

Welcome

Webinar: Consultation on restriction proposal for per- and polyfluoroalkyl substances (PFAS)

5 April 2023

Mercedes Marquez-Camacho
Restriction Process Coordinator
European Chemicals Agency



Programme

Time	Topic	Speaker
11:00	Introduction to the information session and to the REACH restriction process	Mercedes Marquez-Camacho, ECHA
11:10	Why do PFASs need to be regulated?	Wiebke Drost, UBA (Germany)
11:25	Details of the restriction proposal	Thijs de Kort, RIVM (the Netherlands)
11:40	How to participate in the consultation	Michael Gmeinder, ECHA
11:55	Concluding remarks	Mercedes Marquez-Camacho, ECHA
12:00-13:00	Live Q&A	Panel

Live Q&A

- Moderator and ECHA panellist
 - Bastian Zeiger
- Panellists from the Dossier Submitter
 - Frauke Averbeck (BAuA, DE)
 - Thijs de Kort (RIVM, NL)
 - Peter Juhl Nielsen (Danish EPA, DK)
 - Audun Heggelund (NEA, NO)
 - Jenny Ivarsson (Kemi, SE)

Live Q&A

- Join Q&A at: slido.com
Event code: #3448218 or with QR:
- Send questions until **13:00 Helsinki time** (EEST, GMT+3)
- Only questions within scope
- Questions after the webinar?
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Material published

Video recording, presentations and Q&A
echa.europa.eu/support/training-material/webinars

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ECHA > Support > Webinars > All Webinars

All Webinars

Upcoming All Webinars

2023

> **New ECHA public data availability system - Part 1**
19/04/2023
11:00 - 12:00 EEST GMT +2

Introduction to the REACH restriction process

Webinar: Consultation on restriction
proposal for per- and polyfluoroalkyl
substances (PFAS)

5 April 2023

Mercedes Marquez-Camacho
Restriction Process Coordinator
European Chemicals Agency



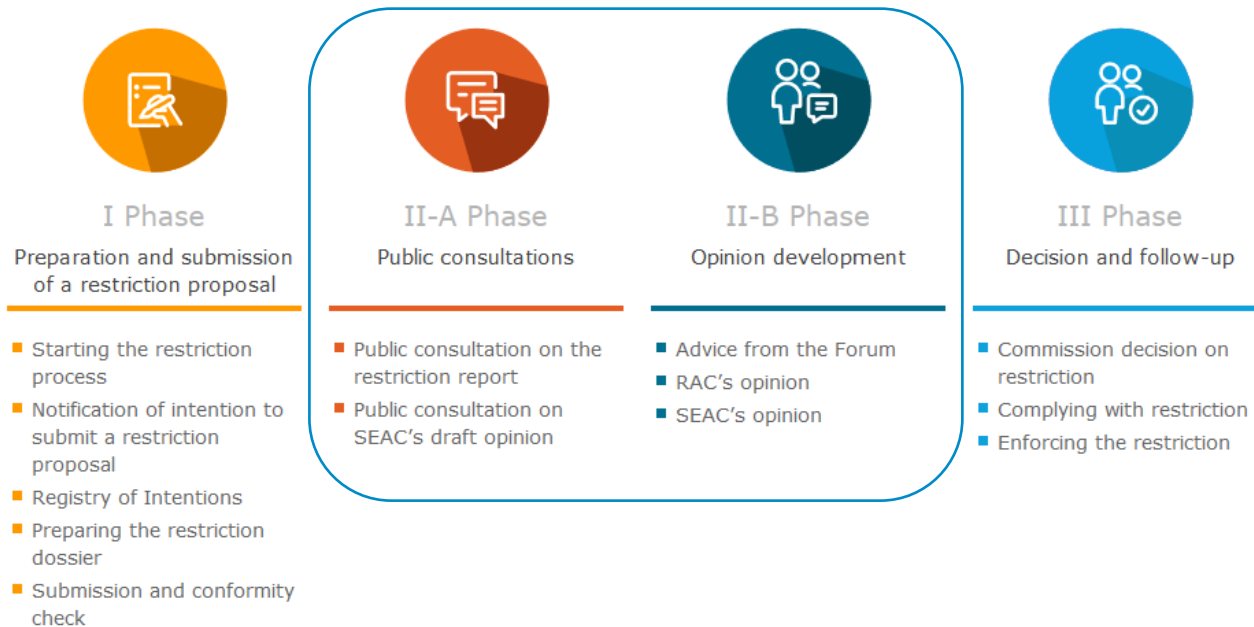
REACH Restriction

- Protects our health and the environment from chemical risks:
 - Addresses a risk that is not adequately controlled
 - Where action is required at Union level
- Limits or bans manufacture, placing on the market or use of a substance or group of substances (also in a mixture/article)
- Can set out specific conditions such as technical measures or labelling requirements
- Can be proposed by a Member State or ECHA

Restriction proposal: Annex XV report

- Annex XV report includes:
 - Information on hazards, exposures and risk
 - Justification for action at EU-wide level
 - Available information on alternatives
- Annex XV report may also include socio-economic impact analysis
- Annex XV report has to show a restriction is the **most appropriate** risk management measure to address identified risk
- Annex XV report informs decision-makers for their final decision (with the Committee's opinions)

Restriction process



Opinion development: Evaluation by the Committees

- Risk Assessment Committee (RAC)
- Socio-Economic Analysis Committee (SEAC)
- 'Effectiveness' of a proposed restriction
 - Targeted to effects or exposures resulting in the risk
 - Capable of reducing these risks within reasonable time period
 - Proportionate to the risk
- Socio-economic impacts
 - Net benefits (human health and environment)
 - Net costs (manufacturers, importers, consumers)

Opinion development:

Opinion of the Committees

- Risk Assessment Committee (RAC)
 - Provides an opinion on whether the suggested restriction is appropriate in reducing the risk to human health or the environment
- Socio-Economic Analysis Committee (SEAC)
 - Provides an opinion on the socio-economic impacts of the suggested restriction

Decision making

- After adoption, RAC and SEAC opinions published and sent to European Commission
- Decision taken by the European Commission together with the Member States at the REACH Committee
- Scrutiny by EU Council and the European Parliament

State of play and next steps



Thank you

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Für Mensch & Umwelt

Umwelt 
Bundesamt

Umwelt 
Bundesamt

Why do PFASs need to be regulated?

Presented by: Wiebke Drost
German Environment Agency/UBA
Germany



Global focus

Exposure to PFASs in general has gained increasing attention

- EU chemicals strategy for sustainability

Use of PFASs is linked to pollution of the environment, including drinking water

Some PFASs already restricted in the EU (PFOS, PFOA, C9-C14 PFCAs)

- This proposal does not affect these existing restrictions
- Decision making for restrictions on PFHxS and PFHxA is ongoing

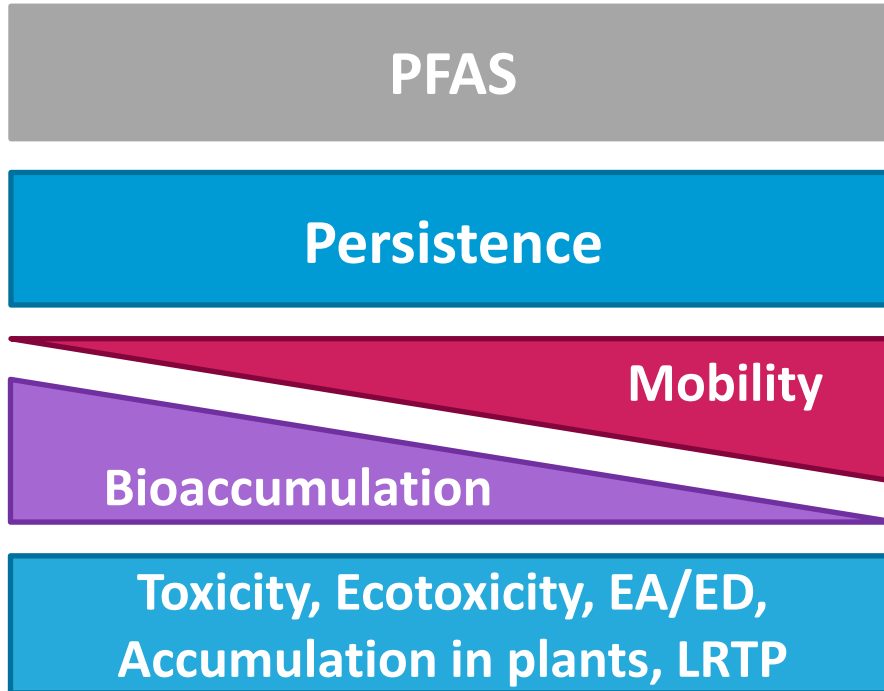
Several restrictions in non-EU countries

- Certain US States (California, Washington, New York, etc.), Australia

Forever chemicals

- All PFASs in scope of this restriction proposal 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

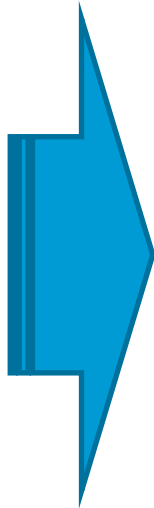
Hazard Assessment



Hazard Assessment

Properties

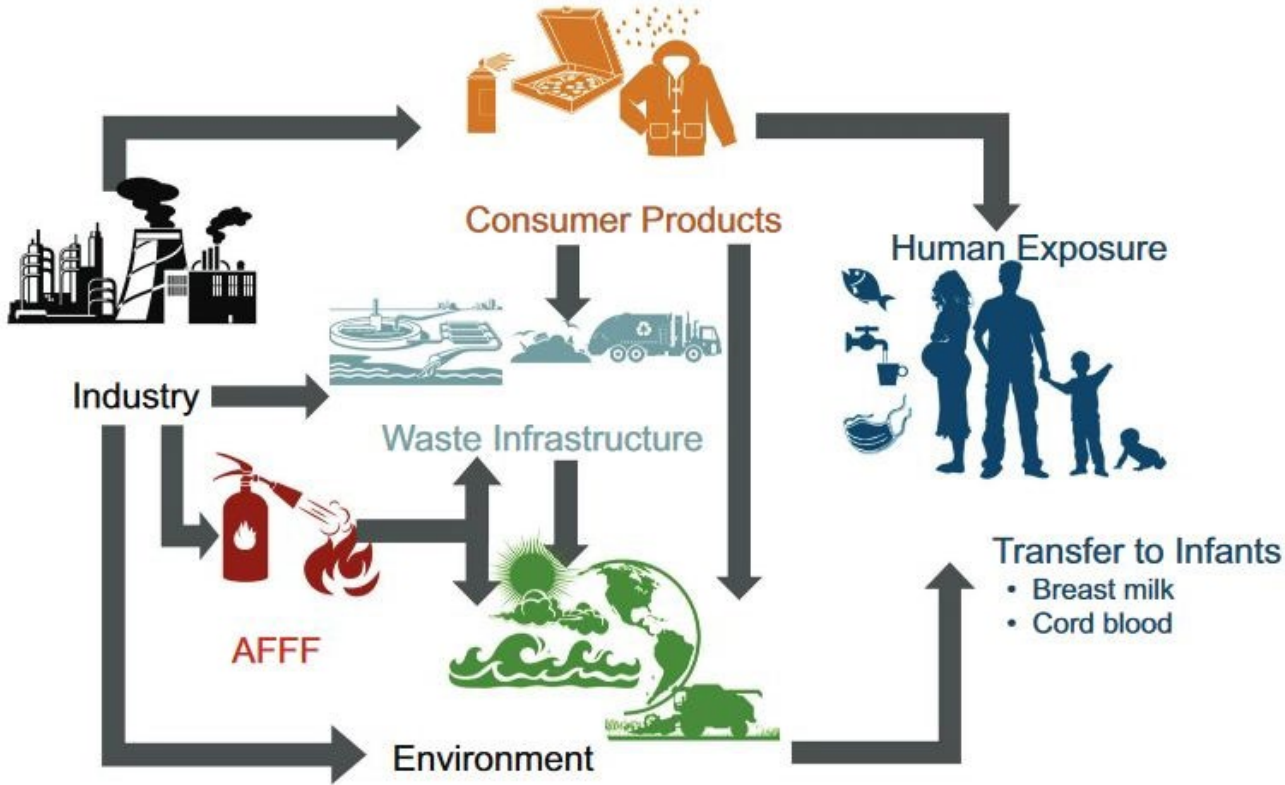
- **Very high persistence**
- Long-range transport potential
- Mobility
- Accumulation in plants
- Bioaccumulation potential
- (Eco)toxicity
- Endocrine activity



Concerns related to combinations of properties

- High potential for ubiquitous, increasing and irreversible exposures of the environment and humans;
- Difficulty to decontaminate raw water for drinking water, low effectiveness of end-of-pipe RMMs and difficulty to treat contaminated sites;
- High potential for human exposure via food and drinking water;
- Potential for intergenerational effects and delay of effects;
- Potential for causing serious effects although those would not be observed in standard tests;
- Estimation of future exposure levels and safe concentration limits is highly uncertain;
- Global warming potential.

Monitoring Data



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

Function of PFASs

Combination of useful properties from technical viewpoint

- Water, oil and dirt repellence
- Durability under extreme conditions:
 - temperature, pressure, radiation, chemicals
- Electrical and thermal insulation
- Surfactants, refrigerants...

Sectors/Uses of PFASs



Rainwear



Cosmetics



Non-stick coating



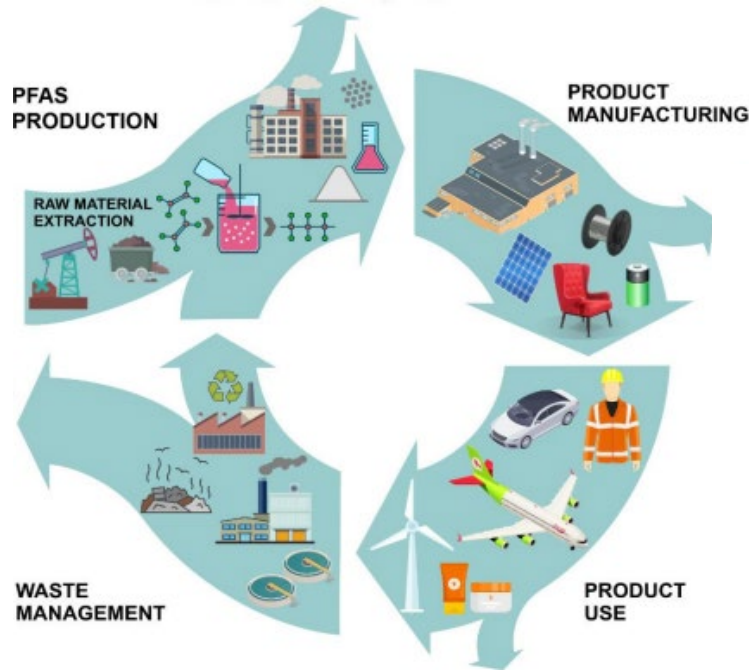
Medical equipment

- Industrial processes
- Firefighting foams
- TULAC
- Food contact materials (incl. packaging)
- Metal plating/metal products
- Consumer mixtures
- Ski wax
- Transport
- Applications of fluorinated gases
- Electronics and semiconductors
- Energy sector
- Construction products
- Lubricants
- Petroleum and mining
- Medical devices
- Cosmetics
- Other uses

Emissions

**75 000 tonnes of emissions
in 2020**

**4.5 million tonnes of
emissions over 30 years
including an estimated
increase of PFAS use**



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

Tonnages and Emissions

Application	Tonnage range	Emission range [% emitted in manufacturing and use phase]	Emission contribution [% contribution to total emissions]
Applications of fluorinated gases	> 10 000	5 – 25	> 50
Textiles, upholstery, leather, apparel & carpets	> 10 000	5 – 25	10 – 50
Medical devices	> 10 000	5 – 25	5 – 10
Manufacture	> 10 000	0 – 5	1 – 5
Food contact materials and packaging	> 10 000	0 – 5	0 – 1
Transport	> 10 000	0 – 5	0 – 1
Construction products	1 000 – 10 000	25 – 75	1 – 5
Electronics and semiconductors	1 000 – 10 000	5 – 25	0 – 1
Lubricants	1 000 – 10 000	5 – 25	0 – 1
Petroleum and mining	1 000 – 10 000	0 – 5	0 – 1
Energy sector	1 000 – 10 000	0 – 5	0 – 1
Metal plating and manufacture of metal products	100 – 1 000	0 – 5	0 – 1
Cosmetics	10 – 100	> 95	0 – 1
Consumer mixtures	10 – 100	75 – 95	0 – 1
Ski wax	0 – 10	25 – 75	0 – 1

Conclusion

- The persistence of PFASs, in combination with the supporting concerns, means that a conventional quantitative risk assessment is not sufficiently reliable or practicable
- No reliable PNEC or DNEL
- Risk assessment is therefore conducted according to Annex I (section 0.1) of REACH
- Risks of PFASs are considered as non-threshold
- Releases are used as a proxy for risk

**Umwelt
Bundesamt**

**Umwelt
Bundesamt**

Thank you for your attention

**Wiebke Drost
German Environment Agency/UBA
Germany**

www.uba.de



Details of the restriction proposal



Presented by: Thijs de Kort

NL Coordinator for the Universal PFAS restriction

National Institute for Public Health and the Environment | RIVM

The Netherlands

Details of the restriction proposal

Broadest restriction proposal under REACH so far

**> 10 000
PFASs**

**Numerous uses
and sub-uses**



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Details of the restriction proposal

The restriction in short

- **If releases are not minimised, adverse effects are inevitable**
- **Broad group restriction proposal**
- **Time-limited derogations for certain uses**
 - Industry: Effort needed to switch to alternatives
 - Environment: Emission reduction of 96% in 30 years with full ban
 - If no action is taken societal costs will exceed costs associated with a restriction

Details of the restriction proposal

Use sectors

- 14 uses / use sectors considered in detail
 - 78 sub-uses (see: table 2, main document)
- Conclusions on alternatives, costs and environmental emissions based on these uses
- Uses / use sectors not mentioned? Proposed ban still applies

Details of the restriction proposal

Main applications	Sub-uses (non-exhaustive) of thoroughly investigated PFAS main applications								
Firefighting foam	Covered by separate restriction proposal								
TULAC (Textile, upholstery, leather, apparel and carpets)	Home textiles	Consumer apparel	Professional apparel	Technical textiles	Leather				
Food contact materials and packaging	Consumer cookware	Industrial food and feed production, e.g. in valves and conveyor belts, and for non-stick coatings	Food and feed packaging, including paper & board packaging and plastic packaging						
Metal plating and manufacture of metal products	Hard chrome plating	Decorative plating with chrome, plating on plastics and plating with metals other than chrome	Manufacture of metal products						
Consumer mixtures	Cleaning agents	Waxes and polishes	Dishwashing products	Windscreen treatments and windscreen wiper fluids	Mixtures used for musical instruments				
Cosmetics	Skin care	Toiletries	Hair care	Perfumes and fragrances	Decorative cosmetics				
Ski wax	Kick wax	Glide wax	Ski skin treatment						
Applications of fluorinated gases	Refrigeration	Air conditioning and heat pumps	Foam blowing agents	Solvents	Propellants	Magnesium casting	Fire suppressants	Preservation of cultural paper-based materials	



Details of the restriction proposal

Main applications	Sub-uses (non-exhaustive) of thoroughly investigated PFAS main applications								
Medical devices	Implantable medical devices	Wound treatment products	Tubes and catheters	Metered Dose Inhalers (MDIs), e.g. as coating and propellant	Cleaning and heat transfer: engineered fluids	Sterilization gases	Diagnostic laboratory testing	Rigid gas permeable (RGP) contact lenses and ophthalmic lenses	Packaging of medical devices
Transport	Body-, hull- and fuselage construction	Sealing applications	Combustion engine systems	Electrical engineering and information technology	Safety equipment (incl. fire prevention and protection)	Hydraulic fluids	HVACR*-systems	Coating and finishings	
Electronics and semiconductors	Wires and cables	Coating, solvents and cleaning	Electronic components	Heat transfer fluids	Advanced semiconductor packaging	Photolithography			
Energy sector	Photovoltaic cells	Wind energy	Coal based power plant	Nuclear power plant	Proton exchange membrane (PEM) fuel cells	Electrolysis technologies (not PEM)	(Lithium-ion) batteries		
Construction products	Roofing	Bridge bearings	Sealings and adhesives	Processing aids and polymer processing aids	Coatings, paints, varnishes and impregnation	Coatings for wind turbine blades and solar cells			
Lubricants	Low viscosity lubricants	Solid/dry-film lubrication	Release-agents	Greases					
Petroleum and mining	Drilling fluids	Well stimulation chemicals	Anti-foaming agents	Water and gas tracers	Metal salts recovery	Lining of piping, seals, sensors, cables, etc.			

Details of the restriction proposal

Justification for an EU-wide measure

- Main concern: very high persistence (intergenerational)
- Manufacture, import and uses in EU
- Global market with growing volumes
- Large variety of emission sources
- Ubiquitous presence and increasing levels in environmental media
- PFASs are mobile and cross borders
- EU internal market: level playing field

EU-wide risk reduction measures: Implement control efficiently and uniformly

Details of the restriction proposal

Which substances fall under the scope?

- Concern-based scope using the OECD (2021) PFAS definition*
 - E.g., PFAAs, polymeric PFASs, fluorinated gases
- Excluded: specific well-defined fully degradable PFAS subgroups (under normal environmental conditions)

* Fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), any chemical with at least a perfluorinated methyl group (–CF₃) or a perfluorinated methylene group (–CF₂–) is a PFAS.

Details of the restriction proposal

Proposed restriction: Ban

Ban on manufacture, use and placing on the market



- As substances on their own
 - As a constituent
 - A mixture
 - An article
- } ≥ 25 ppb for any PFASs
} ≥ 250 ppb for sum of PFASs
} ≥ 50 ppm * for PFASs

* If total fluorine exceeds 50 mg F/kg the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFASs or non-PFASs.

Details of the restriction proposal

Two restriction options (ROs)

- Option 1 (RO1): full ban, 18 months after entry into force
- Option 2 (RO2): full ban, 18 months after entry into force, with time-limited, use-specific derogations

Details of the restriction proposal

Proposed option: RO2

- **Based on:**
 - Analysis of (availability of) alternatives
 - Socio-economic considerations
- **RO2: Considered proportional and most appropriate**
 - Balancing trade-offs

Cost of restriction vs Societal costs of continued use

- Trade-offs explained at sector level in dossier

But: Cost-benefit balance not determining criterion for derogation

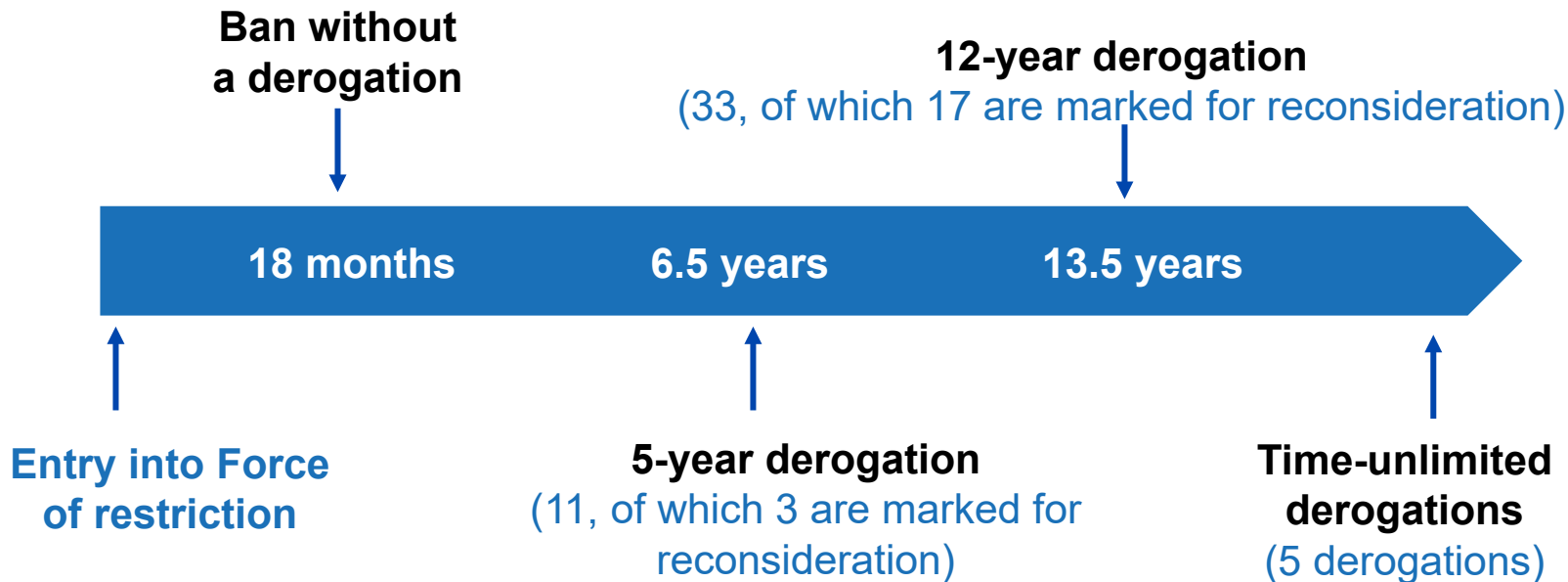
Details of the restriction proposal

Attention!

- **RO2 is also a full ban**, but has longer transition periods for uses with a *time-limited derogation*
- Work on alternatives by industry is necessary
- Very specific uses have time-unlimited derogations

Details of the restriction proposal

Phase out timeline



Details of the restriction proposal

Where to find derogations?

- **Main document:**
 - Draft entry text (page 4 to 8; column 2, par. 4, 5 and 6)
 - Table 9
- **Annex E**
 - More detailed information per use sector

Details of the restriction proposal

Basis for derogations

18 months after EiF	18 months + 5 years	18 months + 12 years
Alternatives exist	Sufficiently strong evidence that technically and economically feasible alternatives are in development	Sufficiently strong evidence that technically and economically feasible alternatives are not available in near future (R&D)
No or not sufficiently strong evidence that alternatives are not available	Sufficiently strong evidence that alternatives exist, but not available in sufficient quantities and/or cannot be implemented by company before transition period ends	Certification or regulatory approval of PFAS-free alternatives cannot be achieved within a 5-year derogation period



Details of the restriction proposal

Proposed vs. Potential derogations

- **Proposed:** sufficiently strong evidence that currently warrants derogation
- **Potential:** weak evidence currently does not warrant derogation, but may be reconsidered based on additional evidence
- **Use not mentioned:** restriction applies



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Details of the restriction proposal

Reporting requirements and management plans

- Gain insight in use of PFASs for derogated uses
- Ensure proper handling at end-of-life
- Facilitate enforcement

Details of the restriction proposal

Reporting

Mandatory reporting in relation to majority of derogations

Who

- Active substances: Manufacturers, importers
- Uses of fluorinated gases & uses with 12 - year derogation period:
 - Substance & articles: Manufacturers, importers
 - Mixtures: Formulators

What

- Information on the use (which derogation)
- Identity and quantity of substance placed on market



Details of the restriction proposal

Management plans

Requirement for a site-specific management plan in relation to fluoropolymers when making use of derogations



Who

- Manufacturers, importers and downstream users

What

- Identity of the substances and the products they are used in
- Justification for the use
- Conditions of use
- Safe disposal

Details of the restriction proposal

Key messages

- PFASs are omnipresent in humans and the environment
- Broad group restriction for PFAS with use-specific time-limited derogations
- Restriction based on persistence and supporting concerns
- Need for regulatory measures on an EU wide level
- Will lead to reduction of >4 million tonnes of PFAS emission over 30 years

Details of the restriction proposal

Thank you!



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How to participate in the consultation

Webinar: Consultation on restriction proposal for per- and polyfluoroalkyl substances (PFAS)

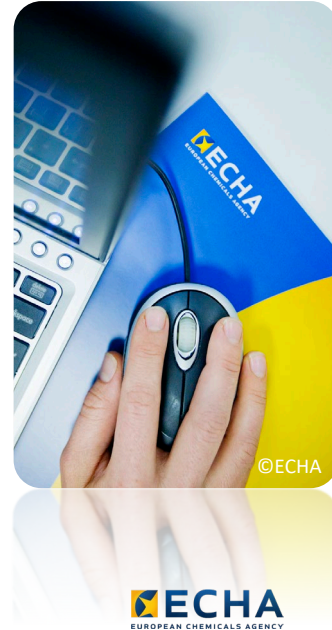
5 April 2023

Michael Gmeinder
Economist
European Chemicals Agency



What to submit?

- Any information you consider relevant
- Information on topics that the Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) committees or the dossier submitter have identified – called 'specific information requests'
- Comments made without supporting evidence unlikely to have much impact
- Joint submissions encouraged – e.g. per sector
- You can claim information confidential



Keep in mind

- Use most recent version of Annex XV restriction report and any annexes – those published with the consultation
- Information sent after closing date or via other channels not considered by RAC and SEAC
- Refer to [Consultation Guidance](#) and [Information Note](#) for further information

Question 1

Sectors and (sub)uses

- Specify all sectors and (sub)uses your comment applies to
- See Table 9 of the main report for list of sectors and (sub)uses identified in the restriction proposal
- Facilitates processing comments

Question 2

Emissions in end-of-life phase

- Per (sub)use, information on share of emissions attributable to different product lifecycle phases (manufacture, use, end-of-life)
- Annual emission volumes in end-of-life phase at sector or sub-sector level
- Per (sub)use, information on share of waste treated through incineration, landfilling, recycling (including information on form of recycling)

Question 3

Emissions in end-of-life phase

- Information on effectiveness of incineration under normal operational conditions with respect to destruction of PFAS and prevention of PFAS emissions
- For different waste types (e.g. hazardous, municipal)

Question 4

Impacts on recycling industry

- Impacts of proposed concentration limits (paragraph 2 of proposed restriction) on technical and economic feasibility of recycling processes
- Clearly indicate waste streams to which the described impacts relate
- Measures that recyclers would need to take to achieve proposed concentration limits
- Costs associated with these measures

Question 5

Proposed derogations

- Paragraphs 5 and 6 of the proposed restriction list several proposed derogations
- For relevant uses, information is requested on:
 - Tonnage of PFAS used per year
 - Resulting PFAS emissions to the environment

Question 6 (Part 1)

Missing uses

- Several PFAS uses not covered in detail (see Table A.1 in Annex A) and some relevant uses may not have been identified yet

- For such uses, information on alternatives and socio-economic impacts is requested, including:
 - a. Annual tonnage and emissions and type of PFAS
 - b. Key functionalities provided by PFAS
 - c. Number of companies affected
 - d. Availability, technical and economic feasibility, hazards and risks of alternatives

Question 6 (Part 2)

Missing uses

- e. Alternatives are not yet available:** information on status of R&D processes and time required for completing substitution
- f. Substitution is technically and economically feasible but more time is required to substitute:**
 - Type and magnitude of costs associated with substitution
 - Time required for completing substitution
 - Functionality differences and consequences for downstream users and consumers
 - Benefits for alternative providers
- g. Substitution is not technically or economically feasible:** information on socio-economic impacts for companies, consumers and other affected actors

Question 7

Potential derogations

- Paragraphs 5 and 6 of proposed restriction list in [square brackets] several potential derogations for reconsideration after the consultation
- For the uses in question, available evidence concerning substitution potential is considered insufficient to allow a firm conclusion
- Additional information requested on alternatives and socio-economic impacts covering points a) to g) described in question 6

Question 8

Other identified uses

- Analysis of alternatives and socio-economic impacts in the restriction proposal generic and qualitative for many (sub)uses
- Evidence on alternatives was inconclusive for some applications within certain (sub)uses (Table 8 in main report)
- More information needed on alternatives and socio-economic impacts covering points a) to g) described in question 6

Question 9

Degradation potential

- Some specific PFAS sub-groups excluded from restriction proposal scope because they are expected to ultimately mineralise in the environment
- RAC appreciates further information on potential degradation pathways, kinetics or produced metabolites in relevant environmental conditions and compartments for:
 - Trifluoromethoxy
 - Trifluoromethylamino-derivatives
 - Difluoromethanedioxy-derivatives

Question 10

Analytical methods

- Annex E contains an assessment of availability of analytical methods for PFAS
- Provide any new or additional information on new developments in analytical methods not yet considered

What happens to your comments?

- Published on our website (monthly intervals)
- Scrutinised by dossier submitter, RAC and SEAC
- Relevant and substantiated information will be addressed in a background document and/or RAC/SEAC opinion
- Dossier submitter, RAC and SEAC respond to issues raised – responses published at the end of the process














Submitted restrictions under consideration

ECHA > Consultations > Submitted restriction under consideration

Name	EC Number	CAS Number	Start of consultation on Annex XV report	1st deadline for comments on Annex XV report	End of consultation on Annex XV report	Start of consultation on SEAC draft opinion	End of consultation on SEAC draft opinion	
Per- and polyfluoroalkyl substances (PFAS)		-	22/03/2023		25/09/2023			Details

echa.europa.eu/restrictions-under-consideration

Substance details

Name	Per- and polyfluoroalkyl substances (PFAS)
EC Number	-
CAS Number	-
Submitted by	Germany
Scope	Restriction on the manufacture, placing on the market and use of PFASs.
Information note on restriction report	
Restriction report	 Annex XV report
Restriction report annexes	<ul style="list-style-type: none"> Annex A Annex B Annex C Annex D Annex E Annex F Annex G Appendix E4 Appendix G1 Appendix G2 Appendix E2
Consultation on restriction report	Give Comments
Start of consultation on Annex XV report	22/03/2023

Comments on 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

Filling in the form

SECTION II. Organisation

SECTION III. Non-confidential comments

- **General comments**
(General comments can be on any aspect of the Annex XV restriction proposal, including issues related to socio-economic analysis)
- **Specific information requests**
(These are several specific questions where we would like to have your input where possible)

Responses can be entered directly into the form or through section IV or V as attachments

SECTION IV. Non-confidential attachment

SECTION V. Confidential Attachment

Submission of comments

- It is **not possible to save your submission** and come back to it. Prepare your comments in an attachment or saved in another format in advance
- Once finished, press submit. You will receive a **submission number** via e-mail. **Refer to it in any communication** with us on this topic
- It is not possible to retrieve your submission. You can take a screenshot, or printed copy, for your reference

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Concluding remarks

Webinar: Consultation on restriction proposal for per- and polyfluoroalkyl substances (PFAS)

5 April 2023

Mercedes Marquez-Camacho
Restriction Process Coordinator
European Chemicals Agency



Live Q&A

- Join Q&A at: slido.com
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- Our panellists reply to questions until **13:00 Helsinki time** (EEST, GMT+3)
- ECHA will publish Q&A based on the questions received in the webinar



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