Proposed restriction - Annex XVII entry PFASs (Restriction Option 2)

Column 1 Designation of the substance, of the group of substances or of the mixture	**Column 2** Conditions of restriction
Per- and polyfluoroalkyl substances (PFASs) defined as: Any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it). A substance that only contains the following structural elements is excluded from the scope of the restriction: CF_3-X or X-CF_2-X', where X = -OR or -NRR' and X' = methyl (-CH_3), methylene (-CH_2-), an aromatic group, a carbonyl group (-C(O)-), -OR'', -SR'' or –NR''R'''; and where R/R'/R''/R''' is a hydrogen (-H), methyl (-CH_3), methylene (-CH_2-), an aromatic group or a carbonyl group (-C(O)-).	1. Shall not be manufactured, used or placed on the market as substances on their own; 2. Shall not be placed on the market in: a. another substance, as a constituent; b. a mixture, c. an article 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. 4. By way of derogation, paragraphs 1 and 2 shall not apply to a. active substances in biocidal products within the scope of Regulation (EU) 528/2012 b. active substances in plant protection products within the scope of Regulation (EC) 1107/2009 c. 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

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

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	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 anti-erosion/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. *The following potential derogations are marked for reconsideration after the Annex XV report consultation:* 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];

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

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	affecting the safety of operators, passengers or goods until 13.5 years after EiF]. 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, 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 stricter restrictions set out in this Annex or in other applicable Union legislation.

Explanatory notes

General

For clauses in between brackets ([]) the evidence base is currently too weak to propose them as derogation even though the Dossier Submitters recognize that such a derogation could potentially be warranted. For these 'potential derogations', additional evidence is needed to justify the derogations. After the Annex XV report consultation, the newly submitted information will be reviewed and the evidence base re-assessed, on the basis of which it will be concluded whether the evidence base is strong enough to propose a derogation with an appropriate derogation duration (5 or 12 years after the transition period). In case the evidence base remains weak, no derogation will be proposed.

Column 1 – Substance identity

PFASs form a broad group of substances that include inter alia non-polymeric PFASs like perfluoroalkyl carboxylic acids, perfluorocarbons, perfluoroalkane sulfonic acids and trifluoromethyl substituted substances as well as polymeric PFASs like fluoropolymers, perfluoropolyethers and side-chain fluorinated polymers. All PFASs subject to this restriction proposal are either persistent themselves or degrade to persistent PFASs, except for a few specific PFAS subgroups with combinations of key structural elements for which it can be expected that they will ultimately mineralize in the environment. As they do not form ultimately persistent PFAS arrowheads, these PFAS subgroups are excluded from the scope definition of this restriction proposal. In section 1.1.1, the substance identity and scope are further explained and justified.

Column 2 - Conditions

(1) Paragraph 2:

This paragraph sets the concentration limits above which the use of PFASs in other substances, in mixtures or in articles shall be restricted. Three different concentration limits are proposed.

The first two values (25 ppb for individual PFASs and 250 ppb for the sum of PFASs) refer to a targeted analysis of PFASs contained in another substance, mixture or article, i.e. the measurement of PFASs with an available analytical method for a specific set of substances and quantified against reference standards. The concentration limit for the sum of PFASs (250 ppb) may be calculated from targeted PFAS analysis either analysed directly as sample or after chemical degradation of the sample material. The latter may include degradation products from e.g. side-chain fluorinated polymers.

However, polymeric PFASs as such are not quantified and are therefore not included in the sum value for comparison with this concentration limit.

The third value (50 ppm) shall apply if targeted analysis is not applicable, e.g. in the case of fluoropolymers. In this case, a total fluorine content analysis is used to demonstrate the presence of organic fluorine. As the measured value will also include potential fluorine from sources other than PFASs, it is necessary to differentiate between PFAS and non-PFAS. Hence, if total fluorine exceeds 50 mg F/kg during enforcement analysis, proof for the fluorine measured being part of either PFASs or non-PFASs should be provided to the authorities. The proof could be either supply chain information or based on analysis. The information put forward should be compared with the 50 ppm limit value.

The relationship between mg F/kg sample material and mg PFASs/kg depends on the percentage of F in the molecular structure of PFASs in the sample. How to calculate this transformation is explained in Annex E.4. In the case of e.g. PFOS, 50 mg F/kg corresponds to 77.4 mg PFOS/kg (PFOS consists of 64.6% F).

(2) Paragraph 5

For the uses listed in this paragraph, derogations from paragraphs 1 and 2 are proposed. It needs to be noted that it is the Dossier Submitters' intention to define the derogations as narrow and specific as possible.

Some derogations in this paragraph refer to typical uses of fluorinated gases, some of which are also regulated in the F-gas Regulation (Regulation (EU) 517/2014). The F-gas Regulation does not per se restrict the use of the substances but rather aims for a reduction of their use.

In addition, there are other fluorinated gases fulfilling the PFAS definition in column 1 which can be used for the same purpose. Therefore, these substances should be in the scope of this restriction proposal. Nevertheless, for some key applications of fluorinated gases alternatives are not yet available. In order to ensure the availability of these commercially relevant applications, specific derogations are proposed by the Dossier Submitters.

In some derogations, reference is made to industrial and/or professional uses. These terms are not defined under REACH. However, the ECHA Guidance on Information Requirements and Chemical Safety Assessment in its chapter R.12 on use description recommends understanding the concept of "professional use" as means to distinguish between use at industrial sites and uses outside industrial sites, but not by consumers or the general public. Uses at industrial sites usually are considered better controlled and less widespread in contrast to uses by professionals.

In the following, some specific derogations of paragraph are further outlined:

5e) PFASs in filtration and separation media have a very broad range of applications across several market sectors. The products affected are capable of operating under severe operating conditions, exhibiting, and maintaining the level of performance for long periods of harsh operating conditions to remove sub-micron dust, water, oil, or salt particles without restricting flow of air or other filtered media. Due to the important functions fulfilled and the low releases into the environment and in line with previous restriction proposals for PFASs, a time-limited derogation is proposed for this use in industrial and professional settings.

5j) The derogation for refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives is included to make sure that such equipment is available where non-PFAS alternatives are restricted at the national level according to standards and building codes due to properties like e.g. flammability. Such standards and codes are reviewed at regular intervals (e.g. every 4th year) and updated according to technical development. The development in HVACR equipment gradually makes refrigerant loadings lower and equipment safer and it is expected that the standards and codes over time are allowing more use of PFAS-free refrigerants.

5m) The derogation applies to fire-suppressing agents in the form of fluorinated gases used for extinguishing fires in high-risk situations where alternatives pose significant risk to health or the assets to be protected. These situations may include aviation, data centres and cultural/historic resources. Such agents are different from fire-fighting foams which are aqueous mixtures.

5n) The derogation for diagnostic laboratory testing includes precision refrigeration (blood bank refrigerator, vaccine storage), ultra-low temperature freezers or cryogenic storage, refrigerated centrifuges for sample separation, process chillers for precise temperature control and freeze-drying equipment. Use in in-vitro diagnostic devices is also covered. Additional information on uses of PFASs in the relevant applications can be found in Table A.103. in Appendix A.3.10.

5s) The derogation relates to the use of lubricants in industrial or professional settings for operations and equipment that require performance under harsh conditions (very high or low temperatures, very high or low pressure, chemical resistance, resistance to radiation etc.) or for safe functioning and safety of equipment (e.g. circuit breakers and switchgear that has to work reliably when required even if not being used for years).

5t) In the quantification of a substance in a sample an analytical reference standard of the same substance is needed. Likewise, some instruments or equipment may rely on calibration

standards in relevant PFAS analyses. These applications require only minimal amounts of PFAS material which are handled under controlled conditions. It is not expected that this will change in the foreseeable future, and the derogation is therefore proposed without a time limit.

Potential derogations marked for reconsideration after the Annex XV report consultation:

5w) The potential derogation related to spray foam applies to expanding foam sprayed on site for buildings for insulation purposes. This application and derogation is not related to fire-fighting foam, which is a different use and is covered in a separate restriction proposal.

5bb) The potential derogation covers use of perfluorinated engineered fluids that can be used to deposit a wide variety of coatings, including silicone, PTFE and heparin. These coatings can be deposited on many different types of surfaces, including metals, plastics and elastomers. Specific deposition applications include hypodermic needles, surgical and cutting blades, blood bags, filters and PVC tubing. Engineered fluids applied as solvents during chemical reactions, as inert media, and in microfluidic applications are also covered.

5cc) The potential derogation refers to fluoropolymer-based membranes with fluorinated side-chain polymer coatings used for (sterile) venting of medical devices, for example cell culture devices, analytical devices, blood tube systems for dialyzer systems, and tube systems for eye surgery.

(3) Paragraph 6

6a) For food contact materials used in the industrial production of food and feed, a time-limited derogation is proposed. The following applications are *inter alia* covered by this derogation:

- Piping and tubing for drinking water applications;
- Filters to capture contaminants from, for example, steam filtration in food processing;
- Seals, O-rings, gaskets, tubing and pipes, expansion joints;
- Valves and fitments, conveyor belting, chutes, guiding rails, rollers, funnels and sliding plates, tanks, funnels, rollers, linings, blades of knives and scissors, springs, filter membranes and sensor covers, lubricants;

Packaging of food and feed products, non-stick coatings in the industrial and professional food and feed production (e.g. industrial cookware, covered under paragraph 6g) as well as food contact materials for use in consumer articles shall not be covered by this derogation.

6b) The derogation covers use in implantable medical devices. A non-exhaustive list of implantable medical devices where PFASs are commonly used can be found in Table A.99. in Appendix A.3.10.

Potential derogations marked for reconsideration after the Annex XV report consultation:

6h) The potential derogation covers hernia meshes made from fluoropolymers, as well as hernia meshes where fluoropolymer coatings are applied to other base materials.

6i) The potential derogation covers wound treatment products such as bandages, surgical tapes and surgical staples.

6j) The potential derogation covers the use of PFASs (primarily fluoropolymers) as coating of medical devices other than Metered Dose Inhalers (MDIs). A list of coatings reported during stakeholder consultations is included in Table A.100. in Appendix A.3.10. Coatings of the inside of Metered Dose Inhalers (MDIs) are covered by the proposed derogation in paragraph 6d.

6k) The potential derogation covers fluoropolymer coatings on ophthalmic lenses and fluorinated monomers used in the polymer matrix of rigid gas permeable contact lenses.

6o) This potential derogation refers to all parts of vehicles where fluoropolymers and perfluoropolyethers are needed to ensure the safety of the vehicles and no alternatives are currently available (e.g. actuator or engine compartment, fuel system or safety features like airbags, ABS, or fire protection). This derogation shall not include the use of fluoropolymers and perfluoropolyethers purely for increasing comfort or optical enhancement (e.g. coating of trim materials, or textiles for carpets or seat covers).

(4) Paragraph 7

Reporting requirements are proposed for derogations with a duration of 13.5 years as well as for all applications of fluorinated gases, with a view of creating an understanding of the magnitude of continuing emissions as well as the progress made in relation to substitution. These reporting obligations would help the European Commission to gather data on the use of these substances in these sectors and to monitor any changes. In the event that the data reveals any concerns for the sector, further actions can be initiated. The reporting requirement will help to monitor whether there are any changes to uses and quantities which in turn may indicate changes in the emissions.

Reporting obligations shall apply to manufacturers, importers of PFASs and PFAS containing articles as well as formulators. The Dossier Submitters are aware that the formulator is, in contrast to the downstream user, not defined in the REACH Regulation. However, reporting by all downstream users is not considered practical by the Dossier Submitters. Manufacturers and importers often lack detailed knowledge on the whole supply chain, in particular if these are complex. Limiting the reporting obligation only to these actors might not provide sufficient use information to enable reviewing of the derogations. Formulators are usually the first downstream users of a substance and already have a good knowledge of the remaining supply chain and the (end)uses of substance. Therefore, it is proposed to include formulators, but not further downstream users in the reporting obligation.