

Welcome

Webinar: Consultation on restriction proposal for per- and polyfluoroalkyl substances (PFASs) in firefighting foams

5 April 2022

Peter Simpson Restriction Process Co-ordinator European Chemicals Agency





With you today



Peter SimpsonRestriction Process
Co-ordinator



Greta Franke Economist



Piotr Sosnowski Scientific Officer



Bastian Zeiger Regulatory Officer



What you can expect today

- Learn about the REACH restriction process
- Learn about the details of the proposed restriction
- Learn about the consultation and how you can send information
- Help to decide if and what information to send
- Get answers to your questions



Programme

Time	Topic	Speaker
11:00	Introduction to the information session and to the REACH restriction process	Peter Simpson, ECHA
11:10	Details of the proposed restriction	Piotr Sosnowski, ECHA
11:30	How to participate in the consultation	Bastian Zeiger, ECHA
11:50	Concluding remarks and next steps	Peter Simpson, ECHA
12:00- 13:00	Live Q&A	

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Live Q&A

Join Q&A at: slido.com
 Event code: # PFASfoams or with QR:

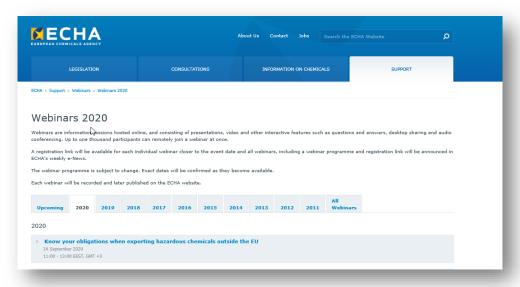


- Send questions from
 11:00 to 13:00 (EEST, GMT +3)
- Only questions within scope
- Questions after the webinar?
 echa.europa.eu/contact



Material published

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





Introduction to REACH restriction

Webinar: Consultation on restriction proposal for per- and polyfluoroalkyl substances (PFASs) in firefighting foams

5 April 2022

Peter Simpson Restriction Process Co-ordinator 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
 - Safety net for other REACH and EU processes
- Usually limits or bans manufacture, placing on the market or use of a substance (also in a mixture/article)
- Can set out specific conditions such as technical measures or labelling requirements
- Dossier submitter can be a Member State or ECHA



Restriction proposal Annex XV report

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



Restriction process



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 Annex XV report
- Consultation on the SEAC 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

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EvaluationAfter submission

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



Timeline after submission

- Restriction dossier publicly available after submission:
 - Not to be used for consultation (pre-publication)
- Opinion-making process (typically 14 months)
 - Conformity check: RAC and SEAC
 - Consultation (six months until 23 September 2022)
 - Evaluations of RAC/SEAC documented as 'opinions'
 - 60 day consultation on SEAC draft opinion
 - Comments submitted in consultation (and responses) published with updated proposal (background document)
- After adoption, opinions published and sent to European Commission
- Scrutiny by EU Council and the European Parliament



Indicative evaluation schedule

Committee plenary meeting	Committee for Risk Assessment	Committee for Socio-Economic Analysis		
	Verify scope	 Verify scope 		
2.5 months after consultation starts	 Conclude evaluation of hazard assessment 	 Conclude evaluation of costs 		
consultation starts	Preliminary evaluation of exposure and risk	 Preliminary evaluation of benefits 		
5.5 months after	 Conclude evaluation of exposure and risk 	 Conclude evaluation of benefits 		
consultation starts	 Preliminary evaluation of effectiveness, including derogations 	 Preliminary evaluation of proportionality, including derogations 		
	 Conclude evaluation of effectiveness, including derogations 	 Conclude evaluation of proportionality, including derogations 		
8.5 months after consultation starts	 Conclude evaluation of practicality and monitorability 	 Conclude evaluation of practicality and monitorability 		
	· Adopt opinion	 Agree draft opinion 		
	Not relevant	 Conclude on issues raised during SEAC draft opinion consultation 		
		 Adopt opinion 		

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Thank you!

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Details of the proposed restriction

Webinar: Consultation on the restriction proposal for per- and polyfluoroalkyl substances (PFASs) in firefighting foams

5 April 2022

Piotr Sosnowski Scientific Officer <u>European Che</u>micals Agency





Global focus

- Exposure to PFASs gained increasing attention
 - EU chemicals strategy for sustainability
- Use of PFASs in firefighting foams linked to environmental pollution, including drinking water
- Some already restricted in firefighting foams in the EU (PFOS, PFOA, C9-C14 PFCAs)
 - Proposal does not affect existing restrictions
 - Decision-making for restrictions on PFHxS and PFHxA ongoing
- Several restrictions in non-EU countries
 - Certain U.S. States (California, Washington, New York, etc.), Australia,
 - some targeting defence sector



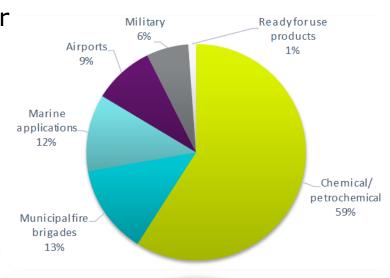
Function in firefighting foams

- Primary function as surfactant
- Rapidly forms film over surface of burning liquid
- Particularly relevant and effective for industrial fires with flammable liquids (Class B fires)



Sectors of use

- Around 18 000 tonnes of PFAS fire-fighting foams sold in EU each year
- Equivalent to around 500 tonnes of PFASs
- Oil/(petro-)chemical sector = largest user
- Most sectors have users that have substituted to fluorine-free foams (typically training)





Substance scope

PFASs defined as:

- Any substance that contains at least one fully fluorinated methyl (CF3) or methylene (CF2) carbon atom (without any H/Cl/Br/I attached)
- Restriction proposal covers all substances containing PFASs as defined above as a constituent (including as impurity or additive) and in mixtures
- Definition equals to OECD definition (2021)



Grouping and hazard

- PFASs considered as a group
- Group boundaries based on OECD definition
- Grouping based on structural similarity (common perfluorinated moieties)
- Structural similarity associated with common hazards and risks among substances covered
 - Primarily related to very persistent property of perfluorinated part(s) of PFAS molecules
 - Other supporting concerns
- Grouping also justified by objective to avoid regrettable substitution



Hazard assessment

Properties

Very high persistence

Long-range transport potential

Mobility

Accumulation in plants

Bioaccumulation potential

Endocrine activity

Ecotoxicity

Effects to human health

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.





Hazard conclusions

- Persistence of PFASs, in combination with supporting concerns, means conventional quantitative risk assessment not sufficiently reliable or practicable
 - No reliable PNEC or DNEL
- Risk assessment conducted case-by-case according to Annex I (section 0.1) of REACH
- Risks considered as non-threshold
- Releases used as proxy for risk



Exposure assessment

- Focus on environmental emissions (PBT/vPvB approach)
- Two 'model PFASs' as surrogates
 - Phys-chem properties
- Emissions estimated for each use and life-cycle stage
- Input parameters based on literature, industry information and expert judgement
 - e.g. in absence of information from industry on treatment of collected PFAS waste, assumed that collected waste sent to WWTP



Emission summary

Baseline:

- All PFASs in firefighting foams released during foam service life
- No effective collection and safe disposal assumed
- Only if foams expire before use, safe disposal assumed

Total environmental emissions of PFASs under baseline per sector or use

Sector/type of use	Annual emissions (t/y)	
Oil/(petro-)chemical industry (Seveso		
establishments)	200	
Other industries	<10	
Civilian aviation	40	
Defence	20	
Municipal fire services	50	
Ready-to-use applications	<10	
Marine applications	50	
Training and testing	80	
All sectors	~470	



Risk characterisation

- Risks not adequately controlled and releases should be minimised due to accumulation over time to levels likely to cause effects for humans and environment
- Effectiveness of proposed restriction based on effectiveness of emission reduction



Analysis of alternatives

- Alternatives already adopted in many sectors and for training or testing
- Alternatives mostly tested in small-scale standard tests with limited number of flammable liquids
- Performance testing against large fires or for certain flammable liquids (oil/chemical industry) advancing but not yet completed
- Performance of application system and technique as relevant as foam itself (properties/behaviour of alternatives is different from PFAS-foams)



Restriction options assessed

Number	Description	Emission reduction profile and possible issues	
1	Restriction on placing on market (use allowed until expiry date of stocks)	Progressive reduction of emissions	
2	Restriction on placing on market and use (transitional periods per sector of use)	Defined substitution deadlines provide strong incentive for substitution	
3	Restriction on placing on market, use and export (transitional periods per sector of use)	Exports also banned Proposed option	
4	Restriction on placing on market and use (transitional periods per sector of use) with derogation mechanism for Seveso/defence	Slower reduction of emissions than other options as largest sector could request derogation for use. Risk management unlikely to be completely effective. Complex enforcement/practicality	
5	Restriction for all uses (transitional periods per sector of use) unless risk management measures in place to minimise emissions	Allows substitution if technically and economically feasible and continued use of PFAS foams where not. Only applicable at limited sites being able to implement strictest risk management measures. Risk management unlikely to be completely effective	

No derogations proposed

All options include mandatory best practice additional risk management measures during transitional periods

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Transitional periods

Length based on:

- Availability of suitable alternatives and time required to implement transition (testing at user's site, installation/equipment adaptation and firefighting methods adaptation)
- Capacity of release containment
- No compromise in fire safety

Sector/type of use or placing on the market	Transitional period from entry into force		
Seveso establishments	10 years		
Other industries	5 years		
Civilian aviation	5 years		
Defence	5 years		
Municipal fire services	18 months		
Ready-to-use applications	5 years		
Marine applications	3 years		
Training and testing	18 months		
Export	10 years		



Additional conditions

6 months after entry into force:

- PFAS foams only allowed for Class B fires
- Set up and implement PFAS firefighting foams management plan aiming at minimising environmental emissions of PFASs as far as technically and practically possible
- Collected PFAS-containing waste and foam concentrates needing disposal handled for adequate treatment, minimising releases of PFASs to environmental compartments as far as technically and practically possible and shall exclude municipal wastewater treatment, irrespective of any pre-treatment
- Label of all containers of PFAS foam concentrates and PFAS waste



Concentration limit

- 1000 ppb of PFASs is proposed
- Well below typical PFAS concentration in foam concentrate (2.5%)
- High enough to allow detection and quantification by analytical methods
- No EU analytical standard yet but several methods exist and have been used in the context of firefighting foams
- Not too low to avoid excessive costs in equipment cleaning/replacement while having marginal impact on emissions reduction

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Emission reductionPer restriction option

Baseline: 14 100 tonnes of emissions over 30 years

Restriction option		Emission reduction (tonnes in 30 years)	
1	Restriction on placing on market but use continued to be allowed until expiry date of stocks	11 800	
2	Restriction on placing on market and use after use/sector-specific transitional periods	13 000	
3	Restriction on export, placing on market and use after use/sector-specific transitional periods	13 200	
4	Restriction on placing on market and use after use/sector-specific transitional periods, with a derogation mechanism via a permit system to which only Seveso establishments and defence sites would be eligible	12 600	
5	Restriction on placing on market and use for all uses after sector or use-specific transitional periods, unless adequate risk management measures are in place to capture all environmental emissions	12 500	



Human health and environmental impacts

- Proposed restriction gives partial solution to prevent increase of general PFAS-exposures
- Human health and environmental risks of fluorine-free foams considered lower than when using PFAScontaining foams
- Expected impact of reduced releases:
 - Avoid need for developing and implementing more appropriate drinking water purification techniques
 - Avoid need to change drinking water supplies in future



Economic impacts

- Cost of additional risk management measures (for use of PFAS foams during transitional period)
- Depreciation of existing stocks
- Cost of incinerating PFAS foams (safe disposal)
- Cost of cleaning equipment (to comply with concentration threshold)
- Cost of technical adaptation of equipment for use of alternative foams
- Incremental cost of using alternative foams (higher price and volume)
- Producer surplus loss related to export ban
- Savings of avoided clean-up of incident site

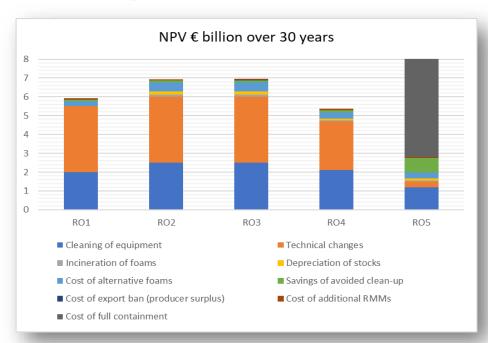


Economic impacts (cont.)

- Environmental/health benefits of reduction of PFAS emissions cannot be quantified, primarily due to lack of knowledge about effects
- Avoided releases used as proxy of environmental and human health impacts
- Possible avoided remediation costs and avoided drinking water purification costs not counted as savings but described qualitatively as a benefit of avoided releases
- ECHA's approach to "Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC" requests dossier submitters to report cost per unit (e.g. kilogram) of emissions reduced as starting point for proportionality assessment



Estimated economic impacts for each option and industrial sector



For option 5, cost of full containment (grey part) is 13 billion € outside of bar chart



Cost-effectiveness

	Restriction option	Emission reduction (kilo- tonnes in 30 years)	Cost to society (€ billion in 30 years, NPV)	Cost- effectiveness (€/kg avoided emission)
1	Restriction on the placing on the market but use continued to be allowed until expiry date of the stocks	11.8	5.9	500
2	Restriction on the placing on the market and use after use/sector-specific transitional periods	13.0	6.8	520
3	Restriction on the export, placing on the market and use after use/sector-specific transitional periods	13.2	6.8	520
4	Restriction on the placing on the market and use after use/sector-specific transitional periods, with a derogation mechanism via a permit system to which only Seveso establishments and defence sites would be eligible	12.6	5.2	415
5	Restriction on the placing on the market and use for all uses after sector or use-specific transitional periods, unless adequate risk management measures are in place to capture all the emissions to the environment	12.5	15.0	1 200

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Conclusion and next steps

- Proposed restriction estimated to reduce
 PFAS emissions by ~13 200 tonnes over 30 years
- Progressive phase-out for each type/sector of use + additional risk management measures during transition
- Appropriate measure to address these risks within a reasonable timeframe
 - · Effective and proportionate
 - Practical and monitorable



Annex XV report structure

Annex XV Report (206 pages)

Proposed restriction (p. 16)

Hazard, exposure/emissions and risk

- Identity of the substance(s)
- Hazard assessment Persistence, LRTP, Mobility
- Risk characterisation
- Baseline

Impact assessment

- Analysis of risk management options (RMOs)
- Overview of impacts
- Proportionality to the risk (including comparison of options)

Assumptions, uncertainties and sensitivities

Conclusion



Annex XV report structure

Annex to Annex XV Report (496 pages)

Annex A. Manufacture and uses

Annex B. Information on hazard and risk

- B.4. Environmental fate properties (p. 69) Degradation, Environmental distribution, Bioaccumulation, Enrichment in plants, Removal from the environment, decontamination and purification.
- B.9. Exposure assessment (p. 261)

Annex C. Justification for action on a Union-wide basis

Annex D. Baseline

Annex E. Impact Assessment

- E.1. Risk Management Options (p. 288)
- E.2. Alternatives (p. 295-358)
- E.4. Economic impacts (p. 358)
- E.8. Proportionality (comparison of options) (p. 421)

Annex F. Assumptions, uncertainties and sensitivities

Annex G. Stakeholder information



Annex XV report structure

Appendices to Annex XV Report (267 pages)

- Appendix 1. Stakeholders survey on techniques to clean equipment
- Appendix 2. Techniques for disposal of firefighting foam concentrates
- Appendix 3. Disposal of PFAS-contaminated fire run off and equipment cleaning water
- Appendix 4. Detailed foam transition timescales (from industry) (source: Wood 2020)
- Appendix 5. List of international standards for firefighting foam performance (from Wood et al. 2020)
- Appendix 6. List of alternative firefighting foam products available on the EU market, as identified by Wood et al. 2020 in the consultation responses
- Appendix 7. RO 4: description of the derogation mechanism as suggested by Eurofeu
- Appendix 8. Details of the calculations used in the emissions model and results obtained
- Appendix 9. Sensitivity calculations for and time profile of costs
- Appendix 10. Measured levels in environmental compartments



Thank you!

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How to participate in the consultation

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5 April 2022

Bastian Zeiger Regulatory Officer European Chemicals Agency





What to submit?

- Any information you consider relevant
- Information on topics that RAC, SEAC or ECHA as dossier submitter have identified
 - Called 'specific information requests'
 - Alternatives
 - · Transitional periods
 - Cost estimates
 - Definitions
 - Other assumptions
- Comments made without supporting evidence unlikely to influence proposal
- You can claim information as confidential



Question 1Status of alternatives

- Information on status of PFAS firefighting foam substitution (not already described in Annex XV report, annex or appendices), specifically in relation to following applications:
 - Portable fire extinguishers for class B fires
 - Tanks and flammable liquids in transportation sector (rail and road)
 - High-temperature climate conditions within EU (e.g. climatechange induced heatwaves)
 - Availability of sufficient quantities of alternatives for replacement of stocks

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Question 2Transitional periods

 Are proposed transitional periods (Table 3 and Section 2.8.2 of Annex XV report) appropriate to implement alternative (PFAS-free) firefighting foams (including any time required for additional performance testing and/or adaptation of fire extinguishing systems/process)?

If not:

- Describe socio-economic impacts that would occur after end of proposed transitional period(s). Refer to Annex XVI of REACH for details of what to consider for impact assessment
- Describe socio-economic impacts that would occur with (i) longer and (ii) shorter transitional periods
- Provide justification for representativeness of information provided for a particular sector or use in EU/EEA



Question 3Seveso definitions

Paragraph 3b and 3e of proposed restriction (see section 2.2.5)
details a transitional period of 10 years after entry into force for
establishments covered by Directive 2012/18/EU (Seveso III
Directive; both upper and lower tiers). Are the definitions in this
Directive appropriate to identify industrial installations that require 10
years to transition to alternative (PFAS-free) firefighting foams? If
not, how else could such a distinction be practically made at a
European level?



Question 4Cost estimates

 Is order of magnitude of cost estimates (see Tables 4 and 5) appropriate?
 If not:

- Justify different assumptions (see Tables 12 and 13) and cost estimations per cost category and/or industry sector/use and;
- Provide a justification for representativeness of information provided for a particular sector or use in EU/EEA



Question 5Cost estimates (contd.)

- Any robust, representative, data on costs to implement operational conditions and risk management measures to minimise emissions to environment and direct and indirect exposures to humans of PFASs in firefighting foams during transitional periods (i.e. requirements of paragraph 4b of proposed restriction)? In the absence of more specific information, dossier submitter estimated these costs based on disposal costs of PFAS-containing foams used for training and incidents (€1 000 per tonne, -50% as a lower bound and +100% as an upper bound, see also Wood et al. (2020), Table 8.14 on p. 163). If you have more appropriate information:
 - Justify different assumptions and cost estimations per cost category and/or industry sector/use and;
 - Provide a justification for representativeness of information provided for a particular sector or use in EU/EEA



Question 6Costs of treatment

 Any specific information on treatments costs (e.g. reverse osmosis) that is effective at removing PFASs from drinking water?



Question 7Fire-extinguishers

 Dossier submitter estimated 15 million handheld fire extinguishers containing PFASs in the EU (see 2.3.2). Are you aware of any specific information at EU or national level that would allow a refinement of this estimate? If so, provide a justification for representativeness of provided information



Question 8Current fire-water treatment

 Any robust, representative, data that challenges assumption that fire-water containing PFASs is currently sent to either on-site or urban waste water treatment plants? If so, how do they relate to Appendix 2 and 3?



Question 9Incineration

 Any robust, representative, data regarding cost and available capacity of incinerating retired foam stock and PFAS-containing firewater collected according to paragraph 4d and 5 of restriction proposal?



Question 10Labelling clause

 Conditions of proposed restriction include clause on labelling of firefighting foam concentrates containing non-PFAS organofluorine substances (column 2, paragraph 7 of proposed restriction) to enable enforcement without requiring targeted analysis of all potential PFASs. Would this requirement facilitate enforcement? Could it be improved?



What happens to your comments?

- Published on our website (monthly intervals)
- Scrutinised by dossier submitter (ECHA), RAC and SEAC and –
 if contain relevant and substantiated information, will be
 addressed in either background document and/or RAC/SEAC
 opinion
- Dossier submitter and RAC and/or SEAC respond to all comments
 - Responses published on our website at the end of the process



Submitted restrictions under consideration

ECHA > Consultations > Submitted restriction under consideration echa.europa.eu/restrictions-under-consideration

Name ≎	EC Number •	CAS Number •	1st deadline for comments on restriction report	Final deadline for comments on restriction report	Deadline for comments on SEAC odraft opinion	
1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropen tacyclo[12.2.1.16,9.02,13.05,10]octadeca-7,15-di ene ("Dechlorane Plus" ^{τм})	236-948-9	13560-89-9	28/07/2021	03/01/2022	16/05/2022	Details
2,4-Dinitrotoluene	204-450-0	121-14-2	20/10/2021	22/03/2022		Details
Lead and its compounds	231-100-4	7439-92-1	05/05/2021	24/09/2021		Details
Per- and polyfluoroalkyl substances (PFASs)	-	-	24/05/2022	23/09/2022	_	Details
Polycyclic aromatic hydrocarbons (PAH)	-	-	25/01/2022	22/06/2022		Details



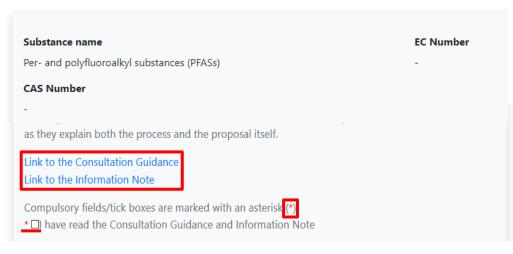
Substance details

✓ Substance Details

Name	Per- and polyfluoroalkyl substances (PFASs)
EC Number	-
CAS Number	-
Submitted by	ЕСНА
Scope	Restricting the use of per- and polyfluoroalkyl substances (PFASs) in firefighting foams.
Information note on restriction report	₽
Restriction report	
Restriction report annexes	
Consultation on restriction report	Give Comments
1st deadline for comments on restriction report	24/05/2022
Final deadline for comments on restriction report	23/09/2022
Comments submitted to date on restriction report	
Response to comments on the restriction report	



Comments for Annex XV restriction report



Consultation guidance

- What information can be submitted and the level of information needed
 - Consultation (6 months) on Annex XV restriction report
- Is it your first consultation?

Information note

- Summary of proposed restriction
- Timeline of consultation
- How to submit a comment



Filling in the form

- **Q** SECTION I. Personal information
- **1** SECTION II. Organisation
- **1** 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

- **1** SECTION IV. Non-confidential attachment
- **3** 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 screen shot, or printed copy for your reference

Once you are ready





Thank you!

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Concluding remarks

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Peter Simpson Restriction Process Co-Ordinator European Chemicals Agency





Live Q&A panel

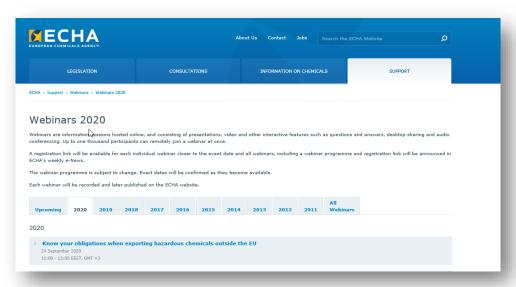
- Our panellists reply to questions until
 13:00 Helsinki time (EEST, GMT+3)
- All questions will be answered in a Q&A document shortly after the webinar
- Send questions at slido.com, event code **PFASfoams**, or with QR code:
- Questions after the webinar? echa.europa.eu/contact





Material published

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





Thank you!

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