



Bundesanstalt für Arbeitsschutz  
und Arbeitsmedizin

# The PFAS Restriction Dossier: Update & State of Play

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BfC – Unit 5.2 „Evaluation of Chemicals and Risk Management“

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# Outline

## Background

- Introduction to PFAS
- Why a PFAS restriction?
- REACH restriction procedure
- Results of the public consultation
- Further consideration of comments
- Scientific discussion at ECHA committees
- Next steps & outlook



# PFAS – Per- and polyFluoroAlkyL Substances

A periodic table of elements. The elements Carbon (C) and Fluorine (F) are highlighted with red boxes. Carbon is located in the second row, fourth column of the main body. Fluorine is located in the second row, eighth column of the main body.

H																	He
Li	Be											B	C	N	O	F	Ne
Na	Mg											Al	Si	P	S	Cl	Ar
K	Ca	Sc	Ti	V	Cr	Mn	Fe	Co	Ni	Cu	Zn	Ga	Ge	As	Se	Br	Kr
Rb	Sr	Y	Zr	Nb	Mo	Tc	Ru	Rh	Pd	Ag	Cd	In	Sn	Sb	Te	I	Xe
Cs	Ba	Lu	Hf	Ta	W	Re	Os	Ir	Pt	Au	Hg	Tl	Pb	Bi	Po	At	Rn
Fr	Ra	Lr	Rf	Db	Sg	Bh	Hs	Mt	Ds	Rg	Cn	Nh	Fl	Mc	Lv	Ts	Og
		La	Ce	Pr	Nd	Pm	Sm	Eu	Gd	Tb	Dy	Ho	Er	Tm	Yb		
		Ac	Rf	Pa	U	Np	Pu	Am	Cm	Bk	Cf	Es	Fm	Md	No		

## Single bond strengths (kJ/mol)

C–H	413
C–C	347
C–N	305
C–O	358
<b>C–F</b>	<b>485</b>
C–Cl	339
C–Br	276
C–I	240
C–S	259

# PFAS – Properties resulting from the C-F bond

**The C-F bond imbues materials with a range of beneficial technical properties!**

- Resistance to/repellency of oil, water, dirt
- Stability under extreme conditions
  - Temperature, pressure, radiation, chemicals
- Electric and thermal insulation
- Efficient refrigerants
- Surfactants

# PFAS – Sectors of use



Rainwear



Non-stick coating



Cosmetics



Medical equipment

- Process chemicals
- Fire-fighting foams
- Textiles ('TULAC')
- Food Contact Materials
- Metal working and galvanisation
- Consumer Products
- Transport
- Fluorinated Gasses
- Electronics and Semiconductors
- Energy Sector
- Construction Materials
- Lubricants
- Oil and Mining
- Medical Devices
- Active Substances (agrochemicals, pesticides)
- Cosmetics
- Other uses

# PFAS – Properties of concern

## Very high persistence

### In combination with

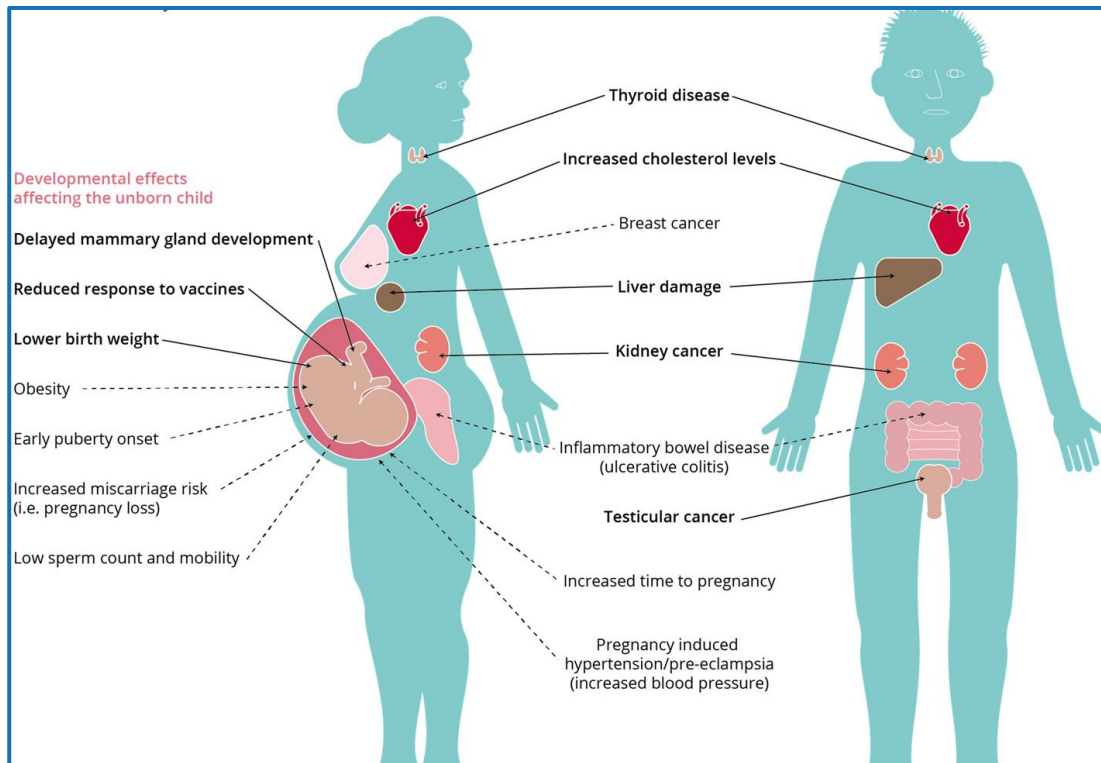
- Bioaccumulation
- Mobility
- Long range transport potential
- Enrichment in plants
- (Eco)toxicity
- Hormone-like effects
- Combination effects

- All PFAS are either very persistent on their own or they degrade to very persistent PFAS
- PFAS remain in the environment for long periods of time
- PFAS accumulate in the environment
- Adverse effects can be expected

# PFAS – Properties of concern

- Developmental effects
- Liver effects
- Different tumours
- Decreased immune response and response to vaccines
- Further effects

Source: EEA, 2019:  
<https://www.eea.europa.eu/publications/emerging-chemical-risks-in-europe>



# Need for regulation

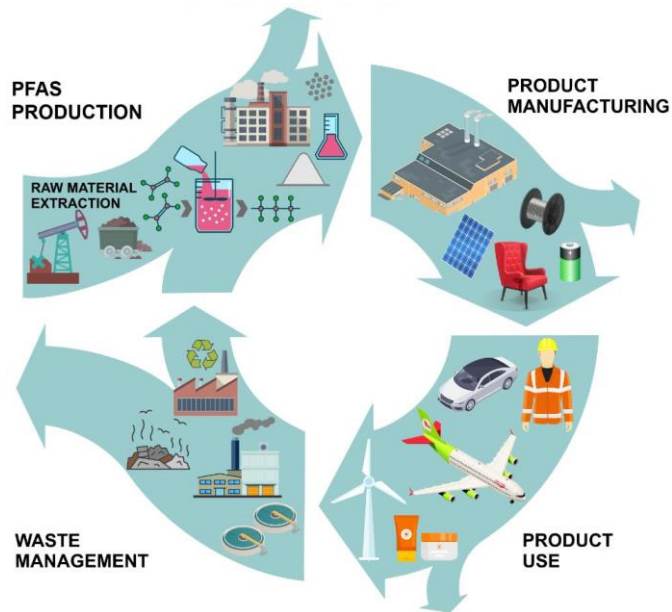
## Hazardous Properties

Persistence

Mobility

Bioaccumulation

(Eco)toxicity, other properties



## Emissions

**75 000 tons**  
of emissions in 2020

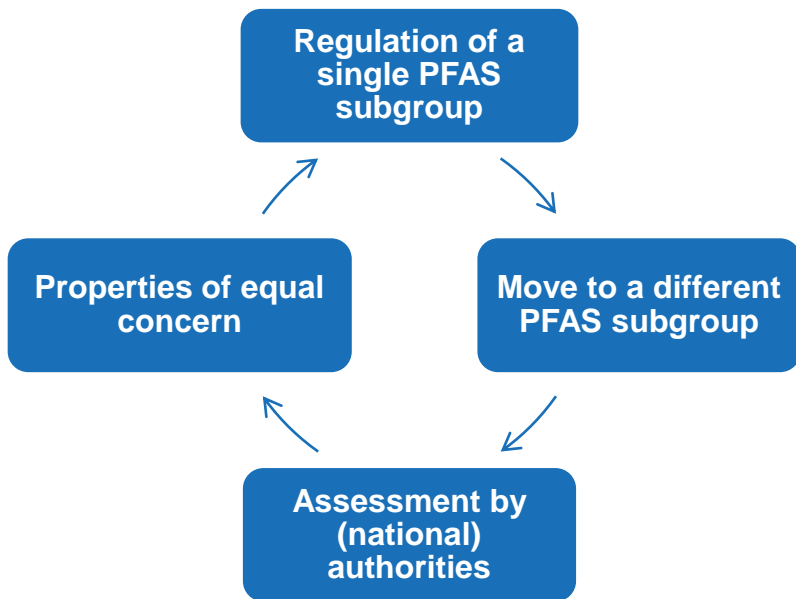
**4.5 Mio. tons**  
of emissions over 30  
years

Scheme adapted from <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52020SC0249>



# ‘Regrettable Substitution’

- **Previous regulatory approach for PFAS**
  - Small groups (various PFCAs and precursors)



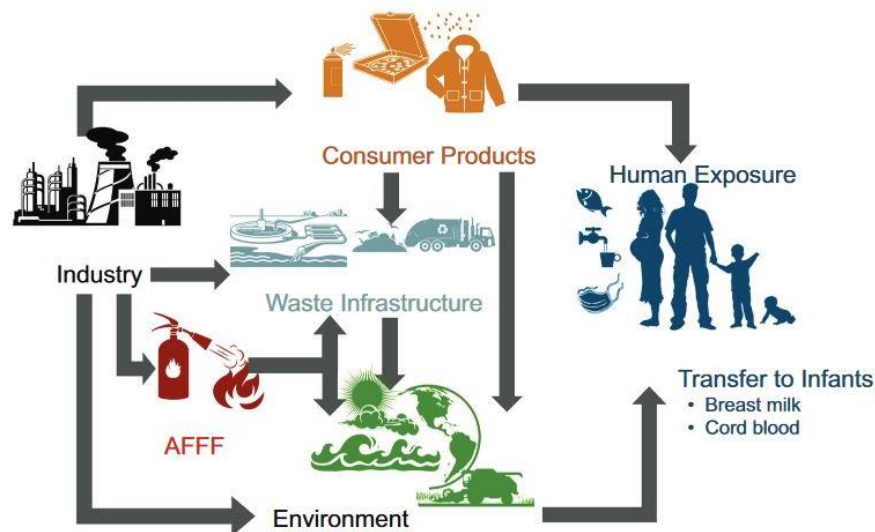
- Further emissions into the environment over decades
- High overhead for authorities
- Uncertainty for stakeholders

## **Solution:**

- ⇒ Regulating all PFAS in one group
- ⇒ Precautionary principle

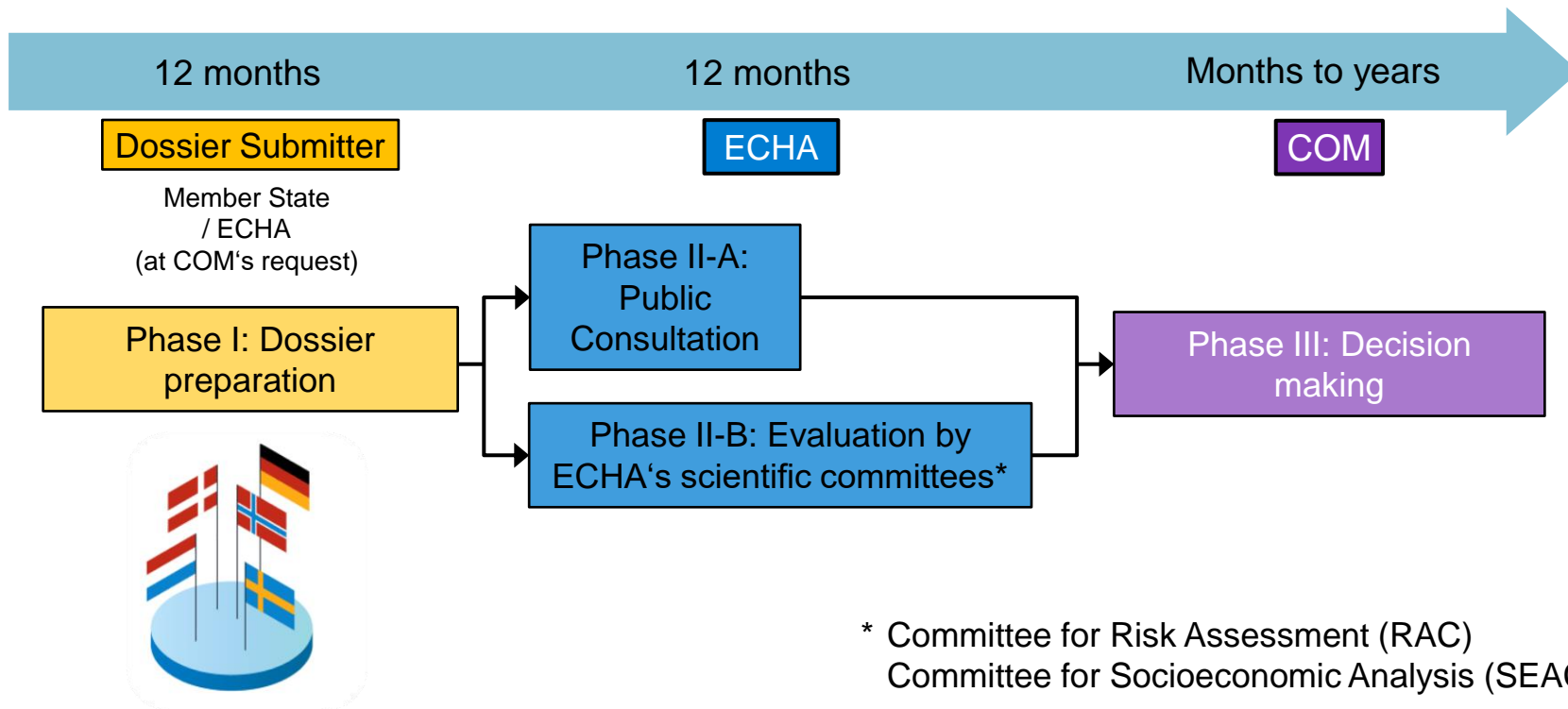
# PFAS restriction proposal

- **Goal: Minimisation of emissions to the environment**
- **Restriction of manufacture, placing on the market and use**
- **Group approach – all PFAS based on OECD definition**

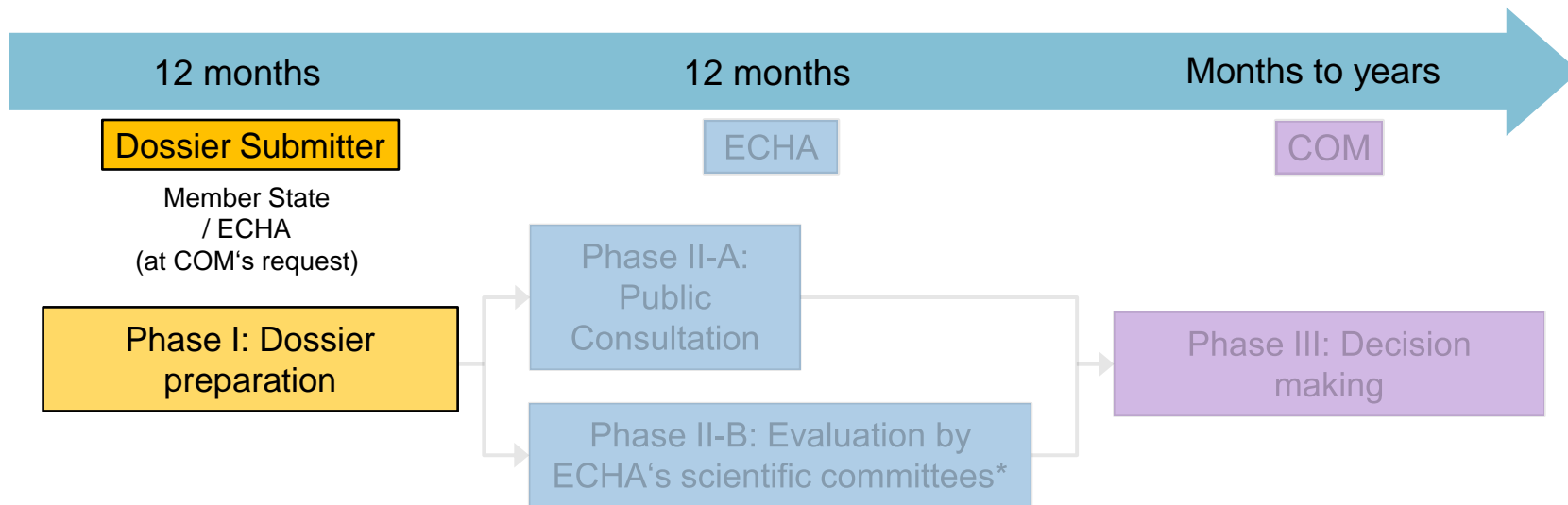


Source: [https://bgc.seas.harvard.edu/assets/sunderland\\_jeseerev\\_2018wsi.pdf](https://bgc.seas.harvard.edu/assets/sunderland_jeseerev_2018wsi.pdf)

# REACH Restriction Process



# REACH Restriction Process



\* Committee for Risk Assessment (RAC)  
Committee for Socioeconomic Analysis (SEAC)

# Phase I (01/2020 to 03/2023)

**May 2020 – June 2020**

Call for evidence

**July 2021 – Okt 2021**

2<sup>nd</sup> Stakeholder Konsultation

**October 2021 – January 2023**

Preparation of proposal

Stakeholder consultations, literature research, meetings...



**Jan 2020**  
Kick-off

**13 Jan 2023**  
Submission

**22 March 2023**  
Start of  
consultation

# PFAS Restriction Proposal



Restriction of manufacture,  
placing on the market and use

Transitional period: 18 months



Derogated uses

Use-specific derogations  
Transitional periods: 6.5 / 13.5 years  
Active substances: unlimited



Reporting obligations

Reporting of substances, uses and  
tonnage

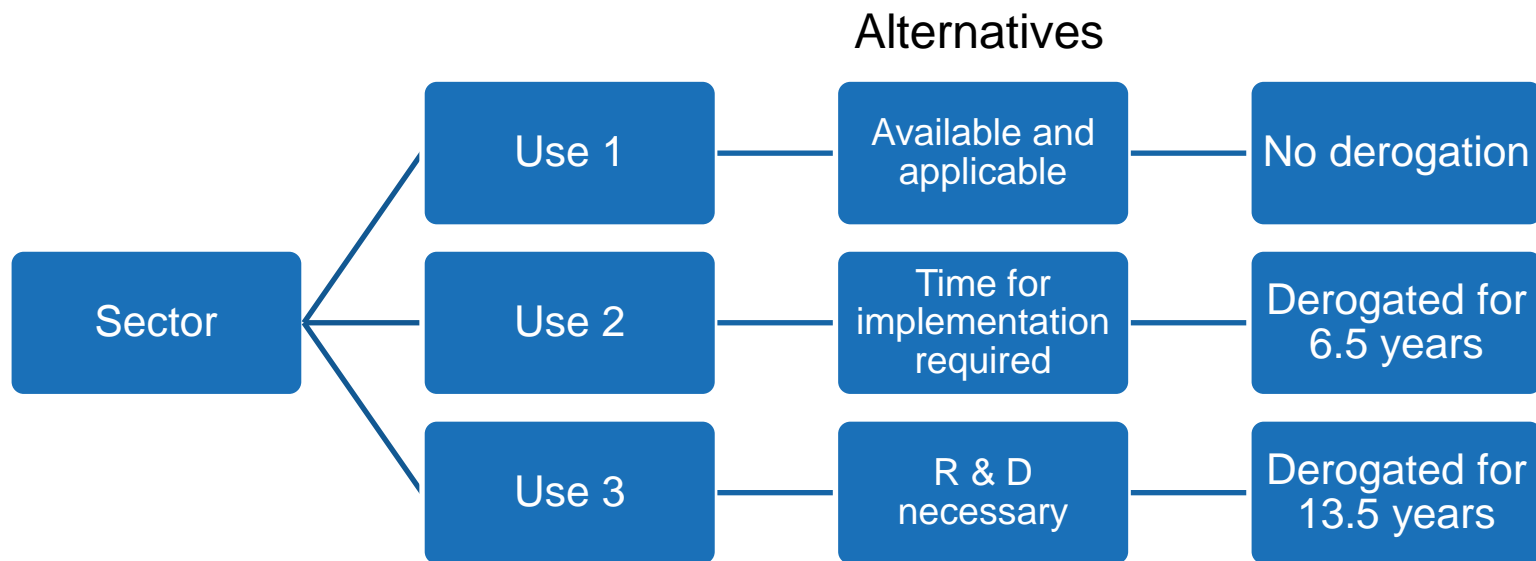


Management Plan

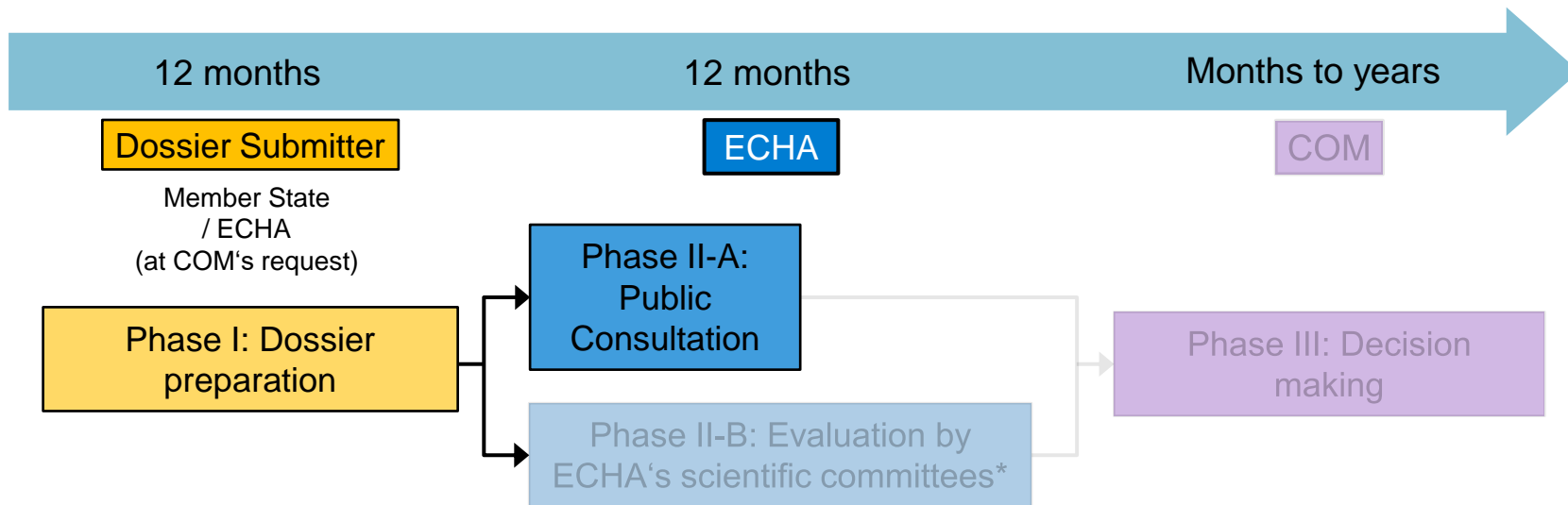
Reporting of substances and products,  
their handling and disposal

# PFAS Restriction Proposal

- Sector-specific assessment: (un)limited derogations / other restriction options



# REACH Restriction Process



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# Phase II-A – Public Consultation (03/2023 – 09/2023)

## – ECHA webform

- „Information note“ provides further information to the consultation
- General comments (free text)
- Specific questions (free text)
- Attachments
  - Non-confidential
  - Confidential (with justification)



### Comments for Annex XV restriction report

**Substance name**

Per- and polyfluoroalkyl substances (PFAS)

**EC Number**

-

**CAS Number**

-

**Scope**

Restriction on the manufacture, placing on the market and use of PFASs.

Before you fill in the form, read the **Consultation Guidance** and the specific **Information Note** as they explain both the process and the proposal itself.

[Link to the Consultation Guidance](#)

[Link to the Information Note](#)

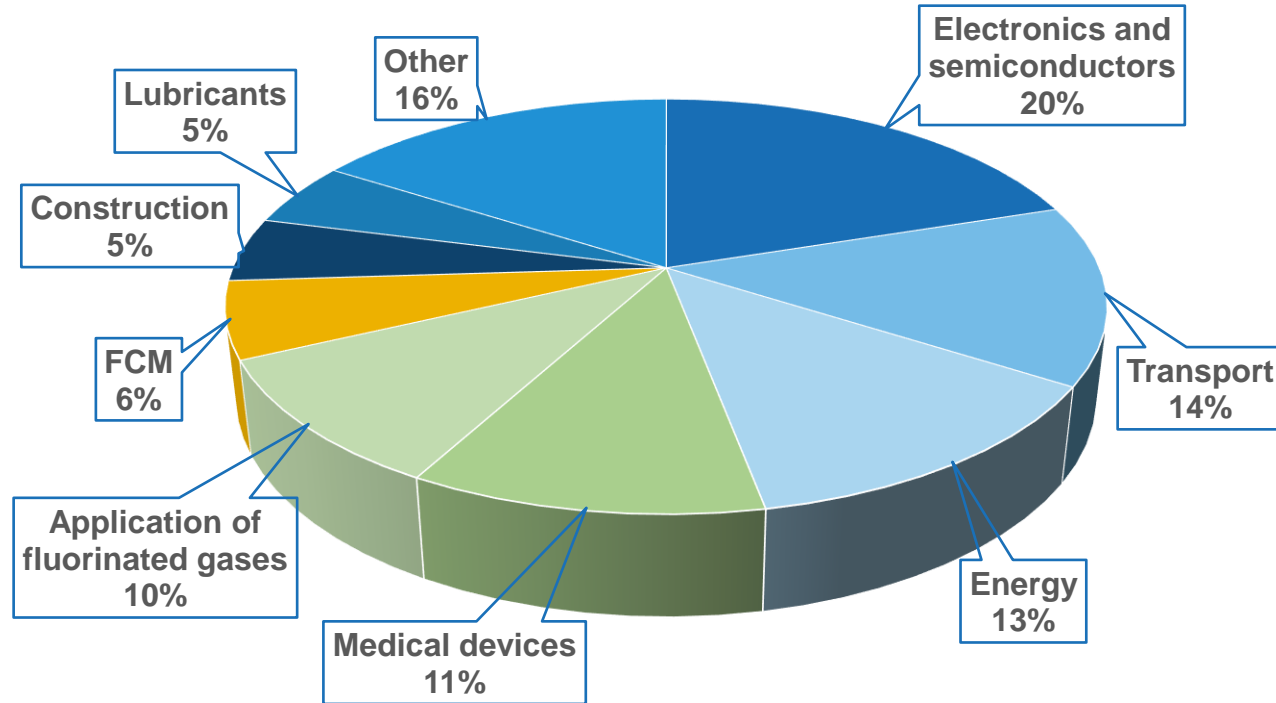
Compulsory fields/tick boxes are marked with an asterisk (\*)

\* ☐ I have read the Consultation Guidance and Information Note

All non-confidential comments will be made publicly available once a month during the duration of the consultation.

The Consultation is intended to provide ECHA's Committees with scientific and technical information. Only relevant information can be submitted, any abusive comments will not be published monthly and only published by the Submitter or the Rapporteurs.

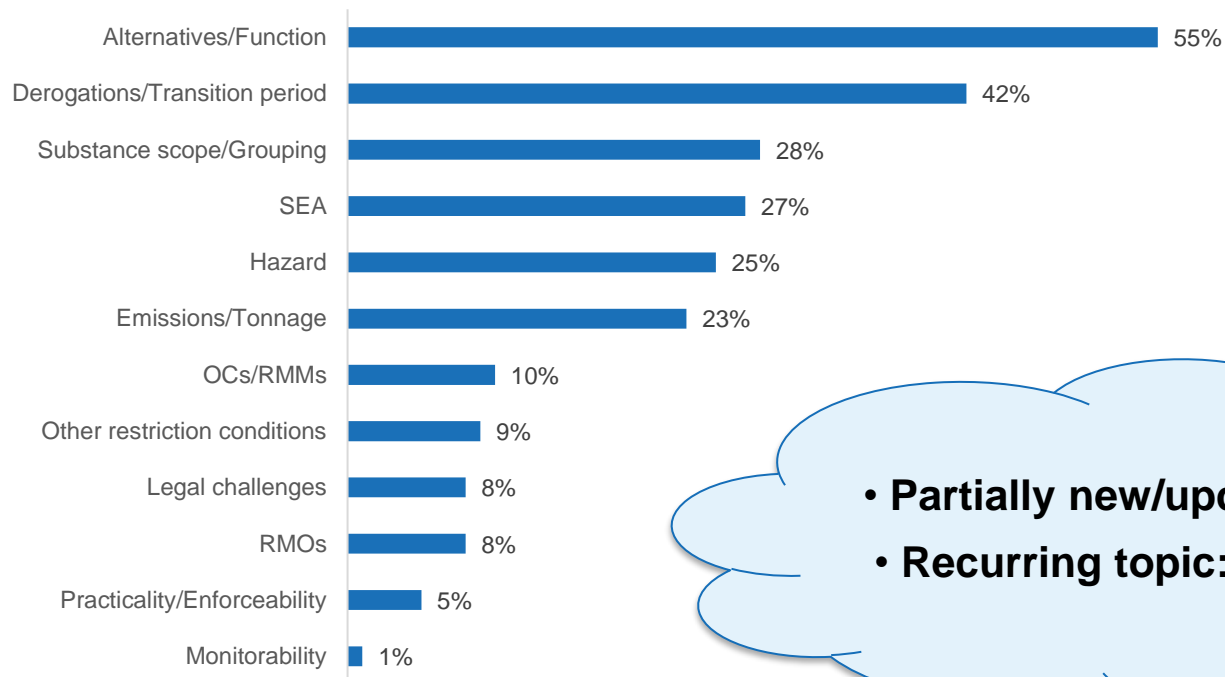
# Findings from the public consultation



5642  
comments

Based on pre-  
screening by ECHA

# Comments based on topic



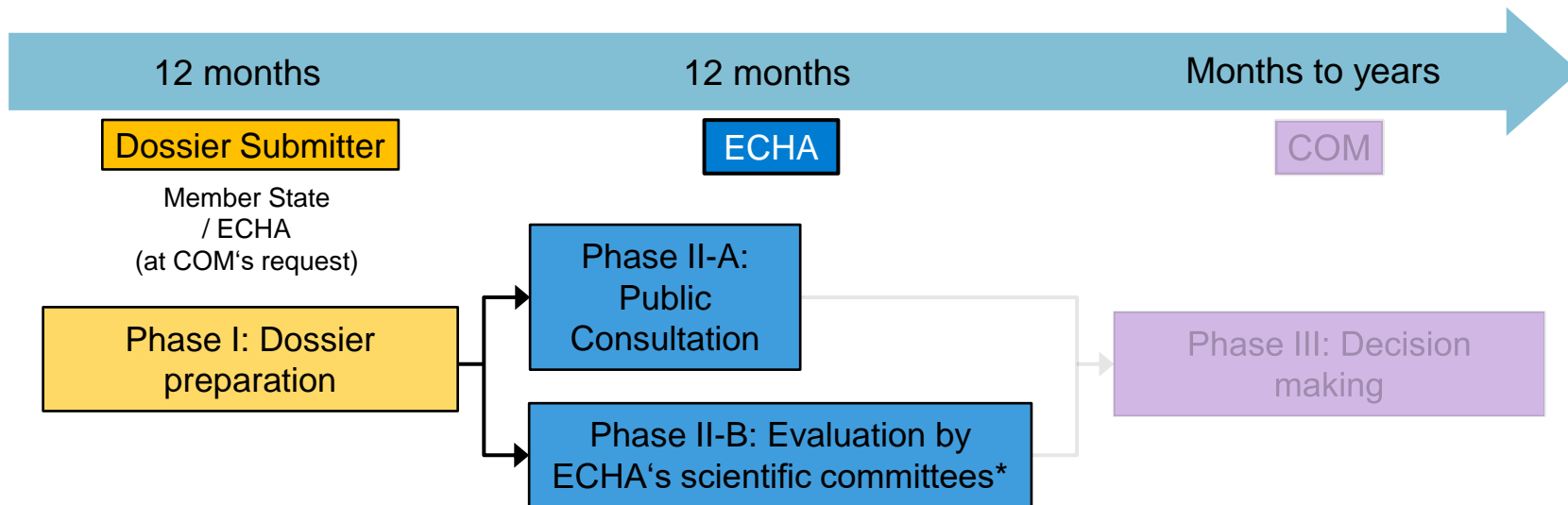
Based on pre-screening by ECHA

Comments can cover more than one topic

Allocation of some comments not possible

- **Partially new/updated information**
- **Recurring topic: Fluoropolymers**

# REACH Restriction Process



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# Phase II-B – Scientific assessment by committees

Annex XV dossier



‘Background Document’



Sequential processing according to RAC/SEAC schedule:

1. Hazards/Risk
2. Sectors
3. Overarching issues

# Assessment of comments by DS

## Revision of submitted dossier based on input from comments

- Called ‚background document‘ after dossier submission
- Basis for opinion of RAC/SEAC
- Assessment sector by sector (according to schedule of RAC/SEAC meetings)

## Response to COMments → RCOM

- Topic and sector-based

# Public information on restriction process

- REACH-CLP-Helpdesk: [Publication by DS, 15 April 2024](#)

Overview of different aspects that are assessed in the comments submitted in the consultation on the Annex XV report

- ECHA website: [Publication by ECHA and DS, 20 November 2024](#)

Overview on state of restriction process, Information on **newly identified uses** and on the consideration of **alternative restriction options** by the DS

## „New“ Uses/Sectors

Technical  
textiles

Sealing  
applications

Printing  
applications

Machinery  
applications

Other medical  
applications

Possibly further  
uses...



**NB: Not all ,sectors‘ are reflected as separate sectors in the dossier; in part, they are covered across different use sectors!**



# Alternative restriction options (RO3)

## Requirements

Universally implementable and enforceable measures

Identified risk over whole life-cycle are addressed → minimization of emissions

Information was submitted in the consultation on the Annex XV report

## Examples

Compliance with requirements, in particular with regard to production and disposal, e.g. closed systems, setting of limit values for waste water/waste air, etc.

Mandatory introduction of return systems/recycling

# Phase II-B – Scientific assessment by committees

Background  
document



&



Comments from  
Public consultation

**RAC:**

Hazards/Risk  
Emissions  
Alternatives

**SEAC:**

Alternatives  
Consequences  
(cost/benefit)  
Enforcability

RAC/SEAC  
Opinion



# Discussion in ECHA's committees: general points

- **Assessment proceeds sector-wise**
- **Preliminary conclusions:**
  - Persistence as the main concern, additional properties of concern of certain PFAS
  - PFAS emissions constitute a risk which needs to be addressed
  - Exclusion of some PFAS from the scope is not justified
  - Fluoropolymers: Whole life cycle needs to be considered
  - Assessment standards RAC/SEAC, deviation from emission estimates for the use and waste phase by RAC

# Discussion in ECHA's committees: sectors

- **Already discussed by RAC and SEAC:**
  - Consumer mixtures, cosmetics, galvanics & metal working, oil & mining, TULAC, food contact materials, construction, fluorinated gases, transportation (RAC), energy (RAC)
- **June 2025:**
  - Electronics & semiconductors, lubricants, medical products, transportation (SEAC), energy (SEAC)
- **September 2025:**
  - Electronics & semiconductors (cont.), remaining sectors

[Overview on ECHA's website](#)

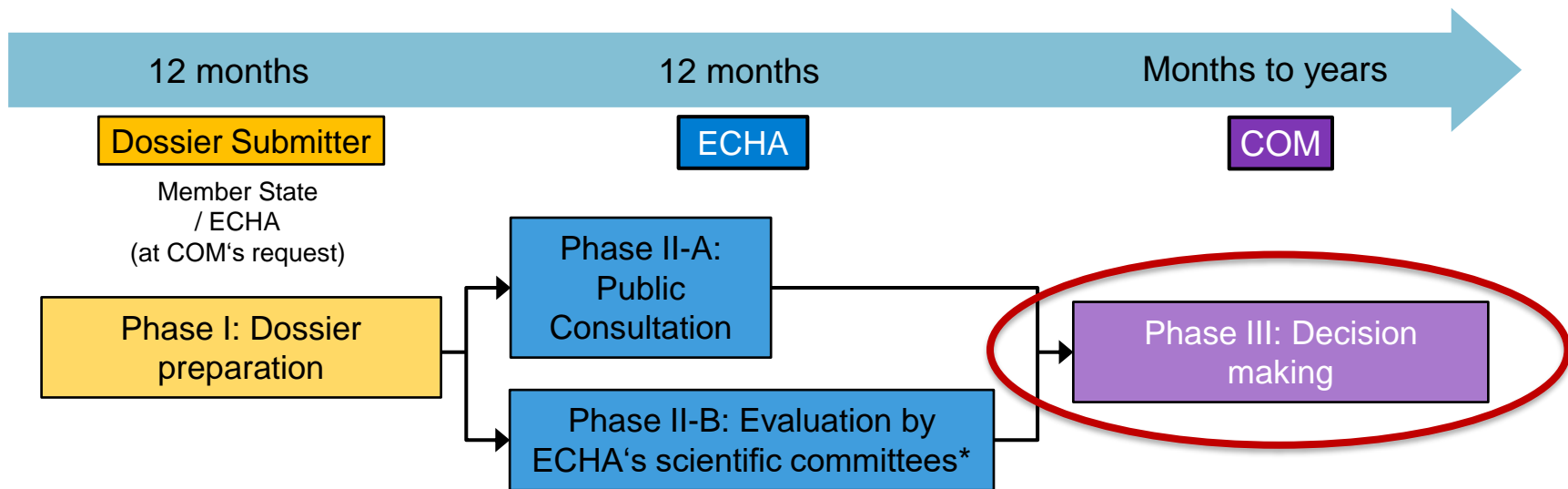
# SEAC consultation

- 60 day duration on specific questions of SEAC
- Targeted, representative (sector/EU) and comprehensible information
- **Possible ideas for stakeholder input:**
  - Seek participation in RAC/SEAC meetings (via ASO associations)
  - Learn from previous SEAC consultations/ORCOM of SEAC ([Registry of restriction intentions until outcome](#))
  - Additional information to submitted comments in consultation on Annex XV report, e.g. tonnage, emissions, alternatives, substitution possibilities or barriers
  - Provision of new information

**Timely preparation recommended**



# REACH Restriction Process



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Committee for Socioeconomic Analysis (SEAC)

# Conclusion & Summary

## Dossier Submitter:

- **Assessment of comments is on-going**
  - All comments will be considered
  - Background document and RCOM are being updated / assembled
  - Sector-by-sector assessment according to RAC/SEAC schedule
  - Identification and evaluation of „new“ sectors
- **Underlying aim: Minimisation of emissions**
  - Assessment of other options of risk minimisation („RO3“)

# Conclusion & Summary

## ECHA committees:

- **RAC/SEAC discussions are on-going**
  - Preliminary conclusions on scope, hazard/risk, single sectors
  - Deviating emission estimate for fluoropolymers
  - Publication of scheduled sectors six months in advance by ECHA
- **SEAC consultation**
  - Prepare your contribution in time!



# Thank you very much for your kind attention!

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