

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

<p><b>Column 1</b></p> <p>Designation of the substance, of the group of substances or of the mixture</p>	<p><b>Column 2</b></p> <p>Conditions of restriction</p>
<p>Per- and polyfluoroalkyl substances (PFASs) defined as:</p> <p>Any substance that contains at least one fully fluorinated methyl (CF<sub>3</sub>-) or methylene (-CF<sub>2</sub>-) carbon atom (without any H/Cl/Br/I attached to it).</p> <p>A substance that only contains the following structural elements is excluded from the scope of the restriction:</p> <p>CF<sub>3</sub>-X or X-CF<sub>2</sub>-X',</p> <p>where X = -OR or -NRR' and X' = methyl (-CH<sub>3</sub>), methylene (-CH<sub>2</sub>-), an aromatic group, a carbonyl group (-C(O)-), -OR'', -SR'' or -NR''R''';</p> <p>and where R/R'/R''/R''' is a hydrogen (-H), methyl (-CH<sub>3</sub>), methylene (-CH<sub>2</sub>-), an aromatic group or a carbonyl group (-C(O)-).</p>	<ol style="list-style-type: none"> <li>1. Shall not be manufactured, used or placed on the market as substances on their own;</li> <li>2. Shall not be placed on the market in: <ol style="list-style-type: none"> <li>a. another substance, as a constituent;</li> <li>b. a mixture,</li> <li>c. an article</li> </ol> <p>in a concentration of or above:</p> <ol style="list-style-type: none"> <li>i. 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification)</li> <li>ii. 250 ppb for the sum of PFASs measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors</li> <li>iii. 50 ppm for total 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.</li> </ol> </li> <li>3. Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction.</li> <li>4. By way of derogation, paragraphs 1 and 2 shall not apply to <ol style="list-style-type: none"> <li>a. active substances in biocidal products within the scope of Regulation (EU) 528/2012</li> <li>b. active substances in plant protection products within the scope of Regulation (EC) 1107/2009</li> <li>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</li> <li>d. placing on the market of articles which were already in end-use in the Union</li> <li>e. spare parts intended to replace PFAS-containing articles in articles or complex objects until 20 years after the last date when the complex article was allowed to be placed on the market for the first time or until the end of service life for the specific object, when it is shorter than 20 years</li> <li>f. spare parts used in articles or complex objects for which legal obligations related to the use of specific spare parts exist until the end of service life of the complex object</li> <li>g. starting materials and intermediates in the manufacture of PFASs for a use listed under paragraphs 4, 5 or 6</li> <li>h. production of PFAS containing mixtures or articles in the upstream supply chain for a use listed under paragraphs 4, 5 or 6</li> </ol> </li> </ol>

# BACKGROUND DOCUMENT – Per- and polyfluoroalkyl substances (PFASs)

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	<ul style="list-style-type: none"> <li>i. uses under product and process orientated research and development (PPORD; art. 67(1) of EU-REACH)</li> <li>j. paper and board articles containing recovered material, with the exception of food-contact material and packaging</li> <li>k. textile articles containing recovered material, with the exception of toys as defined in Directive 2009/48/EC, until 13.5 years after EiF</li> <li>l. plastic articles containing recovered material, with the exception of food-contact material and food-contact packaging and toys as defined in Directive 2009/48/EC, until 23.5 years after EiF</li> <li>m. production of PFAS with or without the use of fluorinated polymerisation aids in the production of polymeric PFAS under controlled conditions with average emission factors (= Annual emission of PFAS / total annual amount of PFAS manufactured on site) not exceeding               <ul style="list-style-type: none"> <li>i. 0.0090% to air, 0.0010% to water and 0% to soil for emissions of non-polymeric PFAS residues from polymerization aid technology in fluoropolymer manufacturing until end of 2030;</li> <li>ii. 0.0030% to air, 0.0006% to water and 0% to soil for emissions of non-polymeric PFAS residues from polymerization aid technology in fluoropolymer manufacturing from end of 2030 onwards;</li> <li>iii. 0.01% to all compartments for all PFAS emissions not mentioned above from sites manufacturing polymeric and non-polymeric PFAS 6.5 years after EiF.</li> </ul> </li> </ul> <p>Manufacturers and importers of the active substances referred to in points a) – c) shall submit to the Agency every two years the following information:</p> <ul style="list-style-type: none"> <li>i. the derogation that the intended use belongs to;</li> <li>ii. the identity and quantity of the active substance placed on the market</li> </ul> <p>The Agency shall publish on its website a summary of the submitted information referred to in points i) – ii)</p> <p>Suppliers of paper and board articles referred to in point j) containing recovered paper and board, suppliers of textile articles referred to in point k) containing recovered material and suppliers of plastic articles referred to in point l) containing recovered material shall submit to national enforcement authorities upon request documentary evidence to substantiate the claims on the recovered origin of paper and board, textiles and plastic in those articles. Claims made on the recovered origin of paper and board, textiles and plastic in imported articles shall be accompanied by a certificate that provides proof of traceability and recycled content, issued by an independent third party.</p>

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	<p>Suppliers of plastic articles or complex objects falling under the scope of the WEEE Directive (Directive 2012/19/EU) or ELV Directive (Directive 2000/53/EC) as well as suppliers of PVC articles listed in paragraph 18 (a to f) of Regulation (EU) 2023/923 on lead and its compounds in PVC containing intentionally added PFASs in concentrations of or above the limits set out in Paragraph 2 shall ensure, before placing those articles on the market, that they are visibly, legibly and indelibly marked with the statement: "Contains intentionally added PFASs". Where the marking cannot be provided on the article due to the nature of the article, it shall be on the packaging of the article.</p> <p>5. By way of derogation, paragraphs 1 and 2 shall not apply to:</p> <ul style="list-style-type: none"> <li>a. personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, until 13.5 years after EiF;</li> <li>b. personal protective equipment (PPE) specifically designed for armed forces, the maintenance of law and order and other emergency response workers, until 13.5 years after EiF;</li> <li>c. impregnation agents for re-impregnation of articles referred to in paragraph 5b and 5c until 13.5 years after EiF;</li> <li>d. hard chrome plating until 6.5 years after EiF;</li> <li>e. refrigerants in low temperature refrigeration below -50 °C until 6.5 years after EiF;</li> <li>f. refrigerants in laboratory test and measurement equipment until 13.5 years after EiF;</li> <li>g. refrigerants in refrigerated centrifuges until 13.5 years after EiF;</li> <li>h. refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives;</li> <li>i. foam blowing agents in thermal insulation foam until 13.5 years after EiF;</li> <li>j. propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required until 13.5 years after EiF. The derogation does not apply to products intended for entertainment and decorative purposes for the general public;</li> <li>k. fluorinated gases used as 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;</li> <li>l. preservation of cultural paper-based materials until 13.5 years after EiF;</li> <li>m. insulating gases in high-voltage switchgear (above 145 kV) until 6.5 years after EiF</li> <li>n. refrigerants, clean fire-suppressing agents and insulation gases for maintenance and refilling of existing HVACR, fire-suppressing and switchgear</li> </ul>

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	<p>equipment put on the market before 18 months (or placed on the market after 18 months after EiF based on an applicable derogation);</p> <ul style="list-style-type: none"> <li>o. [potential derogation for use of fluorinated gases at the CERN research installation unit until 13.5 years after EiF].</li> <li>p. additives to hydraulic fluids in transport vehicles until 13.5 years after EiF;</li> <li>q. refrigerants in mobile air conditioning-systems and heat pump systems in i) light duty electrical vehicles until 6.5 years after EiF; ii) all other vehicles until 13.5 years after EiF</li> <li>r. refrigerants in transport refrigeration other than in marine applications until 6.5 years after EiF;</li> <li>s. coatings and films on displays and lenses of electronic complex objects for 6.5 years after EiF;</li> <li>t. printed circuit boards and antennas for 13.5 years after EiF</li> <li>u. photonics for 13.5 years after EiF;</li> <li>v. heat transfer fluids for 2-phase immersion cooling for 13.5 years after EiF;</li> <li>w. semiconductor manufacturing until 13.5 year after EiF;</li> <li>x. coatings and films of electronic components (excluding displays and lenses) for 13.5 years after EiF;</li> <li>y. binders and electrolytes in batteries until 13.5 years after EiF</li> <li>z. polymer additives used for fire safety purposes in construction products until 13.5 years after EiF;</li> <li>aa. industrial and professional uses of lubricants or lubricant additives until 13.5 years after EiF;</li> <li>bb. gas and oil tracers until 13.5 years after EiF;</li> <li>cc. toners until 13.5 years after EiF;</li> <li>dd. latex printing inks until 13.5 years after EiF;</li> <li>ee. electrophotographic press units until 13.5 years after EiF;</li> <li>ff. kinetic printing components until 13.5 years after EiF;</li> <li>gg. photosensitive materials until 13.5 years after EiF</li> <li>hh. toners for use in existing equipment put on the market until 13.5 years after EiF;</li> <li>ii. latex printing inks for use in existing equipment put on the market until 13.5 years after EiF;</li> <li>jj. excipients in medicinal products for ophthalmic and dermatological therapies until 13.5 years after EiF</li> <li>kk. propellants in pMDIs until 6.5 years after EiF</li> <li>ll. military applications until 13.5 years after EiF</li> <li>mm. HEPA (H 13-14) and ULPA (U 15-17) filters (according to EN 1822:2009) and in industrial uses for filtration and separation of air and other gases</li> </ul>

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	<p>for 13.5 years after EiF, excluding general (HVAC) ventilation;</p> <p>nn. sound-permeable and vent filters for electrical and electronic equipment for 6.5 years after EiF;</p> <p>oo. oxygen-permeable membranes in zinc-air batteries and other types of alkaline metal-air batteries for 13.5 years after EiF;</p> <p>pp. industrial use as media in liquid-liquid separation for 13.5 years after EiF;</p> <p>qq. technical textiles in engine bays of transport vehicles for noise, vibration and harshness (NVH) insulation and ignition protection until 13.5 years after EiF;</p> <p>rr. technical textiles in transport vehicles for noise, vibration and harshness (NVH) insulation outside the engine bay until 6.5 years after EiF;</p> <p>ss. woven, knitted and nonwoven re-usable medical textiles as specified in Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council with a minimum performance requirement of &gt;20 cm hydrostatic head according to EN 13795 for 13.5 years;</p> <p>tt. impregnation agents for re-impregnation of articles referred to in paragraph 5tt until 13.5 years after EiF;</p> <p>uu. ionic liquids used in industrial uses until 6.5 years after EiF;</p> <p>vv. solvents used in industrial uses until 13.5 years after EiF;</p> <p>ww. catalysts and processing aids used in industrial uses until 13.5 years after EiF.</p> <p>6. By way of derogation, paragraphs 1 and 2 shall not apply to fluoropolymers and perfluoropolyethers for the use in:</p> <ol style="list-style-type: none"> <li>polymer processing aids used in flexible plastic film extrusion (for food and non-food applications) until 6.5 years after EiF.</li> <li>non-stick coatings in industrial bakeware until 6.5 years after EiF;</li> <li>implantable medical devices (including medical implants and meshes) until 13.5 years after EiF;</li> <li>invasive medical devices (e.g. tubes and catheters) until 13.5 years after EiF;</li> <li>packaging for medical devices until 13.5 years after EiF;</li> <li>i) vehicle systems, components or separate technical units [(excluding 'sealing applications', batteries and fuel cells, lubricants, electronic and electrical systems, HVACR, technical textiles*)] that are subject to EU vehicle type approval, where the type approval was obtained within 13.5 years after EiF (e.g., motor vehicles within the</li> </ol>

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	<p>scope of Regulation (EU) 2018/858, (EU) 2019/2144 or Directive 2007/46/EC, agricultural and forestry vehicles with the scope of Regulation (EU) 167/2013, aircraft within the scope of Regulation (EU) 2018/1139 or (EU) 748/2012, watercraft within the scope of Directive 2013/53/EU or 2009/45/EC, and rail vehicles within the scope of Regulation (EU) 2016/797 or Directive (EU) 2016/798); OR</p> <p>ii) systems, components or separate technical units [(excluding 'sealing applications', batteries and fuel cells, lubricants, electronic and electrical systems, HVACR, technical textiles*)] in vehicles that are not within the scope of paragraph a, where the use of fluoropolymers or perfluoropolyethers are strictly necessary for safety or environmental performance of those vehicles until 13.5 years after EiF. e.g., braking, restraint, lighting/signalling, driver assistance systems, emission control.</p> <ul style="list-style-type: none"> <li>g. heat transfer fluids for industrial and professional use of vapor phase soldering for electronics for 13.5 years after EiF;</li> <li>h. wires and cables (incl. connectors) for 13.5 years after EiF</li> <li>i. insulation material of electronic components (excluding wires, cables and connectors) for 13.5 years after EiF;</li> <li>j. anti-drip agent in plastics of electronic components for 13.5 years after EiF;</li> <li>k. fuel cells and electrolyzers until 13.5 years after EiF;</li> <li>l. separator coatings for batteries until 6.5 years after EIF</li> <li>m. PTFE nozzles in high voltage (&gt;145 kV) switchgears and circuit breakers until 6.5 years after EIF</li> <li>n. front- and backsheets in photovoltaic cells until 6.5 years after EIF</li> <li>o. bridge and building bearings until 13.5 years after EiF;</li> <li>p. sealing applications in industrial uses until 13.5 years after EiF</li> <li>q. machinery applications in industrial uses until 13.5 years after EIF</li> <li>r. coatings in release liners and backing film in transdermal patches until 13.5 years after EiF</li> <li>s. blisters for solid oral dose formulations until 6.5 years after EiF</li> </ul>

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	<ul style="list-style-type: none"> <li>t. coated rubber stoppers in vials/flasks for injectable medicinal products until 13.5 years after EiF</li> <li>u. coated canisters in pressurized metered-dose inhalers (pMDIs) until 13.5 years after EiF;</li> <li>v. coated plungers in pre-filled syringes until 13.5 years after EiF</li> <li>w. pre-filled injection pens &amp; autoinjectors until 13.5 years after EiF</li> <li>x. explosives in military applications until 13.5 years after EiF</li> <li>y. industrial use of fluoropolymers in filtration and separation media for water treatment and purification for 6.5 years after EiF.</li> </ul> <p>7. Manufacturers, importers of PFASs or PFAS containing articles as well as downstream users formulating PFAS-containing mixtures making use of any of the derogations according to paragraphs 5 a)-c), e) – r), t) – jj), ll) – mm), oo) – qq), ss) – tt), vv)-ww), and 6c) – k), o) – r), t) – x), shall from (EiF + 18 months) provide by 31 May of each calendar year a report to the Agency containing:</p> <ul style="list-style-type: none"> <li>i. the derogation that the intended use belongs to;</li> <li>ii. the identity and quantity of the substances placed on the market in the previous year.</li> </ul> <p>The Agency shall make the information available to the Commission and Member States by 31st August every year;</p> <p>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:</p> <ul style="list-style-type: none"> <li>i. information on the identity of the substances and the products they are used in</li> <li>ii. a justification for the use;</li> <li>iii. details on the conditions of use and safe disposal.</li> </ul> <p>The management plan shall be reviewed annually and kept available for inspection by enforcement authorities upon request.</p> <p>9. This restriction does not affect existing entries of REACH regulation Annex XVII, apart from entries 28 to 30, as well as substances listed in Regulation 2019/1021 (POP-Regulation). Other Union legislation addressing substances within the scope of this restriction shall be adhered to notwithstanding this restriction.</p>