

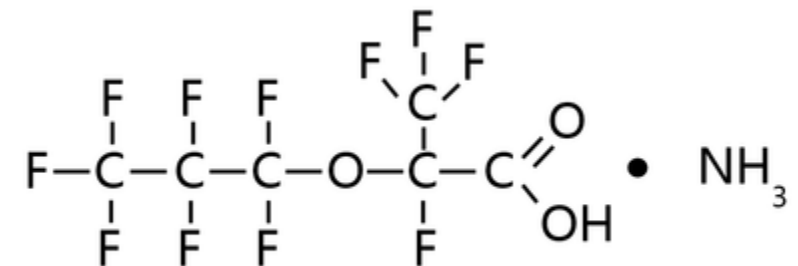
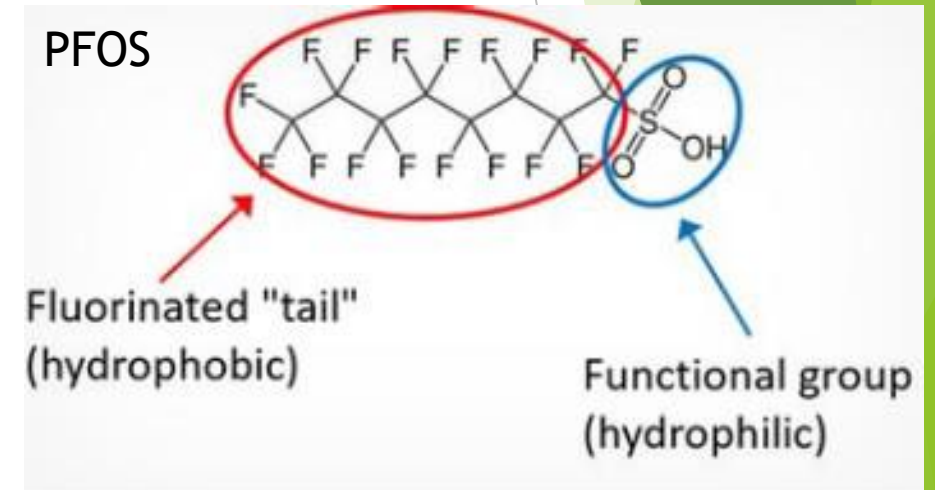
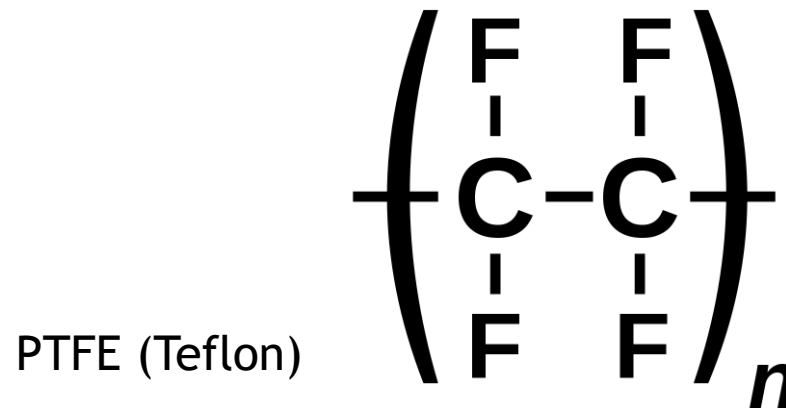
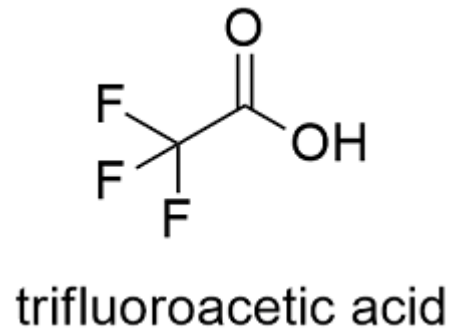
Ad-Hoc BCR on the Universal PFAS restriction proposal

Brief intro on PFAS

PFAS: Per- and Polyfluoroalkyl substances

PFASs are defined as fluorinated substances that contain at least one **fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it)**, i.e. with a few noted exceptions, any chemical with at least a perfluorinated methyl group ($-\text{CF}_3$) or a perfluorinated methylene group ($-\text{CF}_2-$) is a PFAS.

- ▶ Man-made chemicals
 - ▶ Produced since 1950s
- ▶ Defined by Carbon Fluor bond (C-F)
 - ▶ One of the strongest chemical bonds
 - ▶ → “forever chemicals”
- ▶ Large group of substances
 - ▶ Over 4000 according to OECD



PFAS use

- ▶ C-F bond is very strong → very stable molecules → interesting characteristics
 - ▶ Stability and thermo resistance (can withstand high temperatures)
 - ▶ Electrical wire coating
 - ▶ Use in Personal Protection equipment (fire fighting gear)
 - ▶ Fire fighting foams
 - ▶ Water and grease repellent characteristics
 - ▶ Outdoor gear like tents, shoes and raincoats (for example Gore-Tex)
 - ▶ Non-stick pots and pans (Teflon)
 - ▶ Food contact materials (popcorn bags, pizza boxes, ...)





Airconditioning



Fire
extinguishers



Heat pumps



Refrigeration

Essential uses?



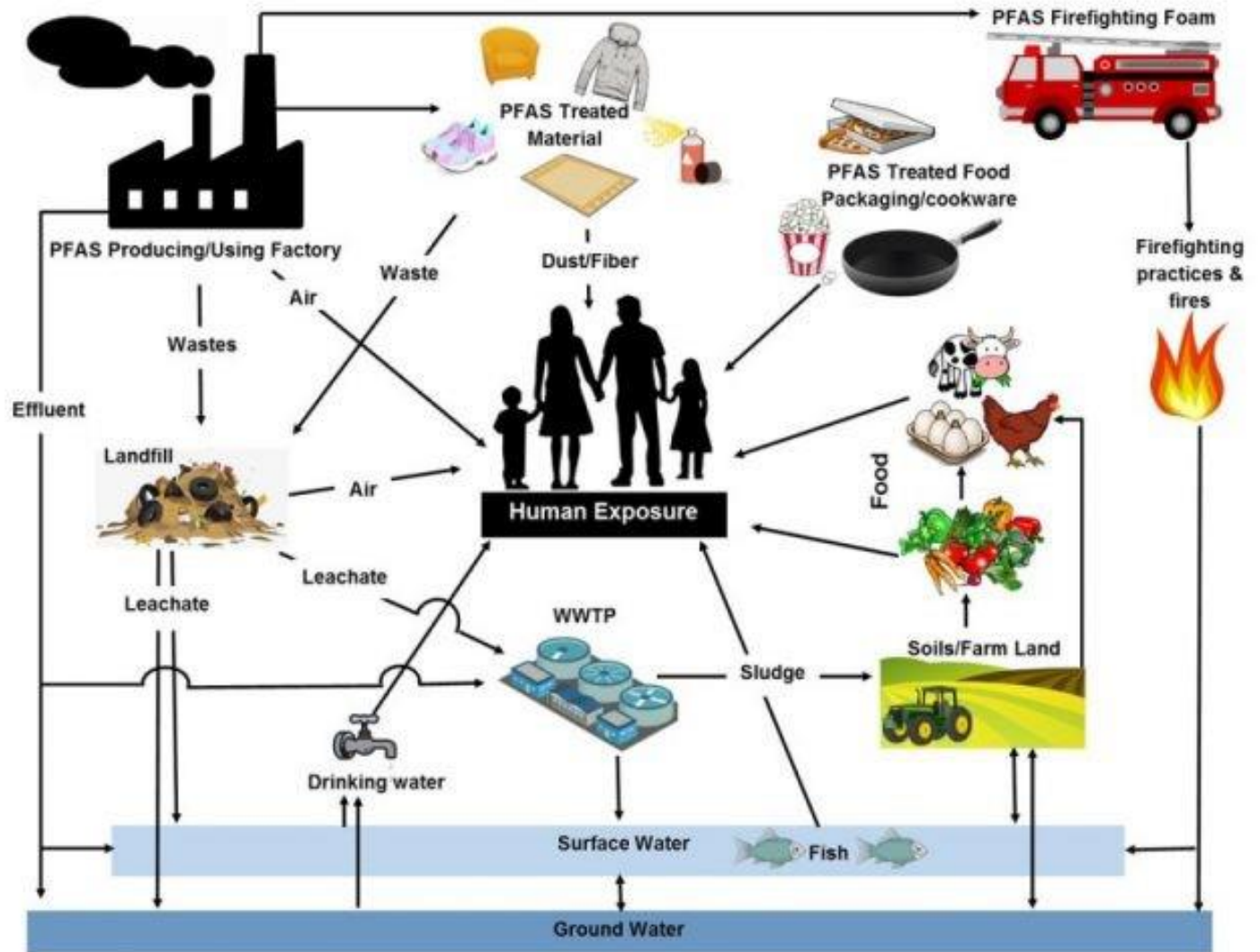
Uses of fluoropolymers

- Promoting sustainable and smart mobility through electric vehicles.
- Extending the lifespan of medical equipment and devices, reducing the need for replacements, risk of failure and cross infections.
- Enabling a data driven economy through the manufacturing of microprocessors and semi-conductors.
- Facilitating the Renovation Wave and the construction of energy efficient buildings.

- Driving innovation and helping decarbonise the aviation industry.
- Assisting the chemicals industry in preventing corrosion in harsh environments.
- Ensuring food and pharmaceuticals remain fresh and uncontaminated.
- Protecting workers in professional protective and high-performance clothing.

Environmental fate and exposure to PFAS

- ▶ C-F bond is extremely persistent in the environment
 - ▶ Irreversible environmental contamination
 - ▶ Very hard to remove from water, soil and air
- ▶ Widespread use in consumer products (textiles, food contact materials, cosmetics)
- ▶ Landfill leachate
- ▶ Incomplete incineration → release of PFAS to atmosphere
- ▶ ...

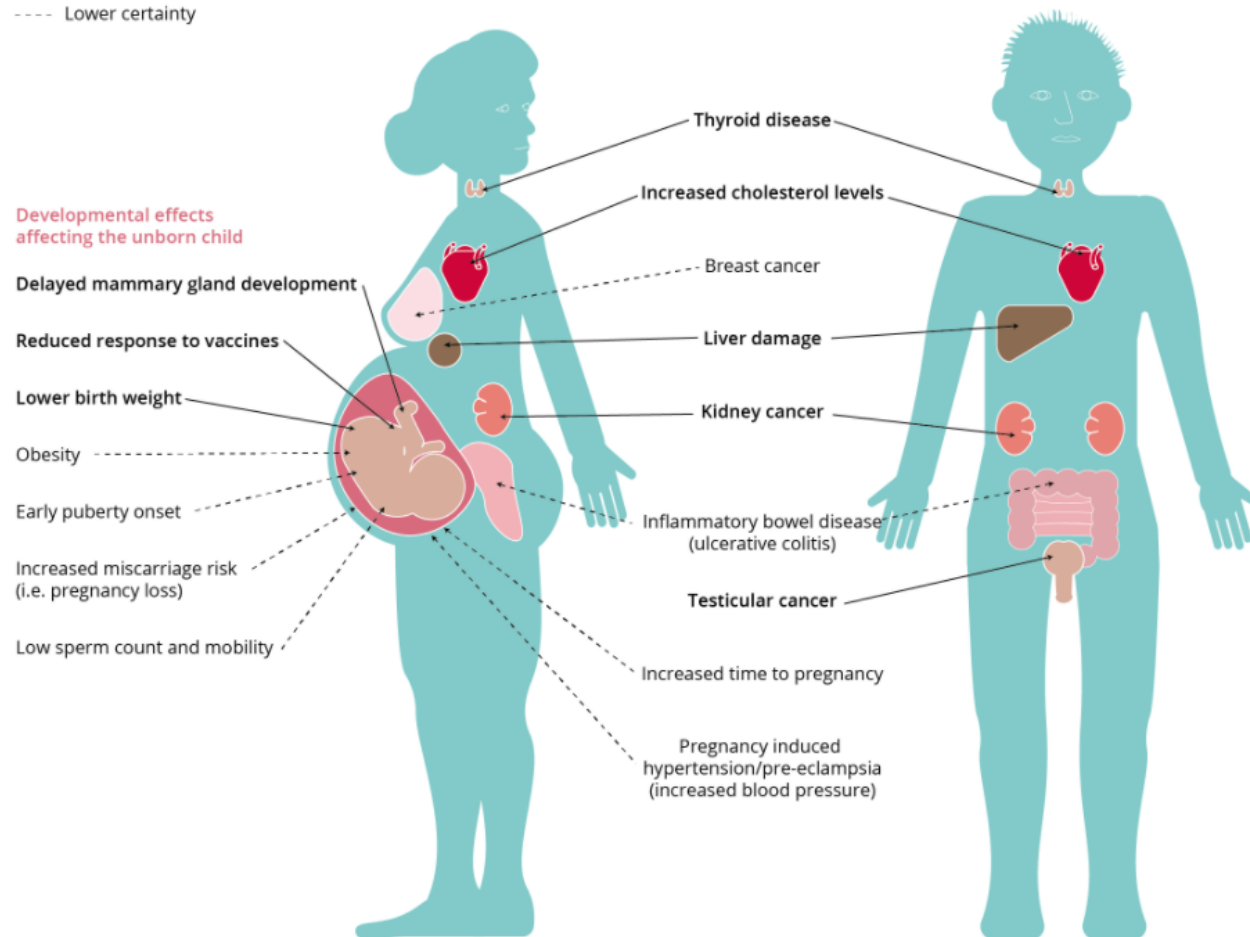


Human Exposure and sources of PFAS
Image: DWP, adapted from Oliaei et al. 2013.

PFAS Hazards

- ▶ Overarching concern: persistence
- ▶ Health concerns defined for specific PFAS are:
 - ▶ Bioaccumulation
 - ▶ Carcinogenicity
 - ▶ Toxicity to reproduction
 - ▶ Effects on immune system
 - ▶ link with COVID vaccine efficiency
 - ▶ ...
- ▶ Only a few PFAS are extensively studied
- ▶ Emerging concerns
 - ▶ Low-dose effects
 - ▶ Non monotonic dose response
 - ▶ Mixture effects

— High certainty
---- Lower certainty



Sources: US National Toxicology Program, (2016); C8 Health Project Reports, (2012); WHO IARC, (2017); Barry et al., (2013); Fenton et al., (2009); and White et al., (2011).

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

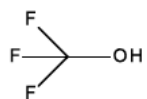
Concerns about adverse effects

- 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



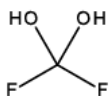
Spontaneous decomposition
above -20°C



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:

CF_3-X or $\text{X}-\text{CF}_2-\text{X}'$,

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>

13

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

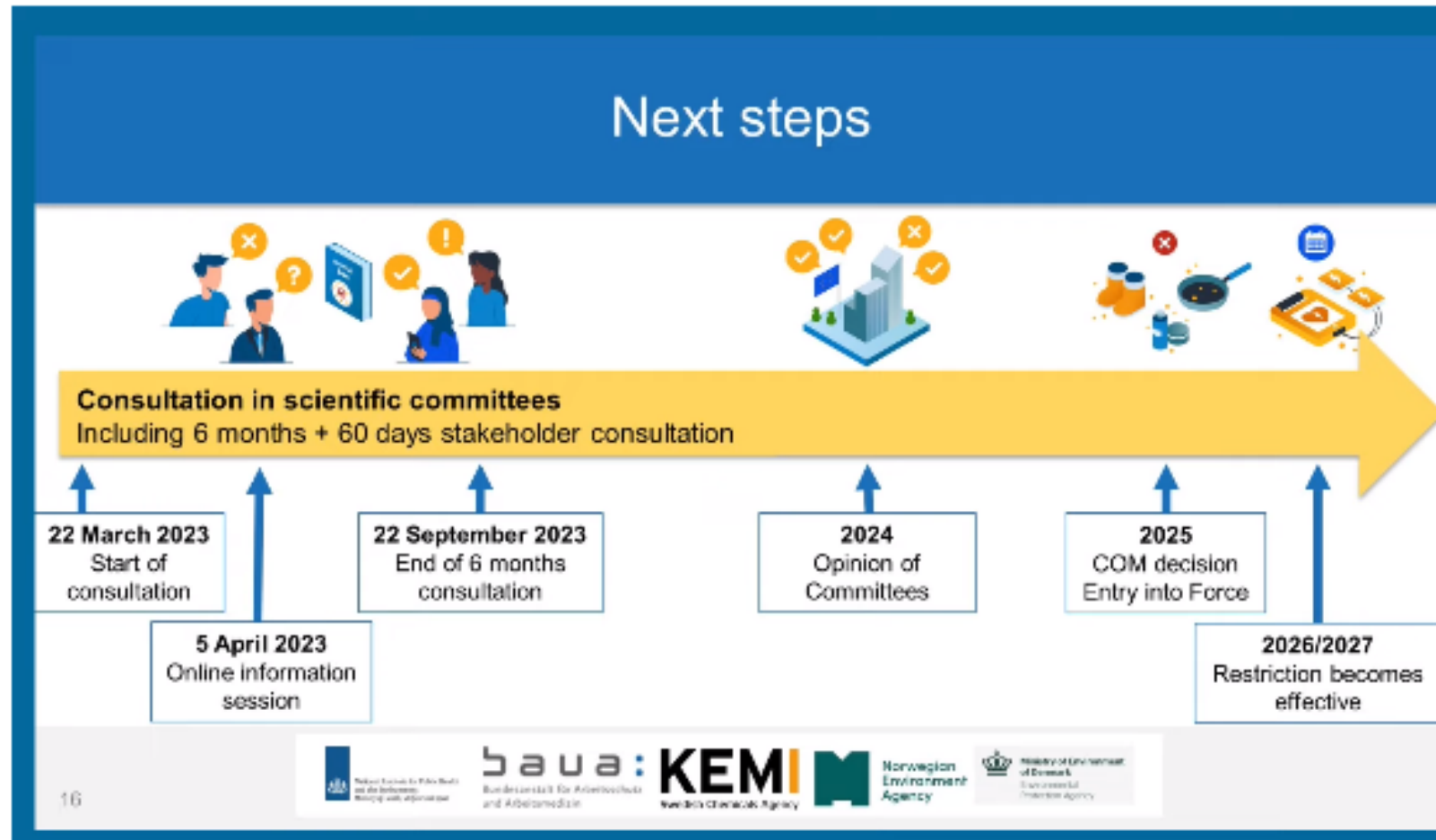


Microsoft
Word-document

→ 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>

Brief Overview of Belgian and EU positions on PFAS

History of PFAS actions in chemical legislation

- ▶ 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
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- ▶ 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 broader grouping approach

December 2019: Elements for an EU-strategy for PFAS

- ▶ <https://www.regjeringen.no/contentassets/1439a5cc9e82467385ea9f090f3c7bd7/fluor---eu-strategy-for-pfass---december-19.pdf>
- ▶ *Actions taken so far have not sufficiently addressed the concerns. This is why we urgently need a coherent and coordinated EU strategy to address PFASs through regulatory and non-regulatory actions. The goal is to minimise environmental and human exposure to PFASs, at all stages of their life cycle. To achieve this:*
 - ▶ (i) PFASs need to be managed as a group.
 - ▶ (ii) PFASs need to be phased out and only essential uses allowed until alternatives are available.
 - ▶ (iii) Limit values need to be set in different pieces of legislation.
 - ▶ (iv) Steps to ensure effective enforcement are needed.
 - ▶ (v) Environmental monitoring, awareness raising, research on alternatives, remediation and environmentally sound management of waste are also needed
- ▶ REACH: “A broad restriction under REACH covering all PFASs would be the preferred option, in order to limit as many non-essential uses as practically possible. This would have the greatest impact on minimising human and environmental exposure to PFASs. A broad restriction would also include unknown PFASs and uses.”

2020: Chemical Strategy for Sustainability (CSS)

- ▶ Published in October 2020
- ▶ Part of the EU Green Deal
- ▶ Several actions on chemicals envisaged:
 - ▶ Revision of REACH and CLP
 - ▶ Take action on the “cocktail effect”
 - ▶ ...
 - ▶ Phase out of all PFAS in the EU, except for “essential uses”



CSS: EU PFAS strategy

- ▶ Goal: minimization of exposure of humans and environment to PFAS, taking into account the complete life-cycle of these substances
- ▶ Proposed actions:
 - ▶ Take action on PFAS as a group
 - ▶ Phasing out all PFAS, except for essential uses, until safer and sustainably alternatives are available
 - ▶ Development of limit values for all relevant EU legislation
 - ▶ Take action on effective enforcement
 - ▶ (Bio)monitoring, researching alternatives, developing new analytical methods, etc.

PFAS SWD



Brussels, 14.10.2020
SWD(2020) 249 final

COMMISSION STAFF WORKING DOCUMENT

Poly- and perfluoroalkyl substances (PFAS)

Accompanying the document

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL
COMMITTEE AND THE COMMITTEE OF THE REGIONS

Chemicals Strategy for Sustainability
Towards a Toxic-Free Environment

29

{COM(2020) 667 final} - {SWD(2020) 225 final} - {SWD(2020) 247 final} -
{SWD(2020) 248 final} - {SWD(2020) 250 final} - {SWD(2020) 251 final}

12/03/2021 - Council Conclusions “Sustainable Chemicals Strategy of the Union: Time to Deliver”

- ▶ « The use of PFAS that are **critical for society** should only be allowed if suitable alternatives are not available. As emphasized by the COM in the COMMISSION STAFF WORKING DOCUMENT on PFAS (SWD(2020) 249 final), such an approach would lead to the development of alternatives and new business opportunities, especially if supported with Research and Development funding. Furthermore, we echo the **request of the European Parliament in its resolution (2020/2531(RSP))** in asking the Commission to **“ensure the speedy phasing out of all non-essential uses of PFAS, and to accelerate the development of safe and non-persistent alternatives to all uses of PFAS”**. To properly reflected this approach in point 13, we would suggest the following changes:
- ▶ “UNDERLINES that PFAS substances require special attention to ensure that they are phased out unless their use is proven to be essential for society and suitable alternatives to be not available, since they pose threats to human health and the environment; CALLS ON the Commission to present a cross-sectoral and holistic PFAS-strategy ensuring the swift phasing out of all non-essential uses of PFAS, and to accelerate the development of safe and non-persistent alternatives to all uses of PFAS, to complement the anticipated PFAS restriction proposals.” »
- ▶ Statement by Belgium:
 - ▶ *“We also regret the lack of any reference to the availability of alternatives to PFAS. We therefore reiterate our support for banning them, except for certain specific uses for which it is proven that they are essential for society and provided that, and for as long as, there is no alternative available.”*

19/04/2023: EU Parliament topical debate on forever chemicals

- ▶ MEPs over alle fracties benadrukten relatief eensgezind het belang van volgende aandachtspunten bij de herziening van EU-wetgeving voor chemicaliën:
 - ▶ Een sterkere nadruk op het voorzorgsbeginsel en de omgekeerde bewijslast, waarbij enkel chemicaliën die niet schadelijk zijn bevonden op de markt kunnen komen
 - ▶ Een onmiddellijk verbod op niet-essentiële toepassingen van forever chemicals Een verbod op de hele groep PFAS-stoffen, in plaats van het huidige systeem van stof-specifieke verboden
 - ▶ Een vergrote aansprakelijkheid voor bedrijven die EU-wetgeving voor PFAS overtreden
- ▶ <https://www.europarl.europa.eu/plenary/en/vod.html?mode=chapter&vodLanguage=EN&internalEPIId=1681901164768&providerMeetingId=5dd7d4ec-b4e0-44b9-5a67-08db3b27e9c5#>

PFAS and the essential use concept

- ▶ Link between PFAS and essential use has been made many times
 - ▶ Several PFAS uses have been identified as “essential for society”
 - ▶ PFAS case has therefore been put forward as “test case” for essential use
 - ▶ However important to note that:
 - ▶ Essential use has not yet been implemented into the legal framework!
 - ▶ Concept is still under development and will not be ready for some time (considering REACH revision might take several years)
 - ▶ Current UPFAS restriction dossier thus had to be build using existing REACH framework (SEA and alternative analysis)
- ▶ Approach for defining “essential uses” under the UPFAS restriction: *“mitigate unwanted effects to society due to the sudden unavailability of products for which alternatives are not yet in place”*