Phase

Preparation and submission of a restriction proposal

- Starting the restriction process
- Notification of intention to submit a restriction proposal
- Registry of Intentions
- Preparing the restriction dossier
- Submission and conformity check

II-A Phase

Consultations

- Consultation on the restriction report
- Consultation on SEAC's draft opinion

II-B Phase

Opinion development

- Advice from the Forum
- RAC's opinion
- SEAC's opinion

III Phase

Decision and follow-up

- Commission decision on restriction
- Complying with restriction
- Enforcing the restriction

See ECHA site: https://echa.europa.eu/restriction-process

Background – PFAS Restriction dossier preparation

- 5 MS (Germany, Netherlands, Norway, Denmark and Sweden) started work few years ago
  - DE and NL are the lead submitters of the dossier
- 2 stakeholder consultations have already been organized in 2020 and 2021
  - One workshop has been organized in 2020
- Originally planned to be submitted to ECHA in July 2022
  - Due to large amount of work it was delayed until 13th of January 2023
- Dossier has been made available on ECHA site 07/02
  - DE and NL held a press conference 07/02 to give first insights: https://echa.europa.eu/-/echa-publishes-pfas-restriction-proposal

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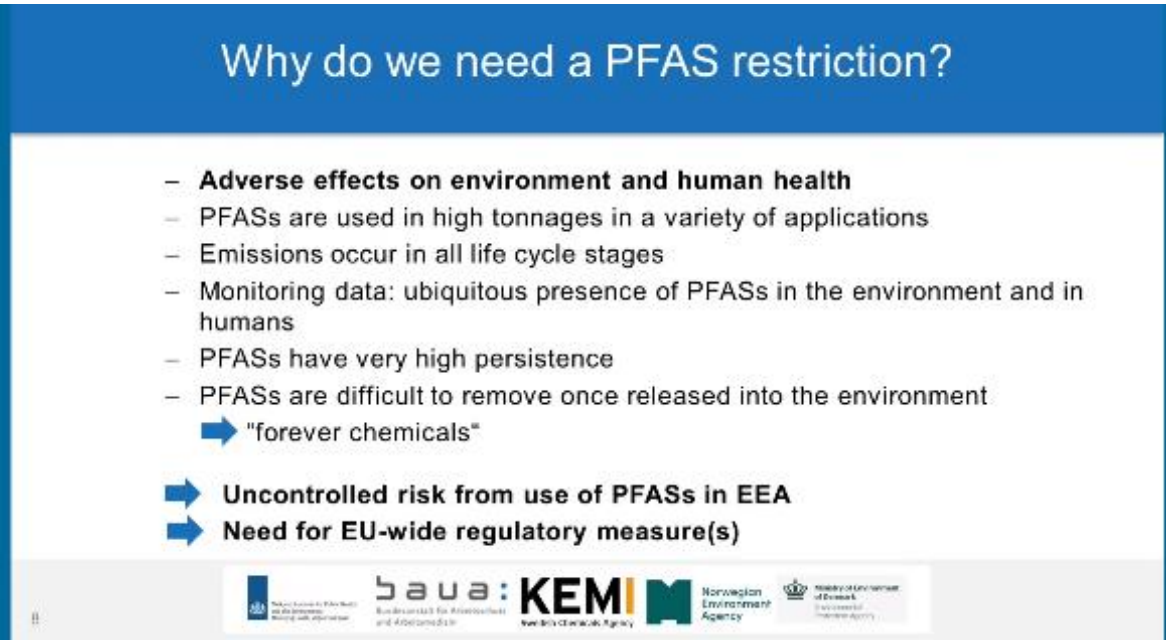
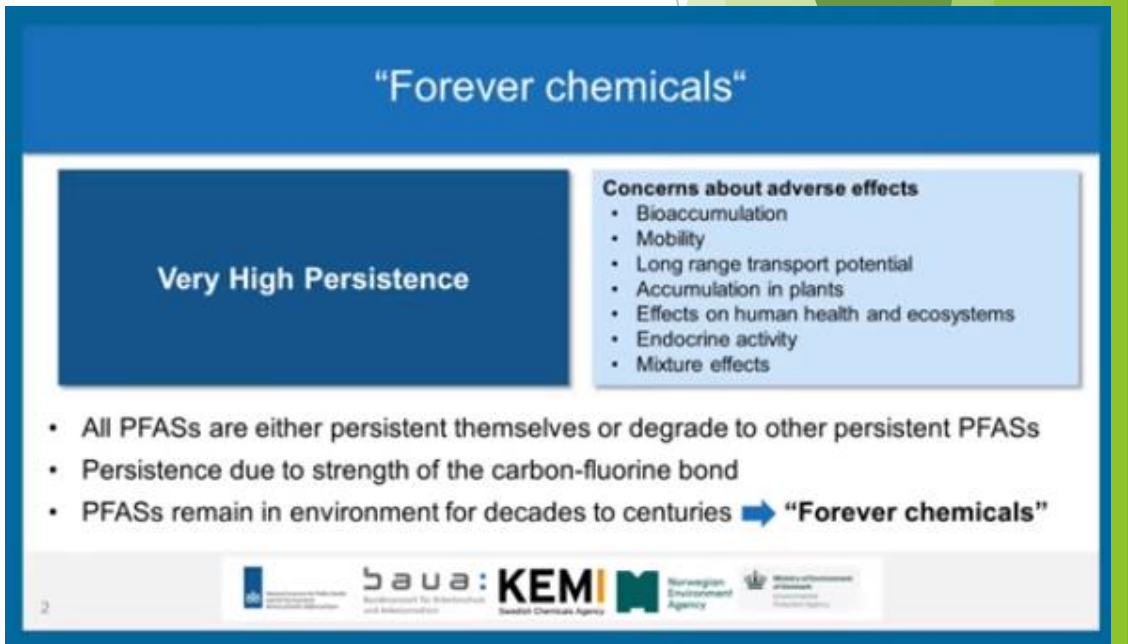
PFAS: Main concern identified

- *"… the **very high persistence**, exceeding the criterion for very persistent (vP) according to Annex XIII of the REACH Regulation by far.*
- *"**supporting concerns** are their bioaccumulation, mobility, long range transport potential (LRTP), accumulation in plants, global warming potential and (eco)toxicological effects."*
- *"With the constantly increasing concentrations of PFASs in the environment due to their **persistence and ongoing emissions**, the exposure of humans and the environment to these substances **will inevitably lead to negative effects**"*
- *"exposure to PFASs has a **high potential for intergenerational effects"***





Restriction Scope – PFAS Substances

- OECD definition → roughly 10 000 substances
- With some specific exemptions
  - According to DS not as persistent as “standard” PFASs
  - See also Annex B section 4.1.4 for more detailed explanation

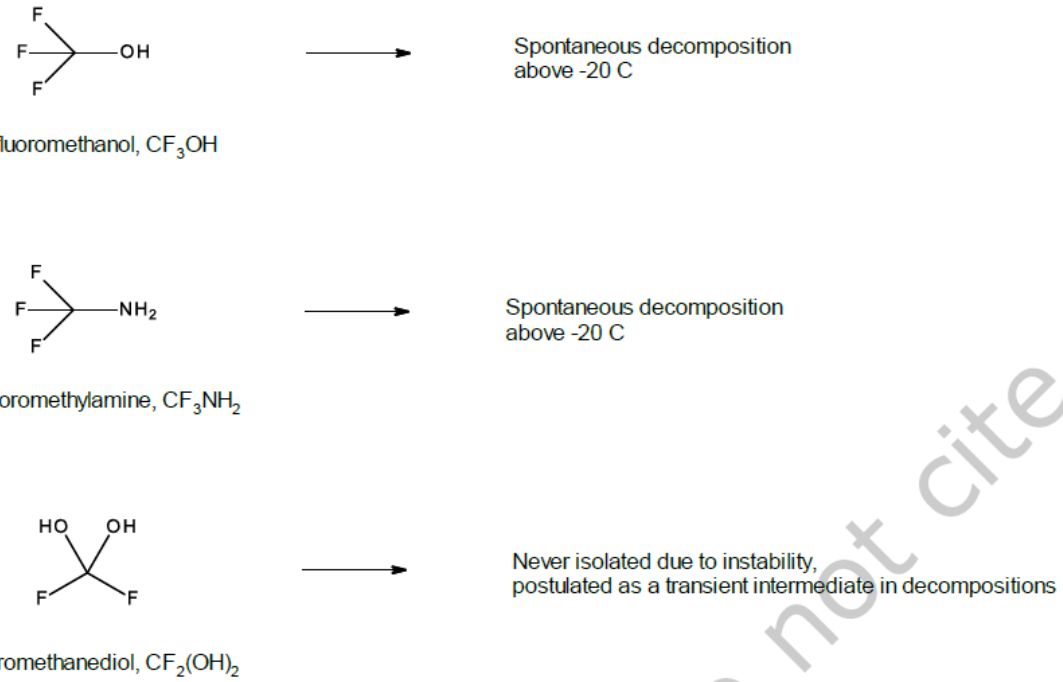


Figure B.46. Inherently unstable key fluorinated compounds.

Per- and polyfluoroalkyl substances (PFASs) defined as:

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).

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)-).

Restriction Scope

- ***"manufacture, placing on the market, as well as the use*** *of PFASs as such and as constituents in other substances,* ***in mixtures and in articles*** *above a certain concentration."*
- ***"All uses of PFASs are covered*** *by this restriction proposal,* ***regardless of whether they have been specifically assessed*** *by the Dossier Submitters and/or are mentioned in this report or not, unless a specific derogation has been formulated."*
- *"****Grouping approach*** *has been chosen to prevent regrettable substitution in the future"*

Proposed concentration thresholds

- After entry into force concentrations of PFAS in mixtures and articles will not exceed:
  - **25 ppb** for any PFAS measured with targeted PFAS analysis (excluding polymeric PFAS from quantification)
  - **250 ppb** for the sum of PFAS measured with targeted analysis (optional with prior degradation of precursors) (polymeric PFAS excluded from quantification)
  - **50 ppm** for PFAS (including polymeric PFAS)
    - If total fluorine exceeds 50 mg/kg F → proof on whether fluorine measured as content of either PFAS or non-PFAS
    - Relationship between F and PFAS content depends on percentage of F in molecular structure

Proposed Risk Management Options

- Two Restriction Options (Ros) have been assessed:
  - **RO1**: A full ban with no derogations and a transition period of 18 months
  - **RO2**: full ban with use-specific time-limited derogations (18-month transition period plus either a 5 or 12-year derogation period).
- *"As specific information on costs of a ban of PFASs for the different actors associated with the addressed uses was scarce and mainly qualitative, the* ***derogations and their duration were mainly based on the availability and applicability of alternatives to PFASs"***

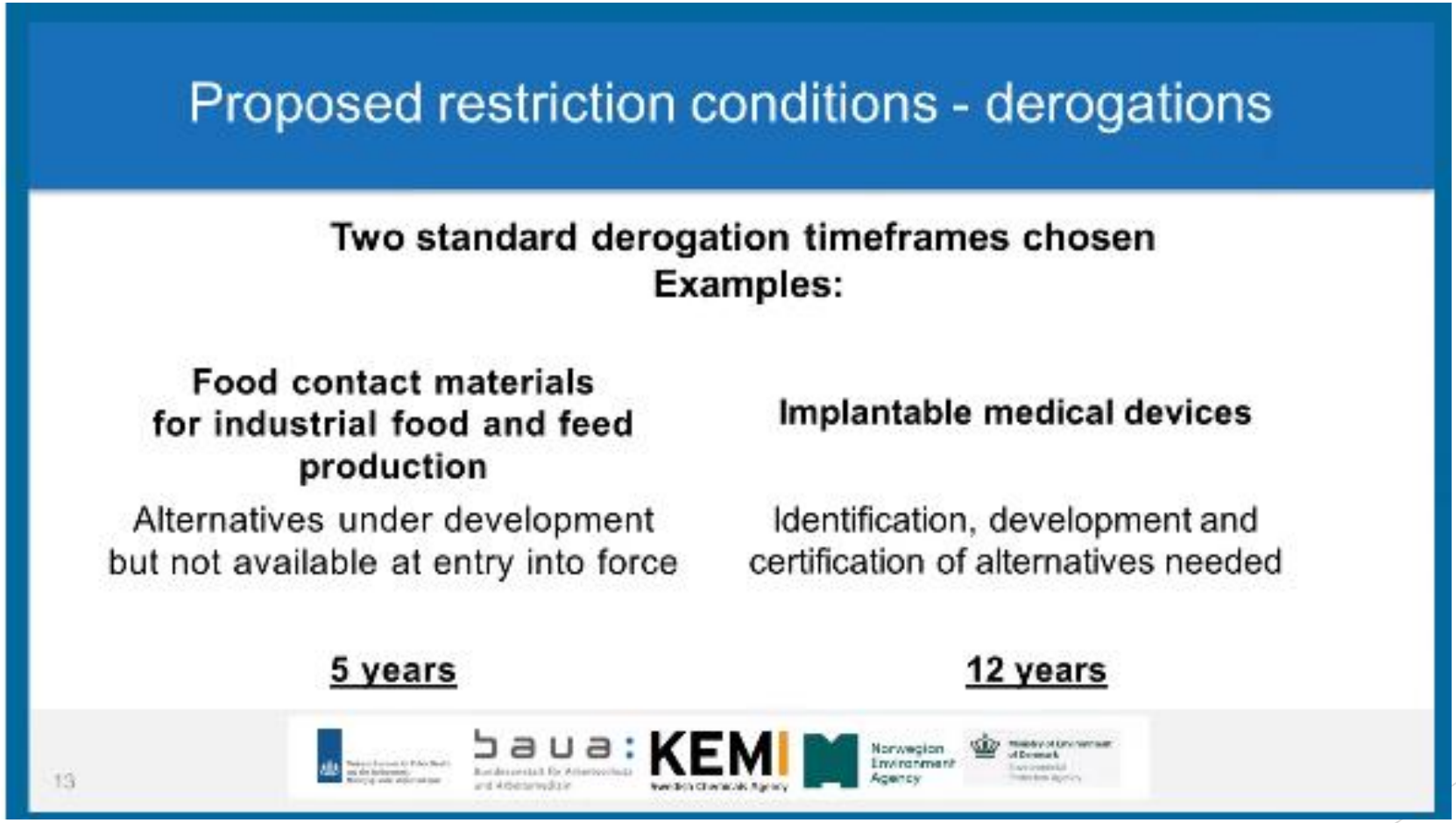
Table 7. Restriction options (ROs) assessed.

Restriction option (RO)	Transition period before RO takes effect	Duration of derogation
RO1: Full ban	18 months	Not applicable
RO2: Ban with use-specific derogations		5 years after transition period ends
		12 years after transition period ends
		Time-unlimited (only for specific uses)

Proposed (temporary) exemptions

- 30+ specific exemptions
- Including some exemptions that will only be retained if sufficient justification is provided
- Exemptions include:
  - Personal protection equipment (PPE) textiles
  - Certain F-gas uses in heating and refrigerants
  - Uses in automotive and electronics
  - Medical uses
- Subdivision between PFAS in general and fluoropolymers
- Some exemptions are “unlimited”
  - To avoid double regulation (Boicidal products, Plant Protection Products and Medical Devices)
    - However environmental concern might not be tackled!
  - National safety standards for buildings
  - Use in analytics (internal standards)

Transition periods proposed under RO2



Reporting requirements and site management plans

- Most derogated uses are proposed to be subject to **reporting:**
  - Specifying under which derogation they fall
  - Identify and quantity of the substance placed on the market
  - Manufacturers, importers and formulators have to report this information
- For derogated fluoropolymers and perfluoropolyethers → **site specific management plans**, including:
  - Information on the identity of the substances and the products they are used in
  - A justification for the use
  - Details on the conditions of use and safe disposal.

Socio-economic analysis – Baseline

- ***"14 sectors and/or applications*** *– subdivided in numerous sub-uses - have been addressed"*
- *"Over a 30-year period the expected mean PFAS tonnage in the EEA is 49 million tonnes, leading to* ***emissions of about 4.4 million tonnes*** *during the manufacture and use phase when no action is taken"*
- *"emissions during the* ***waste phase****, which may be significant, are not accounted for in that estimate as they are highly uncertain. Hence, it can be* ***assumed that emission estimates are severely underestimated****."*
- *"The overall annual* ***health costs*** *following from exposure to PFAS in Europe has been estimated in a Nordic Council report from 2019 to be* ***between €52 and 84 billion****."*

PFAS applications assessed

Table A.1. Overview of PFAS applications and the level at which they were researched.

PFAS applications			
PFAS manufacture	Textile, upholstery, leather, apparel and carpets (TULAC)	Food contact materials and packaging	Metal plating and manufacture of metal products
Consumer mixtures	Cosmetics	Ski wax	Applications of fluorinated gases
Medical devices	Transport	Electronics and semiconductors	Energy sector
Construction products	Lubricants	Petroleum and mining	Waste stage PFAS applications
Laboratory equipment & filtration	Plant protection products and biocides	Chemical industry	Firefighting foam
Medicinal products	Plastics (other than packaging) and rubber/elastomer production (including flame retardants)	Pyrotechnics	Personal care products other than cosmetics
Fracking (currently hardly applicable in EEA)	Immersion cooling (currently hardly applicable in EEA)	Defence industry	Printing inks
Cement industry	Professional cleaning and polishing	Other niche applications	Uses (yet) unknown

- Green uses are researched in detail
- Blue uses are researched in general
- Orange uses not researched in detail
- Purple use: Separate restriction proposal

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Socio-economic analysis – Impact Analysis

- **Benefits**
  - ***"Environmental benefits** are expressed as the expected **total amount of emissions avoided"***
  - ***"Benefits to human health** are evaluated qualitatively as data is limited, or missing, to assess:*
    - *the hazard of many of the individual PFASs;*
    - *the associated thresholds below which exposure is not expected to lead to adverse health effects, if such limits exist, and*
    - *the prediction of future human exposure levels."*
- **Costs**
  - *"costs to industry in the form of **producer surplus losses"***
  - ***"consumer surplus losses** as a result of changes to the product price, welfare losses and/or costs resulting from changes in the characteristics of goods, e.g."*
  - ***"welfare losses** resulting from the absence of the product (where substitution is not feasible) as well as **job losses."***

Example of emission reduction analysis

Example: Textiles

Main function	Impregnation (dirt/oil/water repellency)
Tonnage (2020)	Circa 92 000 tonne per year
Emissions (2020)	Circa 23 000 tonne per year
Estimated emissions (30 years) without restriction	1 400 000
Estimated emissions (30 years) full ban	66 000

➡ **Emission reduction of ~ 95% (in case of full ban)**

Proportionality

- *"Dossier Submitters conclude that the **extent of PFAS emissions warrants regulatory action**"*
- *"**additional emissions** from use sectors and/or uses (as well as from the waste stage) **have not been addressed (in detail)** and thus **only add to the concern** and consequently to the call for regulatory risk management measures"*
  - *"for a large number of uses, functional alternatives are already available"*
- *"**Both RO1 and RO2 are deemed proportionate to the risk**, as eventually the societal cost of inaction will always surpass the costs of a ban on the use of PFASs."*
- *"It has to be realized that **once a restriction is in place, emissions will go on for many years to come** due to the presence of PFASs in technical stock ((long-lived) products in use and on shelf) and waste"*

Proportionality

- *"Although both restriction options (RO) are deemed proportionate to the risk, **the Dossier Submitters propose RO2 as the most balanced option."***
- *"RO2 leaves room to **mitigate unwanted effects to society** due to the sudden unavailability of products for which alternatives are not yet in place and **allows stakeholders and industry to prepare for a smooth transition to alternatives**."*
- *"It should be noted, however, that a delay of banning PFASs as a result of the **proposed derogations under RO2 will shift the cost burden** arising from health and environmental impacts **to future generations."***

Restriction Proposal

Adobe Acrobat Document

Microsoft Word-document

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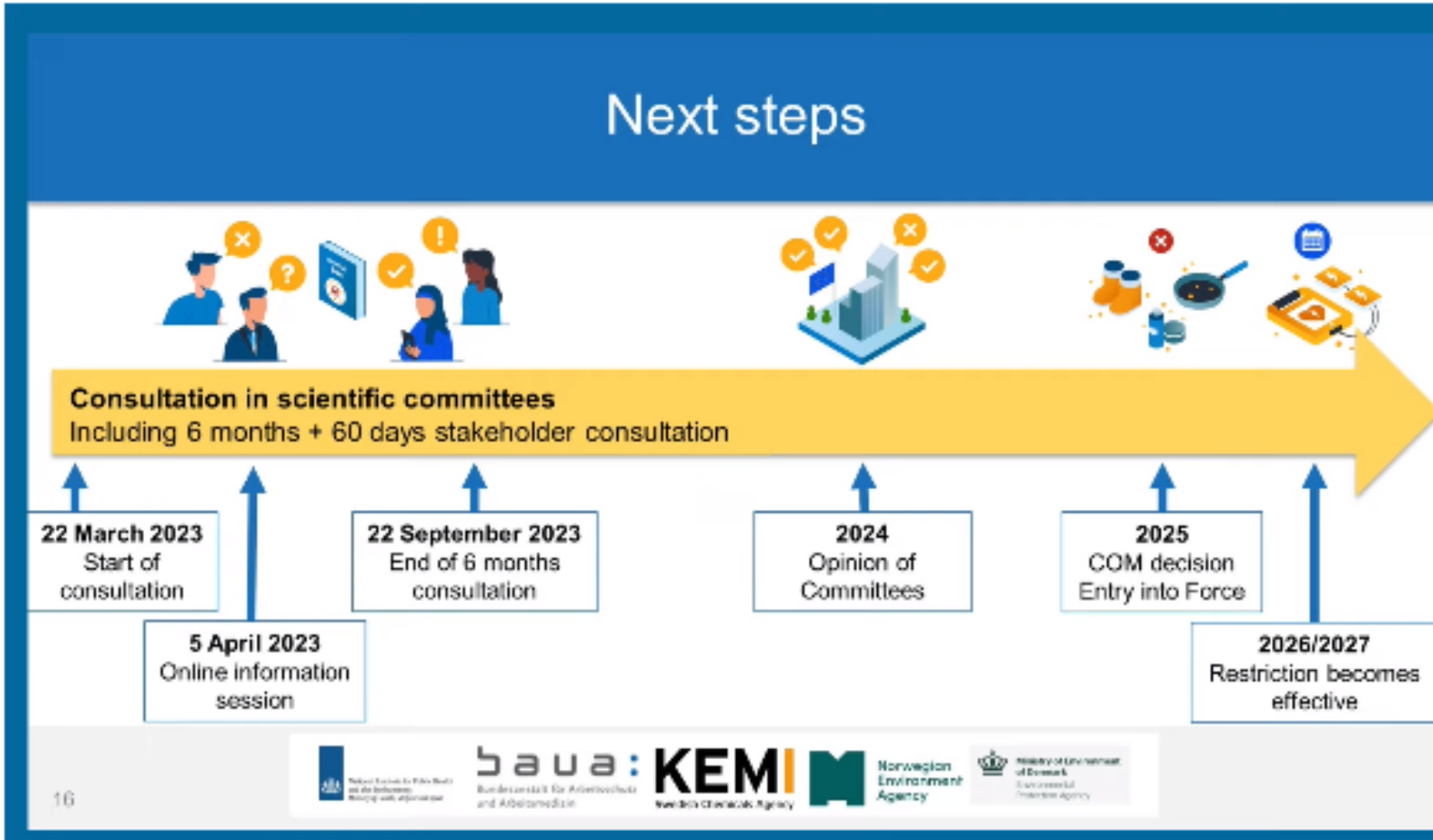
First thoughts on the proposal

- Positive points
  - Very extensive and detailed analysis by the DS
    - All PFAS in all uses are covered in the proposal
    - Even uses not already existing are covered
  - Only limited number of complete derogations proposed
    - Good to see that they would need to be reported on
  - Only very specific (temporary) derogations have been proposed
  - Proposal seems to be following the “P sufficient” approach and the precautionary principle
- Points of concern
  - Uncertainties on the waste phase and incineration of PFAS
  - Uncertainties on derogated uses to be cleared out
  - Only qualitative analysis of the benefits (based on avoided emissions only)
  - Uncertainties on the reporting requirements and the “site management plans”
  - Link between this restriction and other EU actions (IED, WFD, etc.)

Further planning - Restriction process

- **22/03**: Start Public Consultation
  - In Parallel RAC and SEAC will start drafting Opinion
  - 05/04: ECHA info webinar
- **22/09**: End of Public Consultation
  - RAC opinion will be finalized
- **2024**: Draft SEAC Opinion consultation of 60 days
- **2024 - 2025**: Final Opinions and Annex XV adopted
- **2025 - 2026**: COM development of restriction proposal and REACH Cee (Member States) vote
- **2026-2027**: Entry into force
  - +/- 2030: first transition period ends
  - +/- 2045: last transition period ends



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BE input in the process - CCIEP PFAS Working Group

- Network of Authority experts working on PFAS (FPS Health Envi, FOD WASO, FOD economy, OVAM, Envi Brussels, SPW Wallonia, etc.)
- Main objectives
  - Share data and information on ongoing activities regarding PFAS between different BE authorities
  - Share PFAS information and data on EU and international level (REACH, POP, etc.)
  - Act as expert advice body to other coordination structures on PFAS related topics
    - Note: PFAS CCIM group does not have mandate to coordinate formal positions
    - Only provide advice to groups that take the final decision (GDPC, BCR, etc.)
- For PFAS restrictions under REACH: CCIM PFAS group will provide data and input to BCR, who will decide on the final BE positions
  - Example: BE comments to AFFF restriction proposal: drafted by CCIM PFAS group, approved and submitted via the BCR.

Public Consultation - Info needs?

- Information on PFAS tonnages and the fate of PFASs during the full lifecycle, especially the **waste stage**, is needed to allow for a better closed mass balance.
  - Waste stage emissions for fluorinated gas are unknown and therefore not taken into account
- New **data on monitoring and exposure**
  - Link between emission source and exposure
- **Potential derogations** justification
  - Studies/reports that justify that these potential derogations are not needed
- Check within your competence **whether the proposed derogations are justified** and what their impacts can be

Documentation

- Documents can be found on the ECHA page: https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b
  - Annex XV report: this is the base dossier in which you can find a summary, the proposal and general info on the evaluation done by the dossier submitter
  - Annex A: Manufacture and Use of PFAS
  - Annex B: Information on Hazards and Risks of PFAS
  - Annex C: Justification for action on Union-wide basis – *this is an empty document referring to Section 1.2. of the base Annex XV report*
  - Annex D: Baseline – *also an empty document referring to Section 1.3. of the Annex XV report*
  - Annex E: Impact Assessment
  - Annex F: Assumptions, uncertainties and sensitivities
  - Annex G: Stakeholder information
    - Appendix G1: call for evidence on restriction options
    - Appendix G2: second call for evidence on restriction options
  - Appendix E4: available analytical methods

Other interesting info

- Annex XV report
  - Overall Summary and Conclusion
  - Alternative assessment: Table 8 and 9
  - Enforceability: section 2.5.
- Available analytical methods: Appendix E.4
- Uncertainty analysis: Annex F
  - Table F.3 alternative assessment

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

- 03/05: ad-hoc BCR meeting on PFAS

Questions?

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