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These webinar materials are based on the Pre-publication version of the EU PFAS restriction proposal released by ECHA on February 7, 2023. Please note that the proposed restriction is subject to change. Please check the document to be released by ECHA on March 22 and respond to the public consultation.

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3rd FCJ Webinar

Recent trends in PFAS restriction

Feb. 7 Release: Overview of EU PFAS Restriction Proposal and Response to Consultation

March 2023

Conference of Fluoro-Chemical Product Japan (FCJ)

Co-organizer: Japan Fluorocarbon Manufacturers Association (JFMA)

About the FCJ

Organization name: Conference of Fluoro-Chemical Product Japan (FCJ)

Established: March 6, 2021

Established to provide appropriate information dissemination, advocacy activities, etc. as fluorochemical manufacturers.

Business Profile (Excerpt)

- Research on environmental regulation trends, etc. for fluorochemicals
- Collaboration and coordination with domestic and international organizations
- Making recommendations to the government or related organizations

Activities to date (excerpted)

- Information-sharing and exchange on PFAS to related industry associations
- Providing input on proposed chemical evaluation methods (essential use and MT/ED definitions)
(In collaboration with JCIA)
- Recommendations on PFAS to the EU-Japan Business Round Table (EU-Japan recommendations)
- Collaboration with overseas chemical industry organizations

Participating companies (as of March 2023)

AGC Inc., Kitamura Limited, Kureha Corporation, Chemours Kabushiki Kaisha, Central Glass Co., Ltd., Daikin Industries, Ltd., DIC Corporation, Tosoh Finechem Corporation, Chemours-Mitsui Fluoroproducts Co., Ltd.

Reference: “FCJ” Conference of Fluoro-Chemical Product Japan (cfcpj.jp) ;<https://cfcpj.jp/>

Notes on this webinar

PFAS (organofluorine compounds) are widely used in a variety of applications such as semiconductor manufacturing equipment and automotive parts due to their unique properties not found in other materials. However, concerns about the safety of some PFAS, such as PFOA and PFOS, have triggered a shift toward regulation of PFAS as a whole, mainly in Europe and the United States.

Under these circumstances, on February 7, 2023, the PFAS restriction proposal was published in Europe, and public consultation (public comments) is scheduled to begin on March 22. The proposed are intended to restrict all but a few PFAS. Failure to submit a consultation to the authorities means the individual company/organization accepts the proposed restriction, which will have a major impact on future business in various industries.

Therefore, the FCJ has decided to hold this webinar to explain the content of the proposed restriction and to focus on the response to consultation, and to make various industries aware of the importance of submitting consultations.

FCJ's opinion and stance on the EU PFAS restriction proposal

[Opinion]

The EU REACH regulations describe the “restriction” system as “an instrument to protect human health and the environment from unacceptable risks posed by chemicals.” The proposed EU PFAS limit is based only on the fact that “the final decomposition products are highly persistent”, after grouping more than 10,000 of substances as compounds based on their manufacturing processes and molecular structures. Information on the hazardous properties of individual substances/substance groups (bioaccumulation potential, mobility, long-range transport potential, toxicological effects, etc.) is provided for only a small number of substances.

(Reference) EU REACH regulation and restriction : <https://echa.europa.eu/regulations/reach/restriction>

[Stance]

- In cooperation with related industry associations, we are planning to submit a consultation on doubts, etc. regarding the proposed restriction.
- We believe it is better to ask individual companies/organizations that actually use fluorochemicals to submit consultations on individual applications, rather than FCJ, which is involved in the manufacture of fluorochemicals, because we believe that the essentiality and importance of such comments can be conveyed more effectively.

Webinar program

- 1. EU REACH PFAS Restriction Proposal: Overview of Restriction**
- 2. EU REACH PFAS Restriction Proposal: Overview of F-gas Related Regulations**
- 3. EU REACH PFAS Restriction Proposal: Response to Consultation**
- 4. Responses to Questions Submitted in Advance**

1. EU REACH PFAS Restriction Proposal:
Overview of Restriction

Presenter

**Environmental Planning Group, Strategy & Planning Div.,
Performance Chemicals General Div.,
AGC Chemicals
AGC Inc.**

1. EU REACH PFAS Restriction Proposal: Overview of Restriction

- (1) Background to PFAS restriction
- (2) Reasons for PFAS restriction
- (3) Scope of PFAS subject to restriction
- (4) Concept of derogation duration in the restriction proposal
- (5) Overview of restriction proposal
- (6) Evaluation of availability of alternatives in the restriction proposal
- (7) Summary

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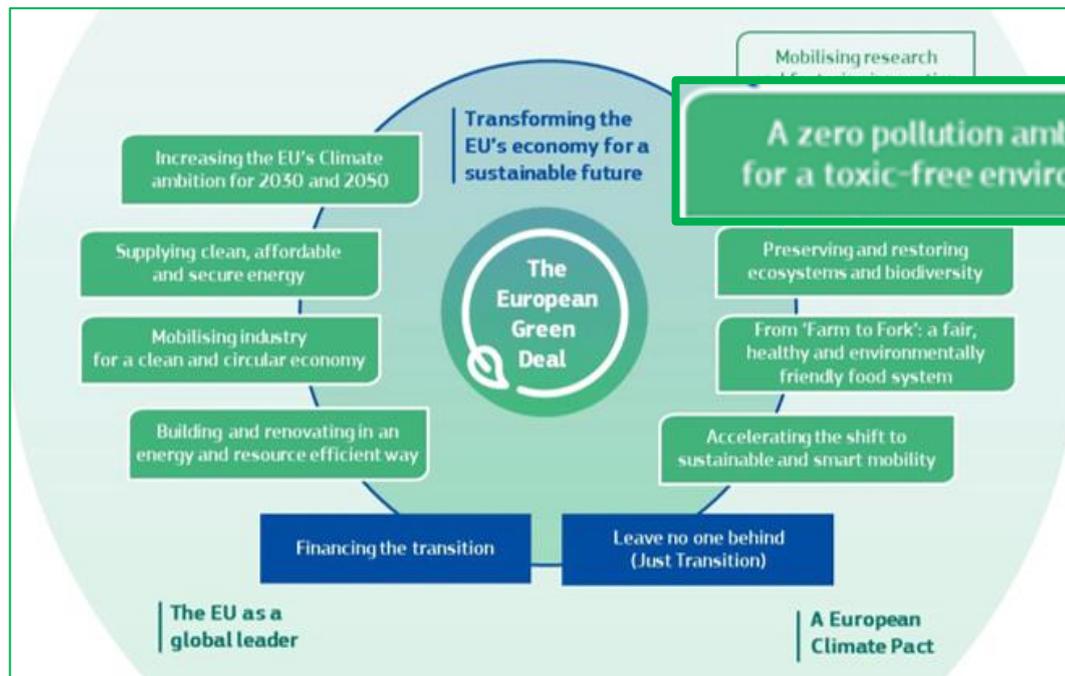
1. EU REACH PFAS Restriction Proposal: Overview of Restriction

(1) Background to PFAS restriction

What is the Chemicals Strategy for Sustainability in Europe?

Chemicals Strategy for Sustainability (CSS):

One of the strategies for the EU Green Deal announced by the EU Commission in October 2020.



Towards a toxic-free social environment

PFAS

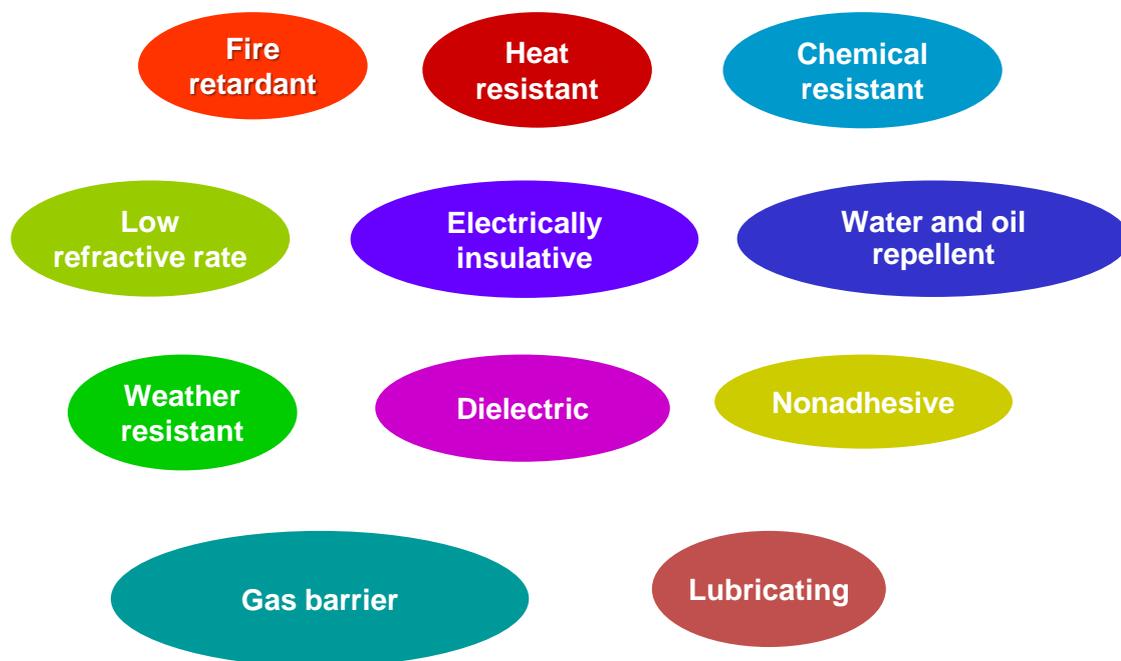
“Phase out the use of PFAS in the EU except for essential uses”
“Group approach”

(Reference)

PFAS: General term for per- and polyfluoroalkyl substances

Indicates a substance group of more than 10,000 organofluorine compounds. It does not include inorganic fluorochemicals (hydrofluoric acid (HF) or lithium hexafluorophosphate (LiPF₆)). The majority of fluorinated refrigerants, fluorinated chemicals (water and oil repellents, PFPE), fluorinated resins (PTFE, FEP, PFA, PVDF, etc.), fluorinated rubbers (FKM, FFKM, etc.), fluorinated paints, etc. are included in PFAS. PFAS also include fluoropolymers that are classified as “low concern” under the OECD definition. Of the thousands kinds of substances, toxicity data exist only for some PFAS, which are of interest to regulatory authorities.

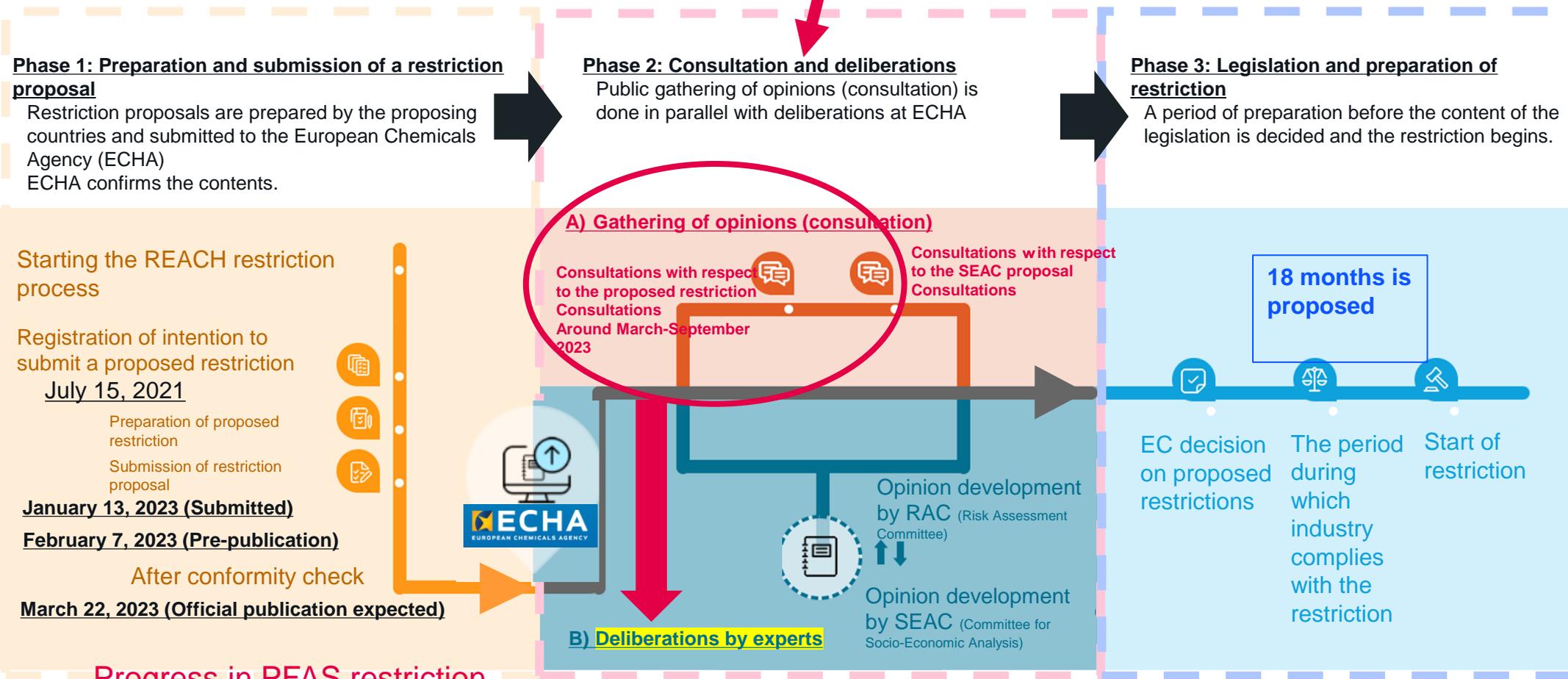
Characteristics of PFAS



PFAS have **multiple characteristics** shown to the left, and are **very useful in improving the performance and functionality of products** in the energy, semiconductor, electronics and communication, transportation, medical, building infrastructure, and other sectors.

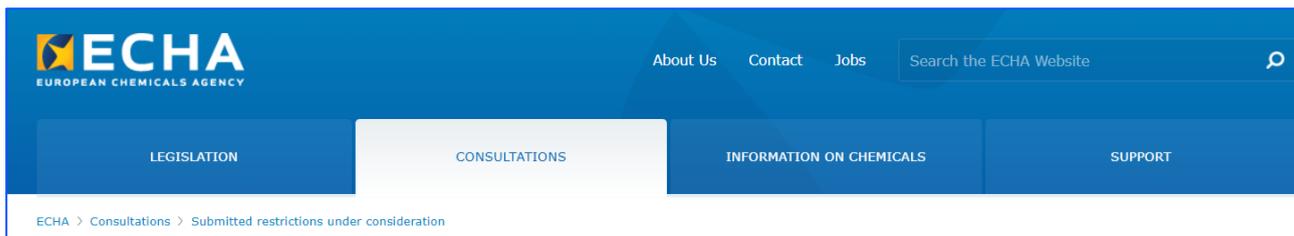
(Reference) REACH regulation restriction process

REACH regulation restriction process: The early submission of consultations (March-September 2023) taking advantage of Phase 1 preparations is a great opportunity **to be reflected in opinion development.**



Progress in PFAS restriction

(Reference) European Chemicals Agency (ECHA) website



Pre-publication on February 7, 2023

ECHA > Consultations > Submitted restrictions under consideration

Submitted restrictions under consideration

This table shows ongoing consultations on conforming restriction proposals and SEAC draft opinions; the links to the web forms for submitting comments to ECHA during the relevant consultations can be found by clicking on details. For consultations on conforming proposals, comments submitted before the deadline are often very influential as they will be considered in the first discussion month before the final deadline.

Please note: the ECHA Committees will not take into account the comments received after the deadline.

Consultations close at 23:59 Helsinki time (EET).

[Restriction](#)

[Adopted opinions on Registry of restriction intentions until outcome](#)

[Consultation guidance](#)

< Substance Details

Name	Pre-publication of Annex XV report prior to consultation 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

Reference: [Submitted restrictions under consideration - ECHA \(europa.eu\) ; https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term](https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term)

1. EU REACH PFAS Restriction Proposal: Overview of Restriction

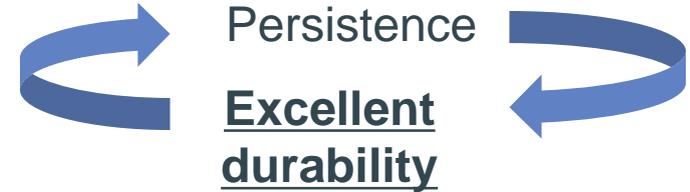
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1. EU REACH PFAS Restriction Proposal: Overview of Restriction

(2) Reasons for PFAS restriction

Scope of REACH Article 68 Restrictions

Unacceptable risk to human health or the environment, which needs to be addressed on a community-wide basis



All fluorine compounds in scope are covered

Reasons for restricting PFAS in Europe

- PFASs and their degradation products may persist in the environment longer than any other man-made chemical (persistence).
- In addition, there is concern over bioaccumulation potential, mobility, long-range transport potential, toxicological effects, etc. = Precautionary Principle

Grouping

A few of all fluorinated compounds targeted

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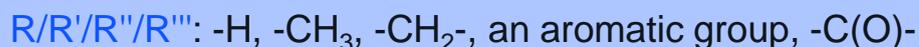
(3) Scope of PFAS subject to restriction

Definition of PFAS in Europe: From PFAS proposed restrictions (Feb. 7 **Pre-publication Version**)

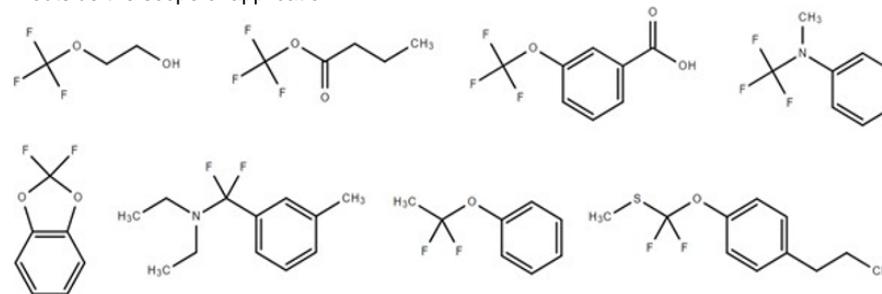
Per- and polyfluoroalkyl substances (PFASs) defined as:

Any substance that contains at least one fully fluorinated methyl (CF₃-) or methylene (-CF₂-) carbon atom (without any H/Cl/Br/I attached to it).^{*1}

A substance that only contains the following structural elements is excluded from the scope of the restriction:^{*2}



Specific examples of structures outside the scope of application



*1: Same as OECD definition published in 2021

Reference :[OECD. Series on Risk Management No. 61, 2021;](#)

<https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/terminology-per-and-polyfluoroalkyl-substances.pdf>

*2: Substances belonging to these PFAS subgroups **are excluded because they completely degrade under environmental conditions.**

Reference :[Submitted restrictions under consideration - ECHA \(europa.eu\);](#)

<https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term>

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1. EU REACH PFAS Restriction Proposal: Overview of Restriction

(4) Concept of **derogation duration** in the restriction proposal

Transition period (Section 3)	18 months after EiF
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Additional derogation period	Availability of alternatives (*)
5 years	(i) Technically and economically feasible alternatives are not available on the market at the time of entry into force (EiF), but areas of PFAS use have been identified and are under development (ii) Known alternatives are not available in sufficient quantities in the market at the time of EiF or cannot be implemented before the transition period ends.
12 years	(i) Technically and economically feasible alternatives are not available at EiF. Research and development (R&D) efforts have not identified potential PFAS-free alternatives. (ii) It will take more than 5 years for certification of non-PFAS alternatives.
Not restricted	Not under consideration (To be determined by individual rules)

EiF: Entry into Force

At the time of publication in the Official Gazette

*In addition, cost impact and emissions data have been considered.

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1. EU REACH PFAS Restriction Proposal: Overview of Restriction

(5) Overview of restriction proposal

Item	Conditions of restriction
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1	Shall not be manufactured, used or placed on the market as substances on their own;
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2	Shall not be placed on the market in: <ul style="list-style-type: none">a. another substance, as a constituent;b. a mixture,c. an article
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in a concentration of or above:

- i. 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification)
- ii. 250 ppb for the sum of PFASs measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors (polymeric PFASs excluded from quantification)
- iii. 50 ppm for PFASs (polymeric PFASs included).

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.

3	Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction.
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Reference: Website for posting
ECHA-related materials
Annex XV

Submitted restrictions under consideration - ECHA (europa.eu) ;
<https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term>
Annex XV reporting format 040615 (europa.eu) ;
<https://echa.europa.eu/documents/10162/f605d4b5-7c17-7414-8823-b49b9fd43aea>

1. EU REACH PFAS Restriction Proposal: Overview of Restriction

(5) Overview of restriction proposal

Item	Conditions of restriction
------	---------------------------

- | | |
|---|--|
| 4 | <p>By way of derogation, paragraphs 1 and 2 shall not apply to</p> <ol style="list-style-type: none">a. active substances in biocidal products within the scope of Regulation (EU) 528/2012b. active substances in plant protection products within the scope of Regulation (EC) 1107/2009c. active substances in human and veterinary medicinal products within the scope of Regulation (EC) No 726/2004, Regulation (EU) 2019/6 and Directive 2001/83/EC |
|---|--|

Manufacturers and importers of the active substances referred to in points a) – c) shall submit to the Agency every two years the following information:

- i. the derogation that the intended use belongs to;
- ii. the identity and quantity of the active substance placed on the market

The Agency shall publish on its website a summary of the submitted information referred to in points i) – ii).

1. EU REACH PFAS Restriction Proposal: Overview of Restriction

(5) Overview of restriction proposal

(Note) Light yellow highlighted areas are subject to the reporting requirements in Section 7.

Item	Conditions of restriction
5	By way of derogation, paragraphs 1 and 2 shall not apply to:
a	polymerisation aids in the production of polymeric PFASs until 6.5 years after EIF. This derogation does not apply to the production of PTFE, PVDF and FKM.
b	textiles used in personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) and (c), until 13.5 years after EiF;)
c	textiles used in personal protective equipment (PPE) in professional firefighting activities intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) - (m), until 13.5 years after EiF;
d	impregnation agents for re-impregnation of articles referred to in paragraph 5b and 5c until 13.5 years after EiF;
e	textiles for the use in filtration and separation media used in high performance air and liquid applications in industrial or professional settings that require a combination of water and oil repellence until 6.5 years after EiF;
f	refrigerants in low temperature refrigeration below -50°C until 6.5 years after EiF;
g	refrigerants in laboratory test and measurement equipment until 13.5 years after EiF;

1. EU REACH PFAS Restriction Proposal: Overview of Restriction

(5) Overview of restriction proposal

(Note) Light yellow highlighted areas are subject to the reporting requirements in Section 7.

Item	Conditions of restriction
h	refrigerants in refrigerated centrifuges until 13.5 years after EiF;
i	maintenance and refilling of existing HVACR equipment put on the market before [18 months after EiF] and for which no drop-in alternative exist until 13.5 years after EiF;
j	refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives;
k	industrial precision cleaning fluids until 13.5 years after EiF;
l	cleaning fluids for use in oxygen-enriched environments until 13.5 years after EiF;
m	clean fire suppressing agents where current alternatives damage the assets to be protected or pose a risk to human health until 13.5 years after EiF;
n	diagnostic laboratory testing until 13.5 years after EiF;
o	additives to hydraulic fluids for antierosion/anti-corrosion in hydraulic systems (incl. control valves) in aircraft and aerospace industry until 13.5 years after EiF;
p	refrigerants in mobile air conditioning-systems in combustion engine vehicles with mechanical compressors until 6.5 years after EiF;
q	refrigerants in transport refrigeration other than in marine applications until 6.5 years after EiF;
r	insulating gases in high-voltage switchgear (above 145 kV) until 6.5 years after EIF
s	lubricants where the use takes place under harsh conditions or the use is needed for safe functioning and safety of equipment until 13.5 years after EIF;
t	calibration of measurement instruments and as analytical reference materials.

1. EU REACH PFAS Restriction Proposal: Overview of Restriction

(5) Overview of restriction proposal

The following **potential derogations** are marked for reconsideration after the Annex XV report consultation:

(Note) Light yellow highlighted areas are subject to the reporting requirements in Section 7.

Item	Conditions of restriction
u	[textiles for the use in engine bays for noise and vibration insulation used in the automotive industry until 13.5 years after EiF];
v	[hard chrome plating until 6.5 years after EiF];
w	[foam blowing agents in expanded foam sprayed on site for building insulation until 6.5 years after EiF];
x	[industrial and professional use of solvent-based debinding systems in 3D printing until 13.5 years after EiF];
y	[industrial and professional use of smoothing agents for polymer 3D printing applications until 13.5 years after EiF];
z	[propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required until 13.5 years after EiF];
aa	[preservation of cultural paper-based materials until 13.5 years after EiF];
bb	[cleaning and heat transfer: engineered fluids for medical devices until 13.5 years after EiF];
cc	[membranes used for venting of medical devices until 13.5 years after EiF];
dd	[use as refrigerants and for mobile air conditioning in vehicles in military applications until 13.5 years after EiF];
ee	[the semiconductor manufacturing process until 13.5 year after EiF].

1. EU REACH PFAS Restriction Proposal: Overview of Restriction

(5) Overview of restriction proposal

(Note) Light yellow highlighted areas are subject to the reporting requirements in Section 7.

Item	Conditions of restriction
6	By way of derogation, paragraphs 1 and 2 shall not apply to fluoropolymers and perfluoropolyethers for the use in:
a	food contact materials for the purpose of industrial and professional food and feed production until 6.5 years after EiF;
b	implantable medical devices (not including meshes, wound treatment products, tubes and catheters) until 13.5 years after EiF;
c	tubes and catheters in medical devices until 13.5 years after EiF;
d	coatings of Metered Dose Inhalers (MDIs) until 13.5 years after EiF;
e	proton-exchange membrane (PEM) fuel cells until 6.5 years after EiF;
f	fluoropolymer applications in petroleum and mining industry until 13.5 years after EiF.

Reference: Annex XV [Annex XV reporting format 040615 \(europa.eu\)](https://echa.europa.eu/documents/10162/f605d4b5-7c17-7414-8823-b49b9fd43aea) ;
<https://echa.europa.eu/documents/10162/f605d4b5-7c17-7414-8823-b49b9fd43aea>

1. EU REACH PFAS Restriction Proposal: Overview of Restriction

(5) Overview of restriction proposal

The following **potential derogations** are marked for reconsideration after the Annex XV report consultation:

(Note) Light yellow highlighted areas are subject to the reporting requirements in Section 7.

Item	Conditions of restriction
g	[non-stick coatings in industrial and professional bakeware until 6.5 years after EiF];
h	[hernia meshes until 13.5 years after EiF];
i	[wound treatment products until 13.5 years after EiF];
j	[coating applications for medical devices other than Metered Dose Inhalers until 13.5 years after EIF];
k	[Rigid gas permeable contact lenses and ophthalmic lenses until 13.5 years after EiF];
l	[PCTFE-based packaging for medicinal preparations, medical devices and medical molecular diagnostics until 13.5 years after EIF];
m	[PTFE in ophthalmic solutions packaging until 13.5 years after EIF];
n	[packaging of terminally sterilised medical devices until 13.5 years after EIF];
o	[applications affecting the proper functioning related to the safety of transport vehicles, and affecting the safety of operators, passengers or goods until 13.5 years after EiF].

1. EU REACH PFAS Restriction Proposal: Overview of Restriction

(5) Overview of restriction proposal

Item Conditions of restriction

- 7** Manufacturers and importers of PFASs or PFAS containing articles as well as formulators of PFAS containing mixtures making use of any of the derogations according to paragraphs 5 b)-d) and f) –t) [and u), w)-ee)], and 6 b)-d) and f) [and h)-o)], shall from (EiF+18 months) provide by 31 March of each calendar year a report to the Agency containing:
- i. the derogation that the intended use belongs to;
 - ii. the identity and quantity of the substances placed on the market in the previous year.
- The Agency shall forward the information to the Commission by 30 June every year;
- 8** Without prejudice to paragraph 7, manufacturers, importers and downstream users of fluoropolymers and perfluoropolyethers making use of any of the derogations in paragraphs 5 or 6 shall establish a site-specific management plan which shall include:
- i. information on the identity of the substances and the products they are used in
 - ii. a justification for the use;
 - iii. details on the conditions of use and safe disposal.
- The management plan shall be reviewed annually and kept available for inspection by enforcement authorities upon request.
- 9** Paragraphs 1 and 2 shall apply without prejudice to the application of any restrictions set out in this Annex or to other applicable Union legislation.

1. EU REACH PFAS Restriction Proposal: Overview of Restriction

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1. EU REACH PFAS Restriction Proposal: Overview of Restriction

(6) Evaluation of availability of alternatives in the restriction proposal (Electronics sector)

Application	Information on current PFAS	Information on alternatives	Evaluation	Additional derogation
Wire and cable Heating cables, coaxial cables	PTFE, PFA, ETFE, FEP, FEPM, FKM	EPDM, silicone material, polyether ether ketone (PEEK), mica, polyvinyl chloride, polyethylene, ceramic base	Technically and economically feasible alternatives can be used after the transition period.	None
Heat conducting fluid	(Z)-1, 1, 1, 4, 4-hexafluoro-2-butane, 1-ethoxy 1, 1, 2, 2, 3, 4, 4-nonafluorobutane, and many others	Mineral oil, synthetic oil, natural oil, hydrocarbon fluids	Alternatives highly likely with 18-month transition period [sufficiently strong evidence]	None
LCD display	- Liquid crystal molecule containing CF3 group	- Liquid crystal molecule containing CN group	Alternatives highly likely with 18-month transition period [weak evidence]	None

While acknowledging that there are few alternatives, and even if there are, they may not meet the requirements, it is expected that alternatives will be available, and the transition period is only 18 months

1. EU REACH PFAS Restriction Proposal: Overview of Restriction

(6) Evaluation of availability of alternatives in the restriction proposal (Transportation sector)

Application	Information on current PFAS	Information on alternatives	Evaluation	Additional derogation
Materials necessary to ensure the proper functioning and safety of vehicles, drivers, passengers or luggage in automobiles, aircraft, railways, ships, aerospace industries, etc.	Fluoropolymers, etc.	Not yet available on the market. Use of alternatives requires testing, certification, and some, perhaps in many cases, redesign of equipment	<p>Considering the diversity of PFAS applications, the need for significant redesign of equipment, and re-certification requirements, we conclude that five years is not sufficient time to introduce PFAS alternatives throughout the sector [sufficiently strong evidence].</p> <p>An additional 12-year period would be sufficient for many applications, but in many cases the industry has not progressed with R&D into alternatives [weak evidence].</p>	[12 years]
Anticorrosive additives for hydraulic systems in the aircraft/aerospace industry	(Not listed)	Currently no alternatives (aviation sector), no information on other transport sectors	<p>Five years is insufficient for development and approval of alternatives (sufficiently strong evidence)</p> <p>A 12-year derogation period is sufficient to introduce alternatives (sufficiently strong evidence)</p>	[12 years]

It is recognized that a derogation period of five years is not enough, but due to lack of information, a **provisional** derogation period [12 years] has been set (Additional information must be provided during the consultation period)

1. EU REACH PFAS Restriction Proposal: Overview of Restriction

(6) Evaluation of availability of alternatives in the restriction proposal (Energy sector)

Application	Information on current PFAS	Information on alternatives	Evaluation	Additional derogation
Photovoltaic cells (Film/coatings, etc.)	PVdF, ETFE, FEVE, PFPE	Polyolefin, polyethylene terephthalate (PET), ethylene vinyl acetate (EVA) Surface coating on front seat	Alternatives are already on the market	None
Wind energy (Film, coating, and cable)	FEVE, ETFE	No information	—	None
Coal-fired power generation (Heat exchanger tubes, filters)	PTFE, fluoropolymers	No information	—	None
Nuclear power generation (Infrastructure gasket material)	PTFE	(Confidential Information included)	Inadequate alternatives	None
Fuel cells	Fluoropolymers, PFPEs	Polysulfone, polybenzimidazole-based electrospun materials, hydrocarbon membrane, sulfonated polyether ether ketone (PEEK)	Sufficient quantities and significant time needed to commercialize membranes, reinforcing materials and sealants [Sufficiently strong evidence, at least 5 to 10 years required from 2022]	5 years
Lithium-ion batteries	Fluoropolymers	Sealants: hydrocarbon elastomer Solid state batteries, lead-acid batteries	Inadequate alternatives	None

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1. EU REACH PFAS Restriction Proposal: Overview of Restriction (7) Summary

Consultations on content of proposed restriction → Matters necessary for opinion development by the expert committees

- ◆ Existence of technically and economically feasible non-PFAS alternatives.
 - Information about alternatives (e.g., existence of alternative technologies or substances)
 - Business impact assessment on each company of in-scope restricted substances and uses
- ◆ Emissions throughout the life cycle, from manufacturing to disposal, and information on their reduction and management
 - Emissions to the environment: (Example: Emissions of PFAS in the use environment during handling of PFAS and after product sales)
- ◆ Widespread socio-economic concerns (e.g., EU Green Deal targets)

2. EU REACH PFAS Restriction Proposal: Overview of F-gas Related Regulations

Japan Fluorocarbon Manufacturers Association (JFMA)

Overview of F-gas related regulations

	Presenter
(1) F-gas regulations and PFAS restriction	Chemours-Mitsui Fluoroproducts Co.,Ltd.
(2) Refrigerants for automobiles	Honeywell Japan Ltd.
(3) HVAC refrigerants	Mexicem Fluor Japan Ltd.
(4) Propellants	Mexicem Fluor Japan Ltd.
(5) Foaming agents	Central Glass Co., Ltd.
(6) Solvents and cleaning agents	Chemours-Mitsui Fluoroproducts Co.,Ltd.
(7) Summary	Chemours-Mitsui Fluoroproducts Co.,Ltd.

1. F-gas regulations and PFAS restriction

In the EU since 2006, F-gas regulations have been in place, and with the 2014 revision of the regulations, HFC Phase-down began earlier than stipulated in Kigali Amendment to the Montreal Protocol.

The objective is to limit high GWP HFCs to curb global warming, and to promote **environmental measures** by converting them to substances with lower global warming effect. At least in part due to F-gas regulations, there is a shift from HFCs to HFO-based materials with **comparable characteristics (safety (low toxicity, low flammability), efficiency, and cost)**. An additional revision is currently underway.

On the other hand, the PFAS restriction proposal also cover F-gas regulated products (with some exceptions) and their alternatives (such as HFOs), as well as HFEs, PFCs, and PFPEs. The proposed PFAS restriction **stems mainly its “high persistence”** but the decomposition time of F-gas (with some exceptions) is generally very short due to the conversion from HFC to HFO, and it **does not have persistence properties**. In addition, the hazardousness of its degradation products is not explained in the proposed restriction.

Substances identified as alternatives in the proposed restriction do not have equivalent characteristics in most cases.

1. In scope for F-gas regulations and PFAS restriction

Substance name	F-gas regulations (proposed revisions)	PFAS restriction (Applications Annex A)	Substance name	F-gas regulations (proposed revisions)	PFAS restriction (Applications Annex A)
HFC-23	In scope	Out of scope refrigerants	HFO-1234yf	In scope	Refrigerants
HFC-32	In scope	Out of scope refrigerants	HFO-1234ze(E)	In scope	Refrigerants, foaming agents, propellants
HFC-43-10	In scope	Solvents, heat carriers			
HFC-125	In scope	Refrigerants, fire suppressing agents	HFO-1336mzz(E)	In scope	Refrigerants
HFC-134a	In scope	Refrigerants, foaming agents, propellants	HFO-1336mzz(Z)	In scope	Foaming agents, propellants, solvents
HFC-143a	In scope	Refrigerants (blends)	HCFO-1224yd	In scope	Refrigerants
HFC-152a	In scope	Out-of-scope: foaming agents, propellants	HCFO-1224yd(Z)	In scope	Refrigerants, foaming agents, solvents
HFC-227ea	In scope	Foaming agents, fire suppressing agents	HCFO-1233zd(E)	In scope	Refrigerants, foaming agents, solvents
HFC-236fa	In scope	Fire suppressing agents	HFOs blends with HFCs	In scope	Refrigerants
HFC-245fa	In scope	Refrigerants, foaming agents, solvents			
HFC-365mfc	In scope	Foaming agents, solvents	PFCs	In scope	Solvents, heat carriers
HFC blends	In scope	Refrigerants	PFPEs	In scope	Solvents, heat carriers
HFO-1132a	In scope	Out of scope refrigerants	HFES	In scope	Solvents, heat carriers

F-gas related regulations in the proposed PFAS restriction

F-gas applications	12-year derogation	5-year derogation	12-year derogation under consideration	5-year derogation under consideration	Full ban after 18 months
Refrigerants for automobiles	Refrigerants for military vehicles	1) Refrigerants for automotive air conditioners for gasoline engine vehicles 2) Refrigerant for transportation equipment other than for marine applications			Automotive air conditioners for non-combustion engine vehicles (EVs)
HVAC refrigerants	1) Refrigerant for centrifugal refrigeration equipment 2) Refrigerants for research/test/measurement equipment 3) Refrigerant for replenishing existing HVAC&R equipment	1) Refrigerant used in equipment for low temperatures (below -50°C) 2) Refrigerant for transportation equipment other than for marine applications			<ul style="list-style-type: none"> Automotive air conditioners for non-combustion engine vehicles (EVs) Home and commercial air conditioners Commercial refrigeration equipment (temperature range above -50°C)
Propellants	1) Propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required 2) Coatings of the inside of Metered Dose Inhalers (MDIs) for pharmaceuticals				Metered Dose Inhalers (MDIs) for pharmaceuticals
Foaming agents				PU spray foam (work floor foaming of buildings)	<ul style="list-style-type: none"> PU board stock (factory-produced board-shaped insulation) PU integral skin foam (factory-produced cushioning material) Extruded polystyrene foam (factory-produced board-like insulation) Phenolic foam (factory-produced insulation)
Solvents and cleaning agents	1) Industrial precision cleaning applications 2) Cleaning oxygen environments		3) 3D printing applications 4) Preservation of cultural paper-based materials 5) Cleaning medical equipment and heat carriers 6) Semiconductor manufacturing process heat carriers		<ul style="list-style-type: none"> Carriers such as lubricants Adjustments of grease and other Experiment media, etc. Other

F-gas related regulations in the proposed PFAS restriction

F-gas applications	12-year derogation	5-year derogation	12-year derogation under consideration	5-year derogation under consideration	Full ban after 18 months
Refrigerants for automobiles	Refrigerants for military vehicles	1) Refrigerants for automotive air conditioners for gasoline engine vehicles 2) Refrigerant for transportation equipment other than for marine applications			Automotive air conditioners for non-combustion engine vehicles (EVs)
HVAC refrigerants	1) Refrigerant for centrifugal refrigeration equipment 2) Refrigerants for research/test/measurement equipment 3) Refrigerant for replenishing existing HVAC&R equipment	1) Refrigerant used in equipment for low temperatures (below -50°C) 2) Refrigerant for transportation equipment other than for marine applications			<ul style="list-style-type: none"> Automotive air conditioners for non-combustion engine vehicles (EVs) Home and commercial air conditioners Commercial refrigeration equipment (temperature range above -50°C)

2. Refrigerants for automobiles

Proposed restriction: 12-year derogation after 18-month transition period

1) Refrigerants for military vehicles

Five national authorities' opinion: Strong evidence of no alternatives

Response to proposed restriction: Special treatment of out of scope or time-unlimited derogation

Point of appeal:

- Safety and toxicity concerns
- Concerns about deterioration in energy efficiency
- Prolonged development and increased costs to reconvert to alternatives outside of PFAS, despite current transition to lower GWP alternatives at this time

2. Refrigerants for automobiles

Proposed restriction: 5-year derogation after 18-month transition period

- 2) Refrigerants for automotive air conditioners for gasoline engine vehicles
 - 3) Refrigerant for transportation equipment other than for marine applications
- Refrigerants for automotive air conditioners for non-gasoline vehicles (EVs) will be banned in 18 months?

Five national authorities' opinion: Strong evidence of alternatives

Response to proposed restriction: Special treatment of out of scope or time-unlimited derogation

Point of appeal:

- Safety and toxicity concerns
- Concerns about deterioration in energy efficiency
- While the transition to lower GWP alternative refrigerants has not been completed at this time, the derogation period for the development of products compliant with this restriction is short.
- Development is time-consuming and costly due to of the wide variety of transportation refrigeration equipment that play a part in the cold chain.

2. Refrigerants for automobiles

Proposed restriction: Full ban after 18-month transition period

- 4) Automotive air conditioners for non-combustion engine vehicles (EVs)

Five national authorities' opinion: Strong evidence that alternatives are already available

Response to proposed restriction: Special treatment of out of scope or time-unlimited derogation

Point of appeal:

- Safety and toxicity concerns
- Concerns about deterioration in energy efficiency
- CO₂ as an alternative increases system weight due to high pressure conditions
- Prolonged development and increased costs to reconvert to alternatives outside of PFAS, despite current transition to lower GWP alternatives at this time

F-gas related regulations in the proposed PFAS restriction

F-gas applications	12-year derogation	5-year derogation	12-year derogation under consideration	5-year derogation under consideration	Full ban after 18 months
Refrigerants for automobiles	Refrigerants for military vehicles	1) Refrigerants for automotive air conditioners for gasoline engine vehicles 2) Refrigerant for transportation equipment other than for marine applications			Automotive air conditioners for non-combustion engine vehicles (EVs)
HVAC refrigerants	1) Refrigerant for centrifugal refrigeration equipment 2) Refrigerants for research/test/measurement equipment 3) Refrigerant for replenishing existing HVAC&R equipment	1) Refrigerant used in equipment for low temperatures (below -50°C) 2) Refrigerant for transportation equipment other than for marine applications			<ul style="list-style-type: none"> • Automotive air conditioners for non-combustion engine vehicles (EVs) • Home and commercial air conditioners • Commercial refrigeration equipment (temperature range above -50°C)

3. HVAC refrigerants

Proposed restriction: 12-year derogation after 18-month transition period

- 1) Refrigerant for centrifugal refrigeration equipment
- 2) Refrigerants for research/test/measurement equipment
- 3) Refrigerant for replenishing existing HVAC&R equipment

Five national authorities' opinion: Strong evidence of no alternatives

Response to proposed restriction: Special treatment of out of scope or time-unlimited derogation

Point of appeal:

- Safety and toxicity concerns
- Concerns about deterioration in energy efficiency
- Longer development time due to significant changes in pressure conditions of alternative refrigerants compared to conventional refrigerants
- Prolonged development and increased costs to reconvert to alternatives outside of PFAS, despite current transition to lower GWP alternatives at this time

3. HVAC refrigerants

Proposed restriction: 5-year derogation after 18-month transition period

- 4) Refrigerant used in equipment for low temperatures (below -50 °C)
- 5) Refrigerant for transportation equipment other than for marine applications

Five national authorities opinion: Strong evidence of low potential for alternatives

Response to proposed restriction: Special treatment of out of scope or time-unlimited derogation

Point of appeal:

- Safety and toxicity concerns
- Concerns about deterioration in energy efficiency
- No alternatives to lower GWP have been established at this time
- Prolonged development of alternative products and increased costs due to the demand for equipment with a small quantity and variety of products.

3. HVAC refrigerants

Proposed restriction: Full ban after 18-month transition period

Concern that many uses are not be listed as a special treatment

- Automotive air conditioners for non-combustion engine vehicles (EVs)
- Home and commercial air conditioners
- Commercial refrigeration equipment (temperature range above -50°C)
- Industrial refrigeration and air-conditioning equipment excluding turbo refrigerators

Five national authorities' opinion: Strong evidence that alternatives are already available

Recognition that there are safety issues with substituting hydrocarbon refrigerants for residential air conditioners

Recognition that hydrocarbons, ammonia, and CO₂ can be alternatives in the commercial air conditioning and industrial equipment sectors

Response to proposed restriction: Special treatment of out of scope or time-unlimited derogation

Point of appeal:

- Safety and toxicity concerns
- Concerns about deterioration in energy efficiency
- Longer development time due to significant changes in pressure conditions of alternative refrigerants compared to conventional refrigerants
- Prolonged development and increased costs to reconvert to alternatives outside of PFAS, despite current transition to lower GWP alternatives at this time

F-gas related regulations in the proposed PFAS restriction

F-gas applications	12-year derogation	5-year derogation	12-year derogation under consideration	5-year derogation under consideration	Full ban after 18 months
Refrigerants for automobiles	Refrigerants for military vehicles	1) Refrigerants for automotive air conditioners for gasoline engine vehicles 2) Refrigerant for transportation equipment other than for marine applications			Automotive air conditioners for non-combustion engine vehicles (EVs)
HVAC refrigerants	1) Refrigerant for centrifugal refrigeration equipment 2) Refrigerants for research/test/measurement equipment 3) Refrigerant for replenishing existing HVAC&R equipment	1) Refrigerant used in equipment for low temperatures (below -50°C) 2) Refrigerant for transportation equipment other than for marine applications			<ul style="list-style-type: none"> • Automotive air conditioners for non-combustion engine vehicles (EVs) • Home and commercial air conditioners • Commercial refrigeration equipment (temperature range above -50°C)
Propellants	1) Propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required 2) Coatings of the inside of Metered Dose Inhalers (MDIs) for pharmaceuticals				Metered Dose Inhalers (MDIs) for pharmaceuticals

4. Propellants

Proposed restriction: 12-year derogation after 18-month transition period

- 1) Propts for technical aerosols for applications where non-flammability and high technical performance of spray quality are required
- 2) Coatings of the inside of Metered Dose Inhalers (MDIs) for pharmaceuticals

Five national authorities' opinion: Strong evidence of no alternatives

Response to proposed restriction: Special treatment of out of scope or time-unlimited derogation

Point of appeal (examples):

- Is it reasonable to ban use for a specified time limits, even though there are no alternatives due to safety concerns, which is also stated in the proposed restriction?
- This restriction may have a negative impact on the environment due to the suspension of the current development of alternatives to lower GWP.

4. Propellants

Proposed restriction: Full ban after 18-month transition period or 12-year derogation after 18-month transition period

3) Metered Dose Inhalers (MDIs) for pharmaceuticals

- A time-unlimited special treatment has been specified for active pharmaceutical ingredients.
- Special treatments allowing a 12-year derogation after a 18-month transition period for coatings of the inside of Metered Dose Inhalers
- There is no clear description of the derogation period for “propellant” in MDI applications, and it is not clear whether it is to be fully banned after the 18-month transition period or to be regarded as a special treatment of 12-year derogation period after the 18 month transition period as a general propellant.

Five national authorities’ opinion: Strong evidence of alternatives for MDI propellants

Response to proposed restriction: Special treatment of out of scope or time-unlimited derogation

Point of appeal (examples):

- As stated in the proposed restriction Annex, high safety aspects are required for pharmaceuticals. Therefore, similar safety is required for propellants for MDI applications.
- Substitution of “dry powder type” is not a complete alternative for MDI applications. It is unreasonable to eliminate the use of propellants for MDI in the current situation where alternatives has not been established.

F-gas related regulations in the proposed PFAS restriction

F-gas applications	12-year derogation	5-year derogation	12-year derogation under consideration	5-year derogation under consideration	Full ban after 18 months
Foaming agents				PU spray foam (work floor foaming of buildings)	<ul style="list-style-type: none"> • PU board stock (factory-produced board-shaped insulation) • PU integral skin foam (factory-produced cushioning material) • Extruded polystyrene foam (factory-produced board-like insulation) • Phenolic foam (factory-produced insulation)

5. Foaming agents

Proposed restriction: **Consideration of 5-year derogation** after 18-month transition period

1) PU spray foam (work floor foaming of buildings)

Five national authorities' opinion: Weak evidence of no alternatives
(In view of flammability risk, the use of hydrocarbons is not permitted in work floor foaming applications)

Response to proposed restriction: Special treatment of out of scope or time-unlimited derogation

Point of appeal:

- Safety (**can reduce fire risk, especially in work floor use**)
- Excellent insulation performance (good energy efficiency)
- PU foam thickness can be reduced (increase available space)

⇒ **Non-PFAS alternatives (such as hydrocarbons) fail to offer both of the advantages of F-gas safety and insulation performance.**

5. Foaming agents

Proposed restriction: **Full ban** after 18-month transition period

* **There are many uses for which there is no derogation period**

- 2) PU board stock (factory-produced board-shaped insulation)
- 3) PU integral skin foam (factory-produced cushioning material)
- 4) Extruded polystyrene foam (factory-produced board-like insulation)
- 5) Phenolic foam (factory-produced insulation)

Five national authorities' opinion: Sufficiently strong evidence of alternatives (view that some markets are moving away from F-gas use)

Response to proposed restriction: Special treatment of out of scope or time-unlimited derogation

Point of appeal:

- **Safety aspects (Fire risk in work floor, product combustibility)**
- Excellent insulation performance (good energy efficiency)
- Insulation thickness can be reduced (increase available space)

⇒ **It would be useful to quantitatively compare the performance of F-gas and non-PFAS alternatives and submit a consultation that F-gas is indispensable as a foaming agent.**

F-gas related regulations in the proposed PFAS restriction

F-gas applications	12-year derogation	5-year derogation	12-year derogation under consideration	5-year derogation under consideration	Full ban after 18 months
Solvents and cleaning agents	<ol style="list-style-type: none"> 1) Industrial precision cleaning applications 2) Cleaning oxygen environments 		<ol style="list-style-type: none"> 3) 3D printing applications 4) Preservation of cultural paper-based materials 5) Cleaning medical equipment and heat carriers 6) Semiconductor manufacturing process heat carriers 		<ul style="list-style-type: none"> • Carriers such as lubricants • Adjustments of grease and other • Experiment media, etc. • Other

6. Solvents and cleaning agents

Proposed restriction: 12-year derogation after 18-month transition period

- 1) Industrial precision cleaning applications
- 2) Cleaning oxygen environments

Five national authorities' opinion: Strong evidence of no alternatives

Response to proposed restriction: Special treatment of out of scope or time-unlimited derogation

Point of appeal (examples):

- Advances in miniaturization technology and difficulty in achieving equivalent or better performance with alternative technologies
- Proof of resource consumption (such as water) and increased energy consumption by alternative technologies
- Status of waste management after use

6. Solvents and cleaning agents

Proposed restriction: Consideration of 12-year derogation after 18-month transition period

- 3) 3D printing applications
- 4) Preservation of cultural paper-based materials
- 5) Cleaning medical equipment and heat carriers
- 6) Semiconductor manufacturing process heat carriers

Five national authorities' opinion: Weak evidence of no alternatives

Response to proposed restriction: Special treatment of out of scope or time-unlimited derogation

Point of appeal (examples):

- Performance comparison data with considered alternatives
- Performance requirements in the use cases and the reasons for them
- Non-repeatability data for other substances of the specificity of fluorine compounds in physical properties
- Status of waste management after use

6. Solvents and cleaning agents

Proposed restriction: Full ban after 18-month transition period

- 7) Carriers such as lubricants
- 8) Adjustments of grease and other
- 9) Experiment media, etc.
- 10) Others (Uses not listed in proposed restriction text, ANNEX A)

Five national authorities opinion: Non-definitive basis or no basis

Response to proposed restriction: Special treatment of out of scope or time-unlimited derogation

Point of appeal (examples):

- Performance comparison data for fluorine lubricants, etc.
- Comparative data of other materials in affinity with fluorinated materials
- Performance comparison data with considered alternatives
- Performance requirements in the use cases and the reasons for them
- Non-repeatability data for other substances of the specificity of fluorine compounds in physical properties
- Status of waste management after use

7. Summary F-gas Related

Confirmation for use exclusion items and seeking derogation

Existence of information on application sectors (proposed restriction body text, ANNEX A)

→ Evaluation of alternatives and derogation period

(1) Not mentioned (e.g. fire extinguishing agents)

- If there is no mention because it was not submitted in the previous year's CfE...
 - Provide information on what is being used, for what functions, the size of the market, etc.
- In the case, of submitted as information but there are no comments...
Further quantify and resubmit information already submitted → May remain overlooked

(2) There are comments

- If there is no derogation period...

It is determined that alternatives can be used after the transition period.

→ Stress the difficulty of assumed alternatives

- Derogation period of 5 years under consideration
 - Provision of quantitative information on problems with alternatives
- Derogation period of 12 years is under consideration
 - Provision of information on difficulties in developing alternatives (technical and use cases)
- 5-year derogation period → Provision of quantitative information on problems with alternatives
- 12-year derogation period → Are alternatives/technology development and use possible within the derogation period

3. EU REACH PFAS Restriction Proposal: Response to Consultation

**Presenter: Daikin Industries, Ltd.
Chemical Business Unit,
Planning Department**

3. EU REACH PFAS restriction proposal: Response to consultation

- (1) What is consultation?
- (2) Submission steps and past examples of consultations
- (3) Specific case proposals for this submission
- (4) Future schedule

Note: This webinar presentation is prepared for the purpose of making it easier for participants to understand the official PFAS restriction proposal, which will be published on March 22, 2023 and the consultation briefing (Web) to be held on April 5. Please refer to the above materials for exact details.

3. EU REACH PFAS restriction proposal: Response to consultation

(1) What is consultation?

A public consultation (public comments) can be submitted by any individual, company, or organization. The public comments and opinions of the European Chemicals Agency (ECHA)'s two committees will be compiled to form the restriction proposal.

Phase 1: Preparation and submission of the restriction proposal

Restriction proposals are prepared by the proposing countries and submitted to the EU Chemicals Agency (ECHA)
ECHA confirms the contents.

Phase 2: Consultation and deliberations

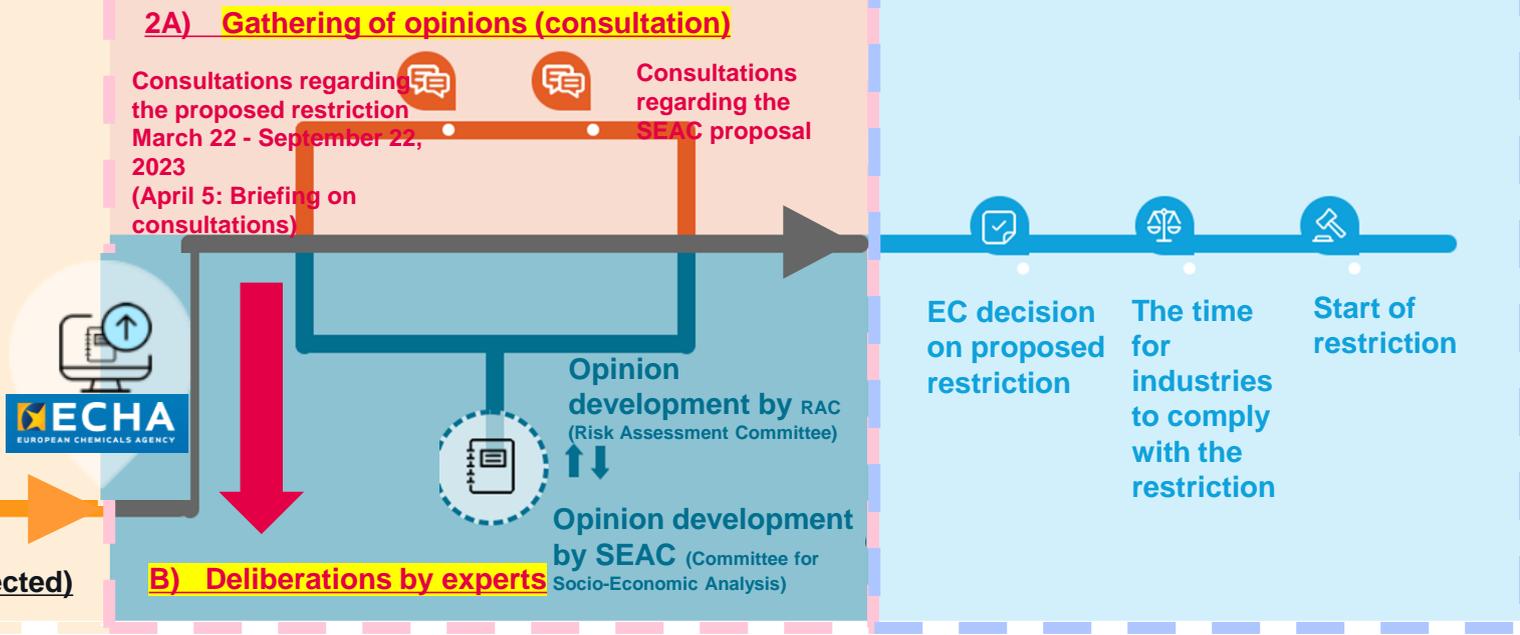
Deliberations at ECHA will be carried out in parallel with the consultations.

Phase 3: Legal decision and preparation of restriction

A period of preparation before the content of the legislation is decided and restriction begins.

Starting the REACH restriction process

- Registration of intention to submit a proposed restriction
July 15, 2021
- Preparation of proposed restriction
- Submission of restriction proposal
January 13, 2023 (Submitted)
- After conformity check
February 7, 2023 (Pre-publication)
- After conformity check
March 22, 2023 (Official publication expected)



Progress in PFAS restriction

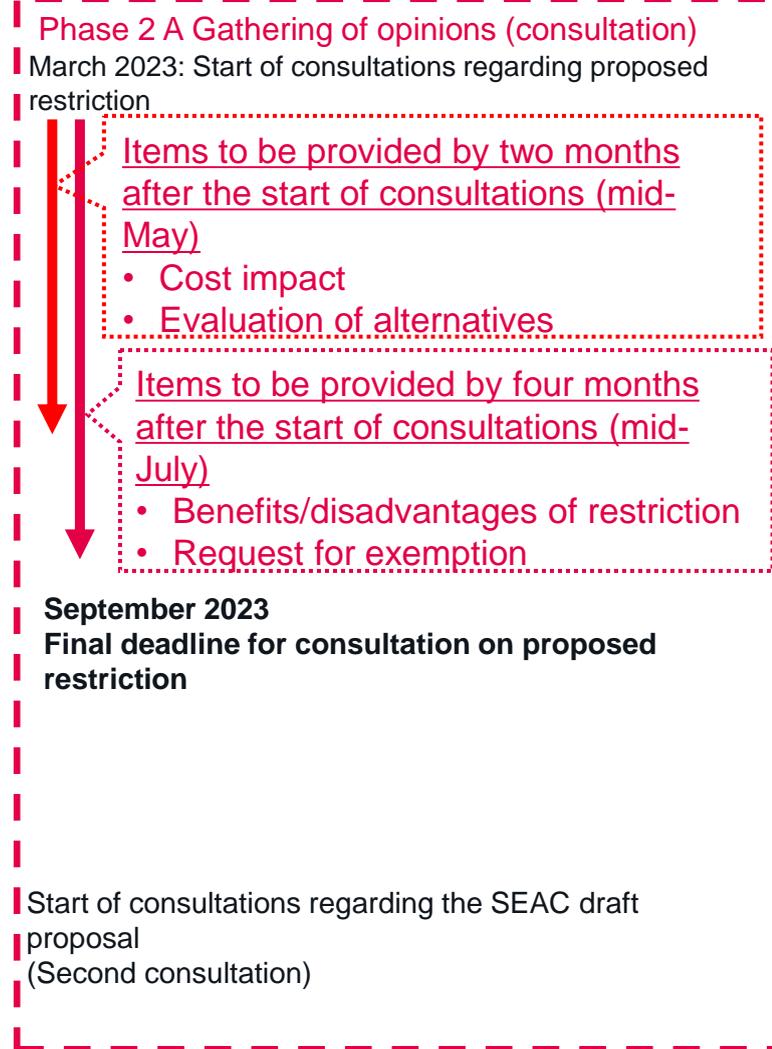
Reference: <https://echa.europa.eu/restriction-process>

3. EU REACH PFAS restriction proposal: Response to consultation

(1) What are public consultations? Planned deliberations by the expert committees and timing for submission of consultations

We recommend that the first round of consultations be submitted by June, when both committees begin their discussions.

Phase 2(B): Deliberations by experts		
Committee	Risk Assessment Committee (RAC)	Committee for Socio-economic Analysis (SEAC)
Convocation timing		
2023 June	<ul style="list-style-type: none"> Verifying the scope of proposed restriction Hazard conclusions and preliminary discussion of exposure/risk 	<ul style="list-style-type: none"> Verifying the scope of proposed restriction Cost impact to industry of the proposal Impact conclusions and preliminary discussion of benefits
September	<ul style="list-style-type: none"> Conclusions on exposure/risk Preliminary discussion on exemptions 	<ul style="list-style-type: none"> Conclusions on the benefits of restriction Preliminary discussion on exemptions
November	<ul style="list-style-type: none"> Conclusions on exemptions Decision on the written arguments and statement of reasons, and adoption of the final opinion. 	<ul style="list-style-type: none"> Agreement on exemptions Decision on written arguments and statement of reasons and agreement on SEAC draft proposal
		<ul style="list-style-type: none"> Publication of SEAC draft proposal
	Not applicable	<ul style="list-style-type: none"> Discussion of the issues presented in the consultations on the SEAC draft proposal and adoption of final opinion



<https://echa.europa.eu/documents/10162/9cb3c4f8-c2d9-c1dd-9a91-65dbb020f95a>

3. EU REACH PFAS restriction proposal: Response to consultation

(1) What is consultation?

■ Handling of submitted consultations

It is used in the deliberations of the Risk Assessment Committee (RAC) and the Committee for Socio-Economic Analysis (SEAC), which are expert committees of ECHA (European Chemicals Agency). **Both committees will develop their opinions as ECHA based on the proposed restriction and the consultations received.**

Risk Assessment Committee (RAC): Consolidates opinions on whether the proposed restriction is appropriate to reduce risks to human health and the environment

Committee for Socio-Economic Analysis (SEAC): Consolidates opinions on the socioeconomic impacts associated with the proposal, i.e., benefits and costs to society

Consultations and committees' responses to consultations

Risk Assessment Committee opinions

Committee for Socio-Economic Analysis opinions

Consultations on the Committee for Socio-Economic Analysis proposal

PFHxA case Reference: [Registry of restriction intentions until outcome - ECHA \(europa.eu\)](https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e18323a25d) ;
<https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e18323a25d>

3. EU REACH PFAS restriction proposal: Response to consultation (1) What is consultation?

■ Risks of not submitting consultations

Generally, it is said that not providing an opinion is an admission by the individual company/organization that they accept the proposed restriction.

(Alternatives, rebuttal to derogation periods, and description of uses not listed are required)

In some cases, they may also ask for individual opinions from those who submit consultations, which means that they will not be on the negotiating table. **Therefore, it is important to have written arguments from both the individual companies and the industry organizations.**

■ Examples of successful consultations so far

As for the restrictions on PFOA and C9-14, **the opinions of industry have been adopted** and exemptions have been obtained for each.

* Detailed information is provided as a basis for submitting a written opinion.

3. EU REACH PFAS restriction proposal: Response to consultation

- (1) What is consultation?
- (2) Submission steps and past examples of consultations**
- (3) Specific case proposals for this submission
- (4) Future schedule

Note: This webinar presentation is prepared for the purpose of making it easier for participants to understand the official PFAS restriction proposal, which will be published on March 22, 2023 and the consultation briefing (Web) to be held on April 5. Please refer to the above materials for exact details.

3. EU REACH PFAS restriction proposal: Response to consultation (2) Submission steps and past examples of consultations

■ Steps for submitting consultations

1. Understanding and evaluation of the proposed restriction: Accurate understanding and evaluation based on the original text.

URL:ECHA (European Chemicals Agency)

Reference: Registry of restriction intentions until outcome - ECHA (europa.eu)

<https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b>

2. Extracting objections to the proposed restriction from the application and technical information of each company or organization

After that, gather evidence for opinions to be expressed and prepare a framework for consultations.

3. Check the site where you can submit your consultation to see how to submit it (ECHA's site).

March 22: URL for submissions published April 5: Check with instructions on how to submit consultation (Web)

(The latest information will be posted on the FCJ website as it becomes available.)

Based on the outline to be commented on, prepare the document to be entered in accordance with the guidelines of the site to be submitted.

4. Access the URL for submission and enter the information online. (Avoid the day of the first submission deadline in mid-May, **due to the high concentration of access.**)

Submit the opinion content that may be made public, or submit the opinion content as confidential information, separately (follow the instructions on how to submit the information).

Precaution: Be aware of the character limit when filling out the form within the frame of the submission site.

(Entering more than the character limit won't be accepted.)

PDF files can also be submitted as attachments (usually indicated as attachable at the end of the online form).

3. EU REACH PFAS restriction proposal: Response to consultation (2) Submission steps and past examples of consultations

■ Introduction of past cases

A. Example of publication of submitted consultation

- Proposed PFHxA restriction

URL: Registry of restriction intentions until outcome - ECHA (europa.eu)

<https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e18323a25d>

Consultation field: Comments on Annex XV report File name: RCOM, RCOM Part 2-5 (5 files)

- Published consultations on proposed PFAS restriction for fire suppressing foam applications

URL: Registry of restriction intentions until outcome - ECHA (europa.eu)

<https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e1856e8ce6>

Consultation field: Comments on Annex XV report File name: RCOM (110 pages in total)

- Published consultations of proposed BPA (Bisphenols A) restriction

URL: Registry of restriction intentions until outcome - ECHA (europa.eu)

<https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e1853413ea>

Consultation field: Comments on Annex XV report File name: RCOM (194 pages in total)

B. Example of site for input

- For proposed BPA (Bisphenols A) restriction (Consultation period: January 25-June 22, 2023)

URL: Submitted restrictions under consideration - ECHA (europa.eu)

<https://www.echa.europa.eu/web/guest/restrictions-under-consideration/-/substance-rev/71401/term>

Submission field: Consultation on restriction report Click field: Give Comments

Move to input screen after clicking → URL: ECHA Website

https://comments.echa.europa.eu/comments_cms/AnnexXVRestrictionDossier.aspx?RObjctId=0b0236e1881acad7

➔ The screens will be explained in the following sections.

3. EU REACH PFAS restriction proposal: Response to consultation (2) Submission steps for consultation and past examples (Example of submission screen: BPA)

Submitted restrictions under consideration

This table shows ongoing consultations on conforming restriction proposals and SEAC draft opinions; the links to the web forms for submitting comments to ECHA during the relevant consultations can be found by clicking on details. For consultations on conforming restriction proposals, two deadlines are given; comments submitted by the first deadline are often very influential as they will be considered in the first discussion on the proposed restriction and more substantial comments should be submitted at the latest 1 month before the final deadline.

Please note: the ECHA Committees will not take into account the comments received after the final deadline in their opinion making process.

Consultations close at 23:59 Helsinki time (EET).

[Restriction](#)

[Adopted opinions on Registry of restriction intentions until outcome](#)

[Consultation guidance](#)

[Substance Details](#)

Name	4,4'-isopropylidenediphenol (Bisphenol A) as well as other bisphenols and bisphenol derivatives with endocrine disrupting properties for the environment
EC Number	-
CAS Number	-
Submitted by	Germany
Scope	Restricting the placing on the market of mixtures and articles where concentration is equal to or greater than 10 ppm (0.001 % by weight). The first condition shall not apply to mixtures and articles where the bisphenols in the scope of the restriction are either covalently bound to any type of matrix (e.g. via functioning as a cross-linker) or are used as intermediates in the manufacture of polymers, and for which <ul style="list-style-type: none"> i. contact to aqueous media in any form can be excluded during their reasonable and foreseeable use throughout their service life or ii. the migration limit in the respective mixtures and articles does not exceed 0.04 mg/L over the entire service life.
Information note on restriction report	
Restriction report	Annex XV report
Restriction report annexes	Annex Annex H
Consultation on restriction report	Give Comments
Start of consultation on Annex XV report	21/12/2022

Click here

3. EU REACH PFAS restriction proposal: Response to consultation

(2) Submission steps for consultation and past examples

(Example of submission screen: BPA)

Comments for Annex XV restriction report

Substance name

Bisphenols with endocrine disrupting properties for the environment and their salts

EC Number

-

CAS Number

-

Scope

Restricting the placing on the market of mixtures and articles where concentration is equal to or greater than 10 ppm (0.001 % by weight).

The first condition shall not apply to mixtures and articles where the bisphenols in the scope of the restriction are either covalently bound to any type of matrix (e.g. via functioning as a cross-linker) or are used as intermediates in the manufacture of polymers, and for which

- i. contact to aqueous media in any form can be excluded during their reasonable and foreseeable use throughout their service life or
- ii. the migration limit in the respective mixtures and articles does not exceed 0.04 mg/L over the entire service life.

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 to assist them in the development of their opinions. Although other information can be submitted, any abusive comments will not be published monthly and only published at the end of the process without any response from the Dossier Submitter or the Rapporteurs.

Where did you learn about this consultation? (please select all that apply):*

- ECHA
- European Commission
- National Authorities
- Social media
- Industry organisation
- NGOs and trade unions
- Press
- Other (please specify)

3. EU REACH PFAS restriction proposal: Response to consultation

(2) Submission steps for consultation and past examples

(Example of submission screen: BPA)

SECTION I. Personal information

We may contact you about your comment and to request additional information.

Information on submitter

* First Name :

* Family Name :

Email: *

* Country :

Phone :

Any personal data submitted is subject to [ECHA's data privacy rules](#)

SECTION II. Organisation

I am submitting information: *

On behalf of a Member State Competent Authority

As an Individual

On behalf of an organisation or institution

Type of organisation/institution:

Country where the organisation or institution is legally established:

Name of organisation / institution:

Select one of the following options : *

I agree to the disclosure of the name of my organisation/institution to the public

I want to keep the name of my organisation/institution confidential

Note: the type and country of your organisation/institution will always be disclosed.

Submitter affiliation: Company, organization, individual

Selected whether to submit anonymously

3. EU REACH PFAS restriction proposal: Response to consultation

(2) Submission steps for consultation and past examples (Example of submission screen: BPA)

Comments that are not considered confidential (to be published)

SECTION III. Non-confidential comments

It is possible to provide both general comments on the Annex XV restriction report subject to this Consultation and answers to the specific questions posed. In both cases, it is necessary to provide supporting evidence to allow ECHA's Committees to take your comments into account. It is important not to leave the submission of any socio-economic information until the consultation on SEACs opinion but already submit relevant comments at this stage.

General Comments

Select the relevant boxes that cover the content of your comments and provide your non-confidential comments below, (maximum 9 000 characters)

- Scope or restriction option analysis
- Hazard or exposure
- Environmental emissions
- Baseline
- Description of analytical methods
- Information on alternatives
- Information on benefits
- Other socio economic analysis (SEA) issues
- Transitional period
- Request for exemption

* I understand that it is my responsibility not to include confidential information in responses to general comments and in any responses to requests for specific information (e.g. company name, email addresses, phone numbers, signatures etc.). ECHA will not be held liable for any damages caused by making non confidential responses publicly available.

Please provide your general comments in the box below

3. EU REACH PFAS restriction proposal: Response to consultation

(2) Submission steps for consultation and past examples

(Example of submission screen: BPA)

Specific Information Requests

information about specific information

1: Restriction conditions and testing

Do you consider that the restriction conditions (including derogations listed in Appendix Y) and the conditions and methods for migration testing (as described in Annex Z) are clear? Are there conditions that require further clarification? Do you consider that the conditions and methods for migration testing as described in Annex Z are representative to assess migration during the entire article service life? If not, can you propose a more reliable testing?

* Compulsory Fields

- I have information on this topic
- I don't have information on this topic

2: Which analytical methods exist for your sector to test:

- a. the **content** of BPA and BoSC in article or mixtures that are covered in the scope of the restriction
- b. **migration** of bisphenols from your articles, part of articles and/or mixtures?

In your answer, please specify the aim and purpose of the testing (for example, testing in the content or migration testing)

Which solvent do you use to extract BPA and/or BoSC in either content or migration testing?

* Compulsory Fields

- I have information on this topic
- I don't have information on this topic

3: Do you see any challenge in the supply chain communication on the presence of BPA/BoSC in more than 10 ppm of BPA/BoSC and for which contact to water cannot be excluded during its service life (if testing would be required)? Do established methods for the BPA/BoSC content analysis for liquids exist?

* Compulsory Fields

- I have information on this topic
- I don't have information on this topic

Information on alternatives

4: Alternatives

The Dossier Submitter identified different alternatives for the different uses of Bisphenol A and BoSC (e.g. in PVC, thermal paper, hardeners for epoxy resins, polycarbonates, epoxy resins, polysulfones, polyesters, phenolic resins, polyurethanes, vinyl ester resins, polyacrylates, syntans, fluoroelastomers). These are described in section E.2 of the Appendix. Do you agree with the Dossier Submitter's conclusion regarding the availability of alternatives? Do you have additional information on alternatives that should be considered as part of the Impact Assessment.

* Compulsory Fields

- I have information on this topic
- I don't have information on this topic

5: The Dossier Submitter assessed the impacts of the examined restriction options (See Annex E and section 2.4 of the Annex XV report). Please provide additional information on the economic impacts of the proposed restriction. Please consider both the restriction conditions as described in paragraph 1 and 2, as well as the derogations described in Appendix Y. If the derogations are relevant for your sector, please also describe the economic impacts you would expect in case the derogations are removed.

* Compulsory Fields

- I have information on this topic
- I don't have information on this topic

6: Product specific questions

Epoxy resins

For manufacturers or importers of epoxy resins: do you have information on the presence of BPF or BoSC in your products? If BPF or BoSC are present in your products, please can you indicate the concentration, the methods used for the testing and the volumes of epoxy resins produced per year in the EU. Do you have information on the expected growth in demand for epoxy resins in the EU in the next 5 years and more (e.g. up to 20 years)?

* Compulsory Fields

- I have information on this topic

3. EU REACH PFAS restriction proposal: Response to consultation

(2) Submission steps for consultation and past examples (Example of submission screen: BPA)

Information on emissions

9:**Emissions**

During the manufacture of your products or their use, which measures do you employ to minimise the amount of "free" BPA/BosC in them?

* Compulsory Fields

I have information on this topic

I don't have information on this topic

10: Emission estimates are provided in Annexes B8 and H. Please provide any additional information regarding the emission estimates. For example, information on release from the use of hardener as an additive in epoxy resins would be appreciated.

* Compulsory Fields

I have information on this topic

I don't have information on this topic

3. EU REACH PFAS restriction proposal: Response to consultation (2) Submission steps for consultation and past examples (Example of submission screen: BPA)

SECTION IV. Non-confidential attachment

If needed, attach additional non-confidential information (data already provided in section III here. If part of the information is confidential, please use section V to share it

Non-confidential attachment

already provided in section III here. If part of the

Add attachment

Browse

If you would like to submit more than one document, please create a compressed archive where you include all files and upload the compressed file as attachment. Maximum file size is 20 MB.

I have removed/blanked the information I wish to keep/I have claimed confidential from all the attachments in section IV (e.g.: company name, company logo, personal names, email, signatures, other confidential business data). I understand that ECHA will not be held liable for any damages caused by making the attachments publicly available.

Attachment of materials containing confidential information (not to be published)

SECTION V. Confidential Attachment

If needed, attach confidential information below (for example: studies from previous sections here. Confidential information will only be used by

If you upload a confidential attachment, please justify the reasons for confidentiality of the information in the field below. This will facilitate ECHA's work if it receives requests for access to documents.

Upload Confidential Attachment:

Add attachment

Browse

If you would like to submit more than one document, please create a compressed archive where you include all files and upload the compressed file as attachment. Maximum file size is 20 MB.

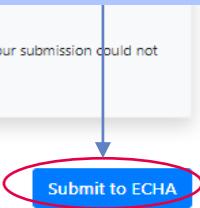
I have the following reasons enumerated in Article 4(1) or 4(2) of Regulation (EC) No 1049/2001 regarding public access to documents why the information submitted as confidential cannot be disclosed to persons requesting access to documents (please explain below in the commenting field those reasons; a reason could be that the protection of your commercial interests, including intellectual property, would be undermined).

No confidential information of any kind should be included:

私はロボットではありません
 reCAPTCHA
 プライバシー・利用規約

Submit from here

1. After the interested party would submit the information he/she would get an automatic reply that the information was successfully submitted.
2. If the user has not filled in the mandatory fields indicated above the IT system displays the user an error message stating 'Please fill in ALL mandatory fields in 'Identification of the party submitting information'. Your submission could not be retrieved due to data lacking from these fields'.
3. If all comment fields are empty and no file is attached, submission should not be possible and there should be an error message: "One comment or one attachment should be provided as a minimum."



3. EU REACH PFAS restriction proposal: Response to consultation

- (1) What is consultation?
- (2) Submission steps and past examples of consultations
- (3) Specific case proposals for this submission**
- (4) Future schedule

Note: This webinar presentation is prepared for the purpose of making it easier for participants to understand the official PFAS restriction proposal, which will be published on March 22, 2023 and the consultation briefing (Web) to be held on April 5. Please refer to the above materials for exact details.

3. EU REACH PFAS restriction proposal: Response to consultation

(3) Specific case proposals for this submission

*Note: Please note that this is information prior to the publication of the proposed restriction.

■ Summary of each file of proposed PFAS restriction

Reference :Registry of restriction intentions until outcome - ECHA (europa.eu);

<https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b>

Annex XV report: Proposed restriction (Main text of the restriction, 211 pages in total)

Annex A: Manufacture and uses (Annex, 302 pages in total)

Annex B: Information on hazard and risk (Annex, 699 pages in total)

Annex C: Justification (Annex, no body text)

Annex D: Baseline (Annex, no body text)

Annex E: Impact assessment (Annex, 534 pages in total)

Annex F: Assumptions, uncertainties and sensitivities (Annex, 17 pages in total)

Annex G: Stakeholder information (Annex, 11 pages in total)

Appendix E4: Attachments to Annex E Publications related to the analysis by application and information description of analytical methods.

Appendix G1: Recruitment materials for the first round of information collection on PFAS restriction (past materials)

Appendix G2: Recruitment materials for the second round of information collection on PFAS restriction (past materials)

The screenshot shows the ECHA website interface. At the top, there is a navigation menu with 'LEGISLATION', 'CONSULTATIONS', 'INFORMATION ON CHEMICALS', and 'SUPPORT'. Below the menu, the page title is 'Registry of restriction intentions until outcome'. The main content area contains text explaining the registry and providing information on how to follow the progress of a proposal. On the right side, there is a 'SEE ALSO' section with links to 'Submitted restrictions under consideration', 'Substances restricted under REACH', and 'Support on restriction'. At the bottom of the page, there is a list of documents for download, including Annex A through G, Appendix E4, Appendix G1, Appendix G2, and the Annex XV report.

3. EU REACH PFAS restriction proposal: Response to consultation (3) Specific case proposals for this submission

Information submitted in the first round of consultations (**past examples**)

- After the submission of the proposed PFAS restriction, the following request for information will be posted on the aforementioned [Information note on restriction report](#).
- **Information in bold is particularly difficult for fluorine manufacturers to respond to because it includes specific details and confidential information**
- **Provision of information from all users of PFAS products is important**

Specific request for information under proposed PFHxA restriction

- 1) Other application information
- 2) PFHxA discharge from polymers
- 3) Information on the textile sector
- 4) **Information on the coatings sector**
- 5) **Information on fire suppressing agent sector**
- 6) **Information for other uses, including the consumer sector**
- 7) **Alternative non-fluorinated compounds or alternative technologies**
- 8) **Uses where alternatives are considered to be impossible**
- 9) **Uses where no alternatives is currently available or alternatives will be available in the short- to medium-term**
- 10) **Uses where alternatives are available, but quality or performance degradation is expected**
- 11) **PFAS-based alternative substance information**
- 12) **Information on costs**
- 13) Analysis method

Specific information request on proposed PFAS fire suppressing agent restriction

- 1) Information on the status of alternatives for PFAS fire suppressing agents
- 2) **Is the proposed transition period appropriate for alternative implementation with non-fluorinated fire suppressing agents?**
- 3) Is the Seveso-III Directive appropriate for identifying industrial facilities with a 10-year transition period to non-fluorinated fire suppressing agents?
- 4) **Is the scale of the cost estimate appropriate?**
- 5) Operational conditions and risk management practices that minimize environmental releases and human exposure to PFAS in fire suppressing agents during the transition period
- 6) Cost information for effective PFAS removal treatment in drinking water
- 7) **Number of handheld fire extinguishers set up in the EU**
- 8) Solid information that disproves the hypothesis that PFAS firefighting water is being sent to municipal wastewater treatment plants.
- 9) **Incineration of recovered PFAS suppressing agents and firefighting water**
- 10) **Effectiveness of labeling of firefighting foam containing non-fluorinated compounds**

Confidential information submitted will **only** be disclosed to the EU Commission and the competent authorities of member states.

3. EU REACH PFAS restriction proposal: Response to consultation
- (3) Specific case proposals for this submission

Consultations on content of proposed restriction → Matters necessary for opinion development by the expert committees

Make the rationale scientific and quantitative

- ◆ Existence of technically and economically feasible non-PFAS alternatives
 - Information about alternatives (e.g., existence of alternative technologies or substances)
 - Business impact assessment on each company of in-scope restricted substances and uses
- ◆ Emissions throughout the life cycle, from manufacturing to disposal, and information on their reduction and management
 - Emissions to the environment: (Example: Emissions of PFAS in the use environment during handling of PFAS and after product sales)
- ◆ Widespread socio-economic concerns (e.g., EU Green Deal targets)

3. EU REACH PFAS restriction proposal: Response to consultation (3) Specific case proposals for this submission

■ Concept behind advocacy in consultations [primarily from the perspective of alternatives]

		Regarding alternatives		Advocacy points for consultations	
Transition period 18 months (1.5 years)	No derogation (Transition period only)	Technically and economically feasible alternatives Alternatives are on the market	Lack of information (Weak evidence)	To add more information for stronger evidence	Appeal for extension of derogation duration
		Alternatives exist with 18-month transition period			
Additional derogation period	5 years	Alternatives are available	Alternatives identified or in development stage	Alternatives are not available	Appeal an exemption
			Insufficient quantities on the market or insufficient transition period	Five years is not enough to develop alternatives or for market supply	
12 years	Alternatives are available	Non-PFAS certification and approval cannot be achieved in five years		Alternatives are not available	
		No non-PFAS have been identified		12 years is insufficient to develop alternatives and introduce technology	
Managed by other regulations Standard material for analysis Legal safety standards	Time-unlimited	No alternatives	Lack of information	It is also not available for those listed in the Annexes.	Extension of derogation period (appeal for time-unlimited)

3. EU REACH PFAS restriction proposal: Response to consultation (3) Specific case proposals for this submission

■ Case 1 [Applications and products proposed to be subject to exemption]

Item	Number	Classification	Applications and products	Duration of derogation
5	s	Lubricants	Lubricants used under extreme conditions or required for safe functioning and equipment safety	12 years

[Concept]

[Appeal for an exemption, not a 12-year derogation](#)

[Original text]

< Proposed restriction and main text > “There is no conclusive evidence of the existence of alternatives”

<Annex E.2.14.2.3>

Citing PCTFE and fluorosilicone oil as alternatives to PFAS-based lubricants, it is written, “there is no information on possible alternatives to other PFAS such as these. However, the technical characteristics of PCTFE and fluorosilicone oils are comparable to those of PFPE base oils.” (Annex A.3.15.1).

3. EU REACH PFAS restriction proposal: Response to consultation (3) Specific case proposals for this submission

■ Case 1 PFPE (perfluorinated polyether) as a lubricant

[Proposed content of consultation]

- Annex XV report (main text), Restriction condition 5s, 12-year derogation period proposed for lubricants.
- Annex E.2.14.2.3 lists PCTFE although there is no conclusive evidence for the existence of alternatives. PCTFE still cannot be an alternative for PFPE because it falls under PFAS and is inconsistent with the proposed restriction itself.
- Similarly indicated fluorosilicones are also listed in Annex E.2.14.2.3. Fluorosilicones need to be specified, but is there a limit to what can be defined as non-PFAS?
- Present comparative evaluation data for specific PFPEs in actual use (if any) and non-PFAS fluorosilicone oils by application (e.g., thermal stability, nonflammability, radiation resistance in the operating temperature range, see Annex A.3.15.1)
- Prepare these information as attachments (may be kept confidential or undisclosed)
- For the above reasons, **the alternative candidate technologies/substances are not used as alternatives because of they are PFAS. Or, in practical evaluation, they are not feasible alternatives. Therefore, the proposed 12-year period is also not appropriate and should be exempted from this proposed restriction.**

3. EU REACH PFAS restriction proposal: Response to consultation (3) Specific case proposals for this submission

■ Example 2: Applications and products proposed to be subject to derogation after consultation

Item	Number	Classification	Applications and products	Duration of derogation
5	ee	Semiconductors	Semiconductor manufacturing process	12 years

[Concept]

Because of the wide scope, specific applications should be identified as much as possible, and information on material comparisons according to each performance requirement must be provided. Indicate that there is no alternative, request an exemption, or indicate that a minimum of 12 years is required specifically considering a period to find an alternative .

Original text

< Proposed restriction Item 5 ee > “Semiconductor Manufacturing Process”

<Annex E.2.11.2 > Discussion on availability and quality of information

It is written, “Some alternatives, especially for polymer applications, are already available. However, the parties’ information on the current feasibility of alternatives remains inconclusive. **Some stakeholders agree that users need to analyze all applications in detail and identify less demanding applications where alternatives are sufficient.** Other stakeholders argue that PFAS-based materials are more expensive than available alternatives and, therefore, are used only when essential, and therefore, there is no possibility of substitution.”

3. EU REACH PFAS restriction proposal: Response to consultation (3) Specific case proposals for this submission

■ Case 2 : Semiconductor manufacturing process

[Proposed content of consultation]

- The term semiconductor manufacturing process covers a wide range of applications and should not be included uniformly.
- In the evaluation (with physical property data attached) for comparison with non-PFAS alternatives in ○○ applications, it is estimated that it will lead to a decrease in reliability and a worsening of production yield.
- In addition, the use of non-PFAS alternatives is expected to increase waste (e.g., equipment shutdown and replacement every ○ months, resulting in a ○% decrease in productivity and a ○% increase in cost impact).
- Prepare these information as attachments (may be kept confidential or undisclosed)
- For the above reasons, the candidate alternative technologies/substances should be exempted from the proposed restriction because they are not substitutable due to being PFAS or are not substitutable in practical evaluation. Also, from a disposal perspective, a restriction should not apply because the use of PFAS generally leads to a reduction in waste.

3. EU REACH PFAS restriction proposal: Response to consultation (Reference) Response to each exemption and proposed exemption under consideration

[Applications and products proposed to be subject to derogation]

Item	Number	Classification	Applications and products	In scope for reporting	Points for response	
5	a	Polymerisation aids	polymerisation aids in the production of polymeric PFASs until 6.5 years after EIF. This derogation does not apply to the production of PTFE, PVDF and FKM.		Appeal that polymers are substances of low concern	
5	b	Textiles	textiles used in personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) and (c), until 13.5 years after EIF;	<input type="radio"/>	Appeal for personal protective equipment (PPE) intended to protect the user from the risks specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a), (c), (d), (e), (f), (g), (h) and (l)	
5	c		textiles used in personal protective equipment (PPE) in professional firefighting activities intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) - (m), until 13.5 years after EIF;	<input type="radio"/>		
5	d		impregnation agents for re-impregnation of articles referred to in paragraph 5b and 5c until 13.5 years after EIF;	<input type="radio"/>		
5	e		textiles for the use in filtration and separation media used in high performance air and liquid applications in industrial or professional settings that require a combination of water and oil repellence until 6.5 years after EIF;			Appeal for the lack of alternatives for filtration and separation media used in high performance air and liquid applications in industrial or professional settings that require a combination of water and oil repellence
5	f		Refrigerants	refrigerants in low temperature refrigeration below -50°C until 6.5 years after EIF;		<input type="radio"/>
5	g	refrigerants in laboratory test and measurement equipment until 13.5 years after EIF;		<input type="radio"/>		
5	h	refrigerants in refrigerated centrifuges until 13.5 years after EIF;		<input type="radio"/>		
5	i	maintenance and refilling of existing HVACR equipment put on the market before [18 months after EIF] and for which no drop-in alternative exist until 13.5 years after EIF;		<input type="radio"/>		
5	j	refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives;		<input type="radio"/>		

3. EU REACH PFAS restriction proposal: Response to consultation
 (Reference) Response to each exemption and proposed exemption under consideration

[Applications and products proposed to be subject to derogation] (continued)

Item	Number	Classification	Applications and products	In scope for reporting	Points for response
5	k	Cleaning agents	industrial precision cleaning fluids until 13.5 years after EoF;	<input type="radio"/>	Appeal for the absence of alternatives
5	l		cleaning fluids for use in oxygen-enriched environments until 13.5 years after EoF;	<input type="radio"/>	Appeal for the absence of alternatives
5	m	Fire suppressing agents	clean fire suppressing agents where current alternatives damage the assets to be protected or pose a risk to human health until 13.5 years after EoF;	<input type="radio"/>	Appeal for the absence of alternatives
5	n	Medical equipment	diagnostic laboratory testing until 13.5 years after EoF;	<input type="radio"/>	Appeal for the absence of alternatives
5	o	Additives	additives to hydraulic fluids for antierosion/anti-corrosion in hydraulic systems (incl. control valves) in aircraft and aerospace industry until 13.5 years after EoF;	<input type="radio"/>	Appeal for the absence of alternatives
5	p	Refrigerants	refrigerants in mobile air conditioning-systems in combustion engine vehicles with mechanical compressors until 6.5 years after EoF;	<input type="radio"/>	Please refer to the announcement from the Japan Fluorocarbon Manufacturers Association in Section 2 above.
5	q		refrigerants in transport refrigeration other than in marine applications until 6.5 years after EoF;	<input type="radio"/>	
5	r	Insulating gases	insulating gases in high-voltage switchgear (above 145 kV) until 6.5 years after EoF	<input type="radio"/>	Appeal for the absence of alternatives
5	s	Lubricants	lubricants where the use takes place under harsh conditions or the use is needed for safe functioning and safety of equipment until 13.5 years after EoF;	<input type="radio"/>	Appeal for the absence of alternatives
5	t	Analysis	calibration of measurement instruments and as analytical reference materials.	<input type="radio"/>	— (It is an essential substance for analysis.)

3. EU REACH PFAS restriction proposal: Response to consultation (Reference) Response to each exemption and proposed exemption under consideration

The following potential derogations are marked for reconsideration after the Annex XV report consultation:

Item	Number	Classification	Applications and products	In scope for reporting	Points for response
5	u	Textiles	[textiles for the use in engine bays for noise and vibration insulation used in the automotive industry until 13.5 years after EiT];	項	Appeal for the lack of alternatives as textiles for the use in engine bays for noise and vibration insulation and ignition protection, not limited to the engine bay
5	v	Plating	[hard chrome plating until 6.5 years after EiT];	5	Appeal for the absence of alternatives
5	w	Construction products	[foam blowing agents in expanded foam sprayed on site for building insulation until 6.5 years after EiT];	5	Appeal for the absence of alternatives
5	x	Printing	[industrial and professional use of solvent-based debinding systems in 3D printing until 13.5 years after EiT];	5	Appeal for the absence of alternatives
5	y		[industrial and professional use of smoothing agents for polymer 3D printing applications until 13.5 years after EiT];	5	
5	z	Aerosol	[propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required until 13.5 years after EiT];	5	Appeal for the absence of alternatives
5	aa	Paper	[preservation of cultural paper-based materials until 13.5 years after EiT];	5	Appeal for the absence of alternatives
5	bb	Medical equipment	[cleaning and heat transfer: engineered fluids for medical devices until 13.5 years after EiT];	5	Appeal for the absence of alternatives
5	cc		[membranes used for venting of medical devices until 13.5 years after EiT];	5	Appeal for the lack of alternatives to woven and non-woven medical textiles as specified in Regulation (EU) 2017/745 with minimum performance requirements for hydrostatic heads over 20cm according to EN 13795
5	dd	Refrigerants	[use as refrigerants and for mobile air conditioning in vehicles in military applications until 13.5 years after EiT];	5	Please refer to the announcement from the Japan Fluorocarbon Manufacturers Association in Section 2 above.
5	ee	Semiconductors	[the semiconductor manufacturing process until 13.5 year after EiT].	5	PEEK is cited as an alternative for chip manufacturing, and brominated and chlorinated flame retardants as candidates for fire retardants, but appeal the technical rationale for not being able to use them as alternatives. In relation to other matters, also appeal the technical rationale that no alternative can be made for each use of semiconductors and semiconductor-related equipment.

3. EU REACH PFAS restriction proposal: Response to consultation (Reference) Response to each exemption and proposed exemption under consideration

Item	Number	Classification	Application	In scope for reporting	Points for response
------	--------	----------------	-------------	------------------------	---------------------

By way of derogation, paragraphs 1 and 2 shall not apply to fluoropolymers and perfluoropolyethers for the use in:

6	a	Food	food contact materials for the purpose of industrial and professional food and feed production until 6.5 years after EiF;		Appeal for the technical rationale that silicon, ceramic, stainless steel, or synthetic rubber cannot be alternatives
6	b	Medical equipment	implantable medical devices (not including meshes, wound treatment products, tubes and catheters) until 13.5 years after EiF;	<input type="radio"/>	Appeal for the absence of alternatives
6	c		tubes and catheters in medical devices until 13.5 years after EiF;	<input type="radio"/>	
6	d		coatings of Metered Dose Inhalers (MDIs) until 13.5 years after EiF;	<input type="radio"/>	
6	e	Batteries	proton-exchange membrane (PEM) fuel cells until 6.5 years after EiF;		Appeal for the absence of alternatives
6	f	Petroleum and mining	fluoropolymer applications in petroleum and mining industry until 13.5 years after EiF.	<input type="radio"/>	Appeal for the absence of alternatives

The following potential derogations are marked for reconsideration after the Annex XV report consultation:

6	g	Food	[non-stick coatings in industrial and professional bakeware until 6.5 years after EiF];		Appeal for the technical rationale that silicon, ceramic, or PEEK cannot be alternatives
6	h	Medical devices and related applications (Packaging)	[hernia meshes until 13.5 years after EiF];	<input type="radio"/>	Appeal for the absence of alternatives
6	i		[wound treatment products until 13.5 years after EiF];	<input type="radio"/>	Appeal for lack of alternatives for medical textiles according to EN 13795
6	j		[coating applications for medical devices other than Metered Dose Inhalers until 13.5 years after EIF];	<input type="radio"/>	Appeal for the absence of alternatives
6	k		[Rigid gas permeable contact lenses and ophthalmic lenses until 13.5 years after EiF];	<input type="radio"/>	
6	l		[PCTFE-based packaging for medicinal preparations, medical devices and medical molecular diagnostics until 13.5 years after EIF];	<input type="radio"/>	
6	m		[PTFE in ophthalmic solutions packaging until 13.5 years after EIF];	<input type="radio"/>	
6	n	[packaging of terminally sterilised medical devices until 13.5 years after EIF];	<input type="radio"/>	Appeal for the need for sterilisation as well as packaging	

3. EU REACH PFAS restriction proposal: Response to consultation (Reference) Response to each exemption and proposed exemption under consideration

[Main applications for which a derogation period is not listed]

Item	Number	Classification	Applications and products	Duration of derogation	In scope for reporting	Points for response
		Electronics	Electronic equipment			Strongly appeal for each application that the alternative candidates for sealing materials and wire sheathing indicated in the proposal are not feasible alternatives in terms of performance, and that there are no alternatives for each of the other applications.
			Functional coating (telomers)			Appeal for functional coatings used in electrical and electronic equipment
		Energy	Solar cells, wind energy, nuclear power plant			Appeal for the lack of alternatives for each individual application
		Construction products	Construction membrane materials (e.g., composite curtains with topcoat)			The membrane material that is considered as an alternative in the proposal is described as having issues with service life, so appeal with technical evidence that there is no alternative in relation to service life.
		Construction products	Bearings for bridges and buildings			The proposal specifies steel rollers as an alternative, but appeal with technical evidence that they are functionally not feasible alternatives.
			Construction paint			Appeal for the absence of alternatives
		Refrigerants	Home air conditioning, commercial air conditioning (excluding R32)			Appeal for the absence of alternatives
		Batteries	Piezoelectric films, film capacitors, lithium-ion batteries, rechargeable and non-rechargeable batteries			Appeal for the absence of alternatives
		Chemical industry	Manufacture, storage, and transportation of hazardous materials Liners, pumps, and valves			Paints/coating: SUS lining powder coating PTFE: Tubes, piping, and packing Molten resins: Appeal for the absence of alternatives, including PFA linings, etc.

3. EU REACH PFAS restriction proposal: Response to consultation

- (1) What is consultation?
- (2) Submission steps and past examples of consultations
- (3) Specific case proposals for this submission
- (4) **Future schedule**

Note: This webinar presentation is prepared for the purpose of making it easier for participants to understand the official PFAS restriction proposal, which will be published on March 22, 2023 and the consultation briefing (Web) to be held on April 5. Please refer to the above materials for exact details.

3. EU REACH PFAS restriction proposal: Response to consultation (4) Future schedule

- PFAS restriction proposal submitted
(January 13, 2023)

- PFAS restriction proposal published
(February 7, 2023)

- **Implementation of FCJ webinar**

- **Start of consultations for PFAS restriction proposal**
(Scheduled for March 22, 2023)

- **Deadline for first round of consultation**
(Mid-May 2023: 2 months after start)

- **Deadline for first round of consultation**
(Scheduled for September 22, 2023: 6 months after start)



Our requests to you

* **Express the following opinions in consultations**

- ✓ **Confirmation of the use of fluorine materials in your products**

- **Where and why it is used**
- **Explanation of the technical basis for the characteristics which make alternatives not feasible, together with the socio-economic perspective**

- ✓ **Prioritization of applications**

- **Consideration of the proposal details in consultations**

- ✓ **Advocacy and coordination with domestic organizations**

- ✓ **Collaboration with EU partner organizations**

- ✓ **The key to obtaining exemptions is to provide specific opinions on even the most detailed applications at individual companies.**

Please check ECHA's website for the latest information.

4. Responses to Questions Submitted in Advance

Question: Regarding survey methods for PFAS substances

- * I would like to know if the CAS number for PFAS is publicly available.
- * I would like to know the specific name of the PFAS (e.g., product name, etc.) that is exempted due to its constituent elements.

Response:

No official list of PFAS-related substances has been published. For reference, the OECD and the U.S. EPA have published the lists below.

However, there are some substances for which CAS numbers are not publicly available, so industry and intercompany collaboration is required. We recommend that you first check with the supplier from whom you are purchasing.

- OECD list of PFAS cas numbers - <https://comptox.epa.gov/dashboard/chemical-lists/PFASOECD>
- EPA list of PFAS cas numbers - <https://comptox.epa.gov/dashboard/chemical-lists/pfasmaster>

Question: Regarding PFAS safety

- * I recognize that the persistence of PFAS has become a problem that led to this restriction. Please let me know if there are any other points that are problematic other than persistency based on clear data (bioaccumulation, carcinogenicity, etc.).
- * What are the five EU countries' evaluations of the safety of fluorinated resins?

Response:

Consideration of restriction began with water pollution caused by some substances (e.g., PFOA/PFOS) that are toxic such as bioaccumulation and carcinogenicity. However, if we look at the proposed restriction as a whole, there are many substances for which there is insufficient data. However, due to the persistence (stability) of PFAS, there are concerns about future health impacts due to their high potential for accumulation in the environment, and the restriction of PFAS as a whole was proposed in accordance with the precautionary principle. However, depending on the application, there may not be sufficient discussion of the concept of risk assessment.

Please refer to Annex B for a description of the risk of hazards.

Question: Regarding the analysis method

- * I think the current situation is that there is no established method for analyzing PFAS that is suitable for each product that falls within the scope of PFAS restriction. Is this recognition correct? And if it is, how can we ensure that the concentration is below the standard value?
- * Please refer me to a testing laboratory for PFAS residues.
- * The quantitative analysis method for polymeric PFAS is indicated as total organic fluorine (TOF) analysis, but I am concerned that this may lead to the analysis of fluorine-containing materials. Is it really possible to analyze only PFAS?

Response:

The method of analysis is specified in the partial restriction proposal. Yet as you say, it is difficult to conduct a suitable analysis for each product, so we believe it is better to check the supply chain back upstream. We recommend that you first check with the supplier from whom you are purchasing.

Question: Regarding alternatives

- * What kinds of raw materials are available as alternatives to PFAS?
- * I would like to know, to the extent that it can be disclosed, what fluoropolymer manufacturers think about the prospects for alternative technologies to PFAS, whether they are bright or challenging.

Response:

PFAS are used in a wide variety of applications and there are many different kinds of substances.

In many applications where PFAS is used, no alternatives have been found at this stage, depending on the performance required. Even in applications where alternatives are listed as being available, there are only a very limited number of applications where equivalent alternatives are available, such as those that do not provide the same performance, have a short life cycle, or have high running costs.

Potential alternative raw materials will vary depending on your application and performance, and each should be considered individually.

Question: Regarding restrictions in other countries

- * How will this affect other countries (such as the U.S.) and other regions?
- * Please tell me about developments in the Toxic Substances Control Act (TSCA) and the Stockholm Convention on Persistent Organic Pollutants (POPs), whether to increase the number of PFAS materials to be restricted or to restrict PFAS as a whole, as the EU is doing this time.

Response:

At this stage, we do not know the impact on other countries and regions. We will consider it separately at the next and future webinars and other events. In Europe, as indicated in the EU Chemicals Strategy for Sustainability, the direction is to restrict PFAS applications in the as a whole, while the U.S. federal regulations are expected to focus on individual high-risk groups or a limited number of applications.

Question: Regarding restrictions in Japan

- * What will happen regarding restrictions in Japan?
- * What legal basis or international treaties might be considered if the restrictions were to be extended to the Japanese market?

Response:

The restrictions in Japan will be considered for each law. For example, the POPs Convention requires a risk assessment process based on data for each substance, which is then listed in Annex A, etc. In Japan, it is governed by the Act on the Regulation of Manufacture and Evaluation of Chemical Substances. Under the Act on the Regulation of Manufacture and Evaluation of Chemical Substances, after adoption of the POPs Convention, it is deliberated by the Chemical Substances Evaluation Committee, and then revised and enforced after TBT notification, public comments, etc. are made.

Regarding questionnaires and materials

After the webinar, a questionnaire screen will appear, so if you have any additional questions, please submit them in the question field of the questionnaire.

We plan to provide responses in the form of Q&A to be posted on the FCJ website at a later date.

FCJ may not be able to respond to questions about specific companies. We appreciate your understanding in advance.

Today's materials can be downloaded from FCJ's website.

These webinars material is based on the pre-publication version of the EU PFAS restriction proposal released by ECHA on February 7, 2023. Please note that the proposed restriction is subject to change. Please check the materials to be released by ECHA on March 22, 2023 and respond to the consultation.

Future schedule and a request

FCJ plans to collaborate with related organizations to submit consultations on questions etc. regarding the proposed restriction.

We believe it is better to have individual companies/organizations that are actually using the products to submit consultations on individual applications, rather than the FCJ, so we request that individual companies/organizations submit their own consultations.

We appreciate your understanding.

Thank you for joining us today.