

Ad-Hoc BCR on the Universal PFAS restriction proposal

UPFAS restriction under REACH

History of PFAS policy actions

- ▶ 2006: EU restriction of PFOS (under Dangerous Substance Directive)
- ▶ 2009: PFOS added to the Stockholm Convention on Persistent Organic Pollutants (POP regulation in EU)
- ▶ 2011: PFOA and APFO identified as SVHC + CLP classification
- ▶ 2012: ICCM3 identifies PFAS as **emerging policy issue**
- ▶ 2016: PFNA identified as Substance of Very High Concern (SVHC) + CLP
- ▶ 2017: PFOA added to the REACH restriction list (Annex XVII)
- ▶ 2017: PFDA identified SVHC + CLP
- ▶ 2019: HFPO-DA (Gen-X) identified SVHC
- ▶ 2020: PFOA added to Stockholm Convention
- ▶ 2020: PFBS identified as SVHC
- ▶ 2021: C9-C14 added to the REACH restriction list (enters into force in 2023)
- ▶ 2023: PFHxS and related substances will be added to the Stockholm Convention

Well know PFAS get regulated → lesser known related PFAS replace them!
= regrettable substitution

Need for faster action using grouping approach: Universal PFAS Restriction preparation

- ▶ 5 MS (Germany, Netherlands, Norway, Denmark and Sweden) started working on proposal in 2020
- ▶ Stakeholder consultations and workshops organized in 2020 and 2021
- ▶ 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 07/02/2023
 - ▶ DE and NL held a press conference 07/02 to give first insights:
<https://echa.europa.eu/-/echa-publishes-pfas-restriction-proposal>
- ▶ Public Consultation of the dossier started March 22nd



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>

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**"

Why do we need a PFAS restriction?

- 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)

"Forever chemicals"

Very High Persistence

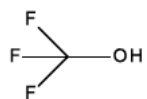
Concerns about adverse effects

- Bioaccumulation
- Mobility
- Long range transport potential
- Accumulation in plants
- Effects on human health and ecosystems
- Endocrine activity
- Mixture effects

- All PFASs 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 ➡ "Forever chemicals"

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



Trifluoromethanol, CF_3OH



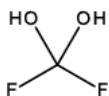
Spontaneous decomposition
above -20°C



Trifluoromethylamine, CF_3NH_2



Spontaneous decomposition
above -20°C



Difluoromethanediol, $\text{CF}_2(\text{OH})_2$



Never isolated due to instability,
postulated as a transient intermediate in decompositions

Per- and polyfluoroalkyl substances (PFASs) defined as:

Any substance that contains at least one fully fluorinated methyl (CF_3 -) or methylene ($-\text{CF}_2$ -) 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:

$\text{CF}_3\text{-X}$ or $\text{X-CF}_2\text{-X}'$,

where $\text{X} = -\text{OR}$ or $-\text{NRR}'$ and $\text{X}' = \text{methyl } (-\text{CH}_3)$, methylene ($-\text{CH}_2-$), an aromatic group, a carbonyl group ($-\text{C}(\text{O})-$), $-\text{OR}''$, $-\text{SR}''$ or $-\text{NR}''\text{R}'''$;

and where $\text{R/R}'/\text{R}''/\text{R}'''$ is a hydrogen ($-\text{H}$), methyl ($-\text{CH}_3$), methylene ($-\text{CH}_2-$), an aromatic group or a carbonyl group ($-\text{C}(\text{O})-$).

Figure B.46. Inherently unstable key fluorinated compounds.

Restriction Scope: all possible uses

- ▶ **"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"
- ▶ Meaning: every presence of PFAS (above certain threshold) planned to be banned in the EU
 - ▶ Including import
 - ▶ Including not yet developed PFAS or uses

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 (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 fluorinated gasses used in heating and refrigerants
 - ▶ Uses in automotive and electronics
 - ▶ Medical uses
- ▶ Some exemptions are “unlimited”
 - ▶ To avoid double regulation (Biocidal products, Plant Protection Products and Medical Devices) → however reporting requirements are included
 - ▶ National safety standards for buildings (not applicable for BE)
 - ▶ Use in analytics (internal standards)

Transition periods proposed under R02

Proposed restriction conditions - derogations

Two standard derogation timeframes chosen
Examples:

Food contact materials for industrial food and feed production	Implantable medical devices
Alternatives under development but not available at entry into force	Identification, development and certification of alternatives needed
<u>5 years</u>	<u>12 years</u>

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Reporting requirements and site management plans

- ▶ For most derogated uses manufacturers, importers and formulators have to **report** the following information:
 - ▶ Specifying under which derogation they fall
 - ▶ Identify and quantity of the substance placed on the market
- ▶ 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.

Restriction Proposal



Adobe Acrobat
Document

→ Proposal as drafted by the DS

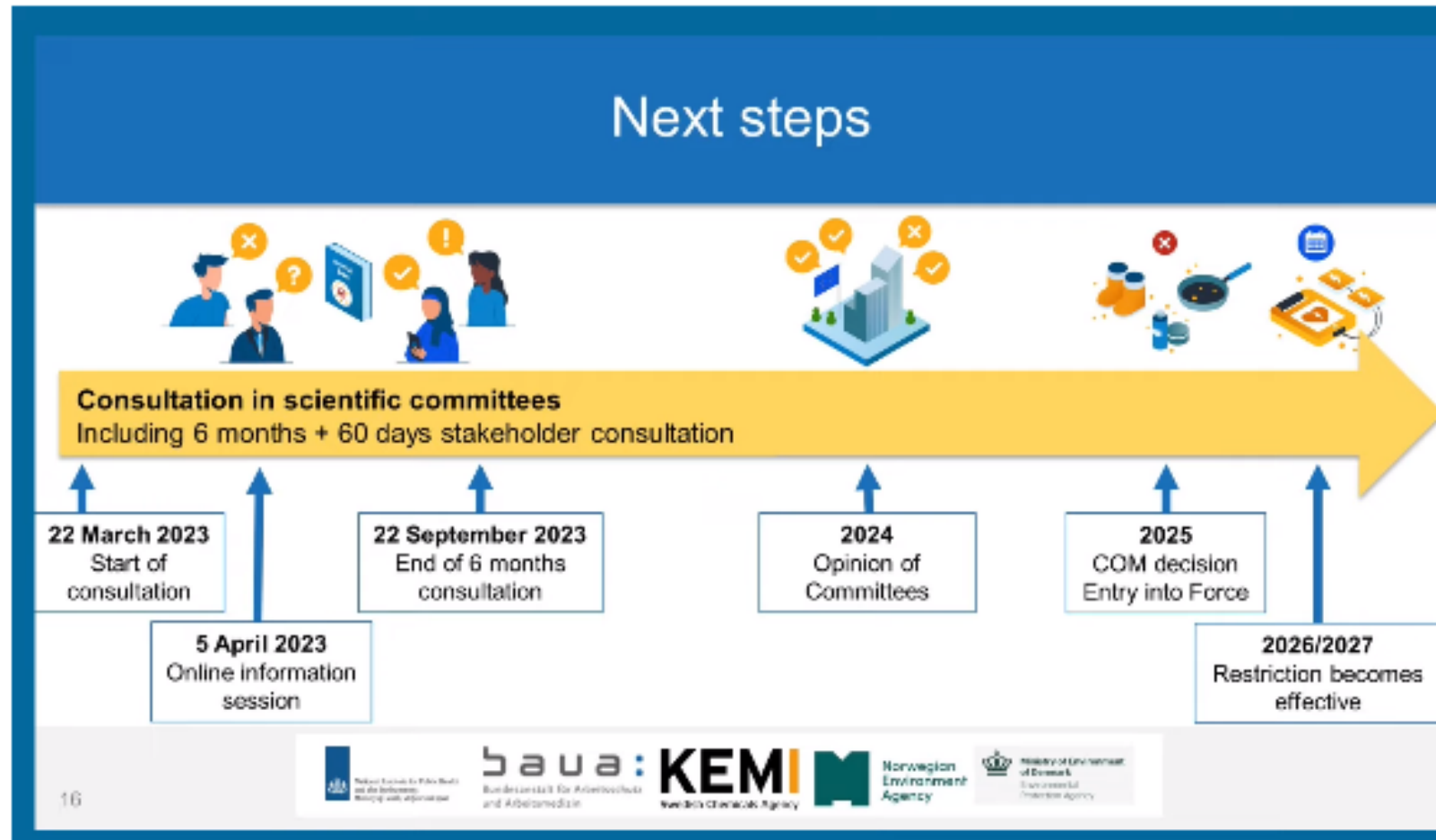


Microsoft
Word-document

→ Same proposal into overview table

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



Input in the restriction process - Public Consultation

- ▶ Public Consultation is the best way to give input into the process
- ▶ Please provide data if:
 - ▶ Specific uses need to be derogated
 - ▶ Identified derogations are not justified
 - ▶ Alternative assessment is incomplete for specific uses
- ▶ Any other comments are welcome → important to substantiate them with data!
- ▶ Check Info note for more detailed requests for data: <https://echa.europa.eu/documents/10162/cad38c27-ed8-2268-00c6-939ea066743c>
- ▶ Any data submitted after the consultation period cannot be taken into account by the RAC!
- ▶ Second Public Consultation on SEAC draft opinion: possible to provide input on the SEA analysis, however very short timeline (60 days)!
 - ▶ Will be planned for 2024/2025

UPFAS 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 whether the proposed derogations are justified and what their impacts can be
 - ▶ Please make sure to inform your stakeholders of this restriction and the potential impact it may have on their sector!

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>