

## **Committee for Socio-economic Analysis (SEAC)**

[Draft] Opinion

on an Annex XV dossier proposing restrictions on  
Per- and polyfluoroalkyl substances (PFAS)

ECHA/SEAC/RES-O-0000007620-79-01/D

**Date: 10 March 2026**

**SEAC**  
COMMITTEE FOR  
SOCIO-ECONOMIC ANALYSIS

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON  
Per- and polyfluoroalkyl substances (PFAS)

10 March 2026

RES-O-0000007620-79-01/D

**Opinion of the Committee for Socio-economic Analysis**

**on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU**

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

**Per- and polyfluoroalkyl substances (PFAS)**

**EC No.:** -

**CAS No.:** -

This document presents the opinion adopted by SEAC and the Committee's justification for its opinion. The opinion of the Committee for Risk Assessment (RAC) as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment, adopted on 2 March 2026, is referenced where relevant.

The Background Document, as a supportive document to both the RAC and SEAC opinion, gives the details of the Dossier Submitter's proposal amended for further information obtained during the consultation and other relevant information resulting from the opinion making process.

**PROCESS FOR ADOPTION OF THE SEAC OPINION**

Germany, the Netherlands, Denmark, Norway and Sweden have submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV dossier conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at <https://echa.europa.eu/restrictions-under-consideration> on **22 March 2023**. Interested parties were invited to submit comments and contributions by **25 September 2023**.

**Rapporteurs, appointed by SEAC:** Simon COGEN and Simone FANKHAUSER (supported by SEAC Adviser Stephanie MOSER-CASTAN)

**Co-rapporteurs, appointed by SEAC:** Oona FREUDENTHAL, Eimear LEAHY, Manuel RODRIGUEZ HERNANDEZ and Jonathan SPITERI

**Supporting the Rapporteurs:** Jean-Marc BRIGNON, Michael BÜCKER, Johanna KIISKI, Andreas LÜDEKE, Alexandra SERRA and Karen THIELE

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The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **10 March 2026**.

The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The draft opinion was published on **26 March 2026**. Interested parties were invited to submit comments on the draft opinion by **25 May 2026**.

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **[date of adoption of the opinion]**. [The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by **[number of days]** by the ECHA decision **[number and date]**].

[The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and] 71(1) of the REACH Regulation.] [No comments were received from interested parties during the consultation in accordance with Article[s 69(6) and] 71(1)].

The opinion of SEAC was adopted **by [consensus.] [a simple majority** of all members having the right to vote.] [The minority position[s], including their grounds, are made available in a separate document which has been published at the same time as the opinion.]

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## 1. OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

**Table 1: Proposed restriction**

Column 1	Column 2
<p>Designation of the substance, of the group of substances or of the mixture</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>	<p>Conditions of the restriction</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> </ol> </li> </ol>

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	<p>h. production of PFAS containing mixtures or articles in the upstream supply chain for a use listed under paragraphs 4, 5 or 6</p> <p>i. uses under product and process orientated research and development (PPORD; art. 67(1) of EU-REACH)</p> <p>j. paper and board articles containing recovered material, with the exception of food-contact material and packaging</p> <p>k. textile articles containing recovered material, with the exception of toys as defined in Directive 2009/48/EC, until 13.5 years after EoF</p> <p>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 EoF</p> <p>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</p> <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 EoF.</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> <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</p>
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	<p>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 EiT;</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 EiT;</li><li>c. impregnation agents for re-impregnation of articles referred to in paragraph 5a and 5b until 13.5 years after EiT;</li><li>d. hard chrome plating until 6.5 years after EiT;</li><li>e. refrigerants in low temperature refrigeration below -50 °C until 6.5 years after EiT;</li><li>f. refrigerants in laboratory test and measurement equipment until 13.5 years after EiT;</li><li>g. refrigerants in refrigerated centrifuges until 13.5 years after EiT;</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 EiT;</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 EiT. 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 EiT;</li><li>l. preservation of cultural paper-based materials until 13.5 years after EiT;</li><li>m. insulating gases in high-voltage switchgear (above 145 kV) until 6.5 years after EiT;</li><li>n. refrigerants, clean fire-suppressing agents and insulation gases for maintenance and refilling of existing HVACR, fire-suppressing and switchgear equipment put on the market before 18 months (or placed on the market after 18 months after EiT based on an applicable derogation);</li><li>o. [potential derogation for use of fluorinated gases at the CERN research installation unit until 13.5 years after EiT];</li><li>p. additives to hydraulic fluids in transport vehicles until 13.5 years after EiT;</li><li>q. refrigerants in mobile air conditioning-systems and heat pump systems in i) light duty electrical vehicles until 6.5 years after EiT; ii) all other vehicles until 13.5 years after EiT;</li><li>r. refrigerants in transport refrigeration other than in marine applications until 6.5 years after EiT;</li></ul>
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	<ul style="list-style-type: none"> <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 for 13.5 years after EiF, excluding general (HVAC) ventilation;</li> <li>nn. sound-permeable and vent filters for electrical and electronic equipment for 6.5 years after EiF;</li> <li>oo. oxygen-permeable membranes in zinc-air batteries and other types of alkaline metal-air batteries for 13.5 years after EiF;</li> <li>pp. industrial use as media in liquid-liquid separation for 13.5 years after EiF;</li> <li>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;</li> <li>rr. technical textiles in transport vehicles for noise, vibration and harshness (NVH) insulation outside the engine bay until 6.5 years after EiF;</li> <li>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</li> </ul>
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	<p>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 5ss 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> <p>a. polymer processing aids used in flexible plastic film extrusion (for food and non-food applications) until 6.5 years after Eif;</p> <p>b. non-stick coatings in industrial bakeware until 6.5 years after Eif;</p> <p>c. implantable medical devices (including medical implants and meshes) until 13.5 years after Eif;</p> <p>d. invasive medical devices (e.g. tubes and catheters) until 13.5 years after Eif;</p> <p>e. packaging for medical devices until 13.5 years after Eif;</p> <p>f. 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 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 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> <p>g. heat transfer fluids for industrial and professional use of vapor phase soldering for electronics for 13.5 years after Eif;</p> <p>h. wires and cables (incl. connectors) for 13.5 years after Eif;</p> <p>i. insulation material of electronic components (excluding wires, cables and connectors) for 13.5 years after Eif;</p> <p>j. anti-drip agent in plastics of electronic components for 13.5 years after Eif;</p> <p>k. fuel cells and electrolyzers until 13.5 years after Eif;</p> <p>l. separator coatings for batteries until 6.5 years after Eif;</p> <p>m. PTFE nozzles in high voltage (&gt;145 kV) switchgears and circuit breakers until 6.5 years after Eif;</p>
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	<p>n. front- and backsheets in photovoltaic cells until 6.5 years after EiT;</p> <p>o. bridge and building bearings until 13.5 years after EiT;</p> <p>p. sealing applications in industrial uses until 13.5 years after EiT;</p> <p>q. machinery applications in industrial uses until 13.5 years after EiT;</p> <p>r. coatings in release liners and backing film in transdermal patches until 13.5 years after EiT;</p> <p>s. blisters for solid oral dose formulations until 6.5 years after EiT</p> <p>t. coated rubber stoppers in vials/flasks for injectable medicinal products until 13.5 years after EiT</p> <p>u. coated canisters in pressurized metered-dose inhalers (pMDIs) until 13.5 years after EiT;</p> <p>v. coated plungers in pre-filled syringes until 13.5 years after EiT;</p> <p>w. pre-filled injection pens &amp; autoinjectors until 13.5 years after EiT;</p> <p>x. explosives in military applications until 13.5 years after EiT;</p> <p>y. industrial use of fluoropolymers in filtration and separation media for water treatment and purification for 6.5 years after EiT.</p> <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 (EiT + 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>
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Note: The original restriction proposal has been revised by the Dossier Submitter based on comments received in the Annex XV report consultation and the version above is thus the revised proposal that this opinion is referring to.

## 1.1. THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction on Per- and polyfluoroalkyl substances (PFAS) is the most appropriate Union wide measure to address the identified risk in terms of the effectiveness in reducing the risk, practicality and monitorability as demonstrated in the justification supporting this opinion, provided that the conditions are modified, as proposed by RAC.

The conditions of the restriction proposed by RAC are **(changes from the Dossier Submitter's proposal in red)**:

**Table 2: Restriction proposed by RAC**

Column 1	Column 2
<p>Designation of the substance, of the group of substances or of the mixture</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><i>The Dossier Submitter proposed to exclude the following substances from the scope on the grounds that they are fully degradable:</i></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</p>	<p>Conditions of the restriction</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 PFAS measured as sum of targeted PFAS analysis <del>optionally</del> with prior degradation of precursors;</li> <li>iii. 50 ppm for total PFAS (polymeric PFAS 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 PFAS or non-PFAS.</li> </ol> </li> <li>3. Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction.</li> </ol> <p><b>4., 5., 6. Derogations from paragraph 1 and 2 (see section 3.4.3.1.5 and 3.4.3.1.6 of the RAC Opinion).</b></p> <ol style="list-style-type: none"> <li>7. Manufacturers, importers of PFAS or PFAS-containing <b>mixtures or</b> articles as well as <b>industrial</b> downstream users formulating PFAS-containing mixtures <del>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)</del>, which continue to manufacture, place on the market or use PFAS for 13.5 years or longer after EIF or for fluorinated gases</li> </ol>

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<p>(-C(O)-).”</p> <p><i>RAC considers that the evidence provided is not sufficient to justify this exclusion (see section 3.1.1. of the RAC Opinion).</i></p>	<p>applications by way of a derogation from paragraph 1 and 2 shall from (EiF + 18 months) provide by 31 May of each calendar year a report to the Agency containing:</p> <ol 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> </ol> <p>The Agency shall make the information available to the Commission and Member States by 31st August every year.</p> <p>8. a) Suppliers of PFAS or PFAS-containing mixtures or articles for an application with continued use of PFAS by way of a derogation from paragraph 1 and 2 shall provide from (EiF + 18 months):</p> <ol style="list-style-type: none"> <li>i. the statement “This product contains PFAS”;</li> <li>ii. instructions for safe use and disposal explaining to industrial and professional users and the general public how to prevent releases of PFAS to the environment;</li> <li>iii. the identity of PFAS and quantity contained that enables manufacturers and industrial downstream users to comply with their obligations laid down in paragraph 7 and 8b.</li> </ol> <p>This requirement does not apply to articles which were already in end-use in the Union, recovered materials, and articles containing recovered materials, with continued uses by way of a derogation from paragraph 1 and 2.</p> <p>8. b) Without prejudice to paragraph 8a, manufacturers, <del>importers</del> and industrial downstream users of <del>fluoropolymers and perfluoropolyethers</del> PFAS or PFAS-containing mixtures <del>making use of any of the derogations in paragraphs 5 or 6</del> with continued uses of PFAS by way of a derogation from paragraph 1 and 2 shall establish a site-specific management plan which shall include:</p> <ol style="list-style-type: none"> <li>i. information on the identity of the PFAS substances and the products they are used in;</li> <li>ii. a justification for the use of PFAS (including an assessment of the technical feasibility of alternatives);</li> <li>iii. details on the conditions of use and safe disposal of PFAS on site to minimise emissions to the environment and direct and indirect human exposure (including plans for the treatment and appropriate disposal of PFAS-containing wastes arising in production, routine cleaning and maintenance of equipment etc.);</li> <li>iv. report of the results of monitoring activities on PFAS presence on site to assess the potential emissions and concentrations into the environment (e.g. air emissions, waste, wastewater, soil).</li> </ol> <p>The management plan shall be reviewed annually and kept available for inspection by enforcement authorities upon request.</p> <p>The results of the monitoring activities on PFAS under paragraph 8b iv shall be reported from (EiF + 18 months) to the Agency. For those actors with obligations described in paragraph 7 the reporting will take place simultaneously.</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>
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## 1.2. THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the proposed restriction on **per- and polyfluoroalkyl substances (PFAS)** is the most appropriate Union wide measure to address the identified risks, taking into account the proportionality of its socio-economic benefits to its socio-economic costs provided that the conditions are modified, as proposed by SEAC, as demonstrated in the justification supporting this opinion.

The conditions of the restriction proposed by SEAC are **(changes from the DS proposal in red)**:

**Table 3: Restriction proposed by SEAC**

Column 1	Column 2
<p>Designation of the substance, of the group of substances or of the mixture</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><i>The Dossier Submitter proposed to exclude the following substances from the scope on the grounds that they are fully degradable:</i></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> <p><i>SEAC notes and supports RAC's conclusion that the evidence provided is not sufficient to justify this exclusion.</i></p>	<p>Conditions of the restriction</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 PFAS excluded from quantification);</li> <li>ii. 250 ppb for the sum of PFAS measured as sum of targeted PFAS analysis, <del>optionally</del> with prior degradation of precursors;</li> <li>iii. 50 ppm for total PFAS (polymeric PFAS 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 PFAS or non-PFAS.</li> </ol> </li> <li>3. Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction.</li> <li>4. <span style="color: red;">[Regarding derogations from paragraph 1 and 2, see section 3.4.3.2.5.8 of the SEAC Opinion.]</span> <span style="color: red;">[Regarding reporting requirements, see section 3.4.3.2.6.1 of the SEAC Opinion.]</span></li> <li>5. <span style="color: red;">[Regarding derogations from paragraph 1 and 2, see section 3.4.3.2.5.8 of the SEAC Opinion.]</span></li> <li>6. <span style="color: red;">[Regarding derogations from paragraph 1 and 2, see section 3.4.3.2.5.8 of the SEAC Opinion.]</span></li> <li>7. <span style="color: red;">[Regarding reporting requirements, see section 3.4.3.2.6.1 of the SEAC Opinion.]</span></li> </ol>

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	<p>8. [Regarding site-specific PFAS management plans and additional conditions considered by RAC, see sections 3.4.3.2.6.2 and 3.4.3.2.6.3 of the SEAC Opinion.]</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>
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## 2. SUMMARY OF PROPOSAL AND OPINION

### 2.1. Summary of proposal

The text below summarises the restriction proposal as presented by the Dossier Submitter in the Background Document and does not necessarily represent RAC's and SEAC's opinion.

Per- and polyfluoroalkyl substances (PFAS) are a group of thousands of almost exclusively man-made substances that are used in numerous applications in the EU and EEA. These applications comprise uses in textiles, (food) packaging, lubricants, refrigerants, electronics, construction and many more. PFAS are used as substances on their own (either non-polymeric or polymeric) and as constituents in mixtures and (complex) articles for consumer, professional, and industrial uses.

The Background Document addresses the risks to the environment and human health of the use of PFAS and provides an assessment of the effectiveness, practicality, monitorability and socio-economic impacts of two restriction options (ROs), i.e. a full ban with a transition period of 18 months (RO1) and a ban with use-specific, mostly time-limited derogations of a duration of 5 or 12 years in addition to a transition period of 18 months (RO2).

Substantiated suggestions for potential alternative regulatory options brought forward during the consultation on the Annex XV report have also been considered by the Dossier Submitter. When these options (as suggested or in an adapted form) have been deemed effective, practical and monitorable and therefore been deemed to constitute a potential valid alternative to the proposed restriction, they are compared to RO1 and RO2 in terms of their proportionality. This refers to options (termed RO3) allowing continued use under strict conditions that minimise emissions over the full life cycle, i.e. regulatory options potentially allowing for adequate control of risks through means other than a ban. In some cases, restriction options with complementary emission reduction measures and requirements attached to use-specific derogations under RO2 have also been considered with a view of improving the effectiveness of the restriction option. Where relevant, such additional restriction options have been assessed in a dedicated section within the sector-/use-specific assessment in Annex E of the Background Document.

Additional restriction options have been assessed for:

- PFAS manufacturing
- Transport
- Electronics and semiconductors
- Energy
- Sealing applications
- Machinery applications
- Some technical textiles

Overall, a restriction under REACH is identified as the most suitable risk management option (RMO) to address the identified risks.

#### Concern

The main concern for all PFAS and/or their degradation products that are in the scope of this restriction proposal is the very high persistence, exceeding the criterion for very persistent

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(vP) according to Annex XIII of the REACH Regulation by far. PFAS and their degradation products may persist in the environment longer than any other man-made chemical. Further supporting concerns are their bioaccumulation, mobility, long range transport potential (LRTP), accumulation in plants, global warming potential and (eco)toxicological effects. PFAS enter the environment via emissions during manufacture, the use phase, and the waste stage.

When these substances and their degradation products continue to be released to the environment, the concentration in the environment will increase as mineralisation under natural conditions does not take place for the PFAS in the scope of this restriction proposal. Once present in the environment, the removal of PFAS from surface water, groundwater, soil, sediment and biota is technically extremely difficult and very costly, if at all possible. Environmental monitoring of PFAS demonstrates ubiquitous distribution in the environment, including organisms and drinking water sources and food crop, as well as remote and pristine areas making exposure unavoidable and irreversible for now and future generations. Human biomonitoring shows the omnipresence of PFAS in humans, with highly exposed communities showing the highest levels. With the constantly increasing concentrations of PFAS in the environment due to their persistence and ongoing emissions, the exposure of humans and the environment to these substances will inevitably lead to negative effects. Also, exposure to PFAS has a high potential for intergenerational effects. Some scientists argue that the planetary boundaries for PFAS have already been exceeded, and human biomonitoring studies show that the cocktail of PFAS to which parts of the general population are exposed to through different sources (e.g. food, drinking water, products containing PFAS, dust, air) already may result in health risks.

### Regulatory risk management options

The irreversibility of the process of a growing environmental stock of PFAS due to emissions from PFAS-containing products during all life cycle stages (manufacture of PFAS, production of products, use phase/service life, and end of life), with associated exposure of humans and the environment, make it necessary to reduce emissions of PFAS to a minimum. Different regulatory risk management options have been considered, e.g. harmonised classification and labelling (CLH) and authorisation, but these options follow a substance-by-substance approach. In contrast, a restriction offers the possibility to define a broad chemical scope, thereby avoiding what is referred to as “regrettable substitution” of one PFAS by another PFAS (some of which may not have even been engineered yet). At the same time, it allows to tackle the problem of ongoing, uncontrollable emissions at the source, as manufacture and use can be restricted to avoid or minimize emissions. End-of-pipe solutions are not deemed to be achievable, as PFAS are ubiquitously present in a wide range of products intended for industrial, professional and consumer uses. A restriction can cover a wide range of uses and can address the risks arising from the manufacture and use of the substances as such as well as in other substances, in mixtures and in articles, including imported articles from outside the EU. Hence, a restriction is the most appropriate and effective option to adequately control such a large and complex group of substances which are used in numerous applications, whilst also taking into account and mitigating socio-economic impacts of a restriction.

### Scope

The chemical scope of the restriction proposal is defined as: 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). There are however a few exceptions (see paragraph below).

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It is aligned with the OECD definition<sup>1</sup> of PFAS that was published in 2021, and that has been scrutinised by the international scientific community and is widely accepted. This definition encompasses more than 10 000 PFAS, including a few fully degradable PFAS subgroups. As these fully degradable subgroups, which can be described by their key structural elements, do not fulfil the underlying concern of high persistence (see above), they are excluded from the scope of this restriction proposal.

As outlined above, the restriction proposal is tailored to address the manufacture, placing on the market, as well as the use of PFAS as such and as constituents in other substances, in mixtures and in articles above a certain concentration. All uses of PFAS are covered by this restriction proposal, regardless of whether they have been specifically assessed by the Dossier Submitters and/or are mentioned in the Background Document or not, unless a specific derogation has been formulated. However, this restriction proposal does not cover the use of PFAS in fire-fighting foams (Aqueous Film Forming Foams; AFFFs), which is covered by a separate restriction. Additionally, this restriction is not meant to affect any other restrictions already included in Annex XVII or prohibitions in other applicable Union legislation (e.g. in the POPs Regulation).

### Socio-economic impacts and proportionality

The Dossier Submitter has identified the PFAS uses in which the largest amounts of PFAS are used and emitted. This has been done through literature research, stakeholder consultations, and a call for evidence. The 2023 consultation on the Annex XV report resulted in over 5 600 comments from stakeholders, a large part also relating to socio-economic impacts. Information from these comments has been used to update the original restriction proposal and also resulted in the inclusion of eight additional applications/use sectors. These updates are reflected in the Background Document.

Twenty-two applications/uses – subdivided into numerous sub-uses – have been addressed in detail in the Background Document. For the EEA, this resulted in an estimated amount of 186 000 to 340 000 tonnes of PFAS introduced to the market in 2020, which – due to the expected economic growth in relation to several applications – is expected to increase further under the baseline scenario. Over a 30-year period (2025-2055) the expected mean PFAS tonnage used in the EEA is 27 million tonnes, leading to emissions of about 4.7 million tonnes during the manufacture of products containing PFAS, the use phase and the end-of-life phase when no action is taken.

The benefits of a restriction are, amongst others, the avoided negative human health effects associated with the continued use of PFAS. The magnitude of the impact of continued use of PFAS on human health cannot be quantified but current combined exposure to some regulated PFAS already exceeds existing limit values. Therefore, due to structural similarities and a similar hazard profile, (co-)exposure to other, non-regulated, PFAS should be minimised. This implies that restriction option RO1 (being a full ban with an 18-month transition period), that reduces the increase of the environmental pollution burden of PFAS the most, compared to the baseline scenario, will result in the highest benefit to society in terms of avoided long-term human health impacts resulting from exposure to PFAS. The socio-economic costs of PFAS emissions to the environment are considerable and are growing with prolonged PFAS use. Complete monetisation of the benefits of a restriction is however not possible, e.g. due

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<sup>1</sup> 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).

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to the inability to quantify human health impacts. As it is concluded that PFAS should be treated as non-threshold substances for the purpose of risk assessment in a similar manner to PBT/vPvB substances, emissions are used as a proxy for risk in line with the standard approach for PBT/vPvB substances. A cost-effectiveness analysis is the standard approach for assessing proportionality of regulatory options for such substances. In most cases, quantification of costs was not possible, e.g. due to data gaps in relation to various relevant elements and challenges with respect to the representativeness of available data. In most cases, the costs of the restriction options have therefore been analysed in qualitative terms. Costs at use group level are graded on a 5-level scale ranging from very low to very high and compared to the level of effectiveness, also graded on a 5-level scale to conclude on proportionality. Details on the expected costs and emission reduction for the 22 uses and associated proportionality of restriction options are provided in section 2.4 of the Background Document.

Overall, a restriction with use-specific derogations (RO2) is deemed to reduce emissions by 83%. In comparison, a full ban is deemed to reduce emissions by around 96%. Costs under RO2 are generally found to be lower than under RO1, rendering RO2 an option that is preferable over RO1. Where analysed, RO3s are deemed to be proportionate for electronics and semiconductors, likely proportionate for energy, PFAS manufacturing and technical textiles and not sufficiently effective for transport, sealing applications and machinery applications.

All restriction options, RO1, RO2 and RO3, are considered sufficiently enforceable. RO1 is likely not implementable, and therefore also not manageable, while RO2 and RO3 are evaluated as implementable and manageable by the Dossier Submitter. Hence, RO2 and RO3 are concluded to be practical with regards to implementability, enforceability and manageability.

### 2.2. Summary of opinion

This opinion contains the Committees' evaluation of the restriction as proposed by the Dossier Submitter. The evaluation addresses both the general elements of the restriction proposal and sector-/use-specific aspects. With respect to the latter, the Committees focused their evaluation on PFAS manufacturing and the 14 sectors of use assessed in detail by the Dossier Submitter in the Annex XV report subject to the six-month consultation, taking into account the updates introduced by the Dossier Submitter for these sectors in the Background Document<sup>2</sup>. The Committees' evaluation of sector-/use-specific aspects is contained in separate documents which should be read in conjunction with the evaluation of the general elements contained in this document. The present document together with the documents containing the evaluation of sector-/use-specific aspects form the Committees' opinion on the proposed restriction.

The sector-specific evaluations include:

- **Sector 1:** PFAS manufacturing
- **Sector 2:** Textiles, upholstery, leather, apparel and carpets (TULAC)

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<sup>2</sup> The Background Document represents the last version of the restriction proposal prepared by the Dossier Submitter taking into account the comments submitted in the Annex XV report consultation.

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- **Sector 3:** Food contact materials and packaging
- **Sector 4:** Metal plating and manufacture of metal products
- **Sector 5:** Consumer mixtures and miscellaneous consumer articles
- **Sector 6:** Cosmetics
- **Sector 7:** Ski wax
- **Sector 8:** Applications of fluorinated gases
- **Sector 9:** Medical devices
- **Sector 10:** Transport
- **Sector 11:** Electronics and semiconductors
- **Sector 12:** Energy
- **Sector 13:** Construction products
- **Sector 14:** Lubricants
- **Sector 15:** Petroleum and mining

Furthermore, in their evaluation, the Committees have also taken into account the eight additional sectors that were assessed by the Dossier Submitter as a result of their analysis of the comments received in the six-month consultation and incorporated later on into the Background Document. These eight additional sectors are as follows:

- **Sector 16:** Printing applications
- **Sector 17:** Sealing applications
- **Sector 18:** Machinery applications
- **Sector 19:** Other medical applications
- **Sector 20:** Military applications
- **Sector 21:** Explosives
- **Sector 22:** Technical textiles
- **Sector 23:** Broader industrial uses

However, considering the time required for a detailed evaluation of these eight additional sectors and that the Dossier Submitter's assessments for these sectors became available only at a later stage in the opinion development process, the Committees did not carry out detailed sector-specific evaluations for these sectors. This is to ensure that the Committees' evaluations for the other sectors (i.e. Sectors 1-15 above) remain relevant and timely.

A brief description of each sector of use is provided in Annex I to this opinion.

### **2.2.1. RAC opinion summary**

See RAC Opinion.

### 2.2.2. SEAC opinion summary

PFAS, whether as substances on their own or as part of mixtures or articles, are produced, placed on the market, transported and used throughout the Union in a variety of sectors. This results in transboundary pollution, as PFAS emitted in one Member State may lead to contamination in another. Based on the key principles of ensuring a high level of protection across the Union and of maintaining the free movement of goods within the Union, SEAC supports the view that any necessary action to address risks associated with PFAS should be implemented in all Member States.

SEAC agrees that a broad restriction under REACH is the most appropriate risk management option to address the risks related to PFAS as a group considering their manufacture, uses and life cycle stages. While current regulatory risk management measures (including existing restrictions and other legislation) address some of the concerns associated with the use of certain PFAS, SEAC finds that these cannot fully, appropriately and effectively address all risks arising from all PFAS uses (i.e. at the source). Furthermore, as indicated in the RAC Opinion, a group restriction based on structural similarity and equivalent hazard will prevent regrettable substitution and future exposure to PFAS that are not currently in use. Therefore, the group approach taken for the proposed restriction is considered more effective than regulating PFAS individually, especially given the large number of PFAS.

Based on SEAC's evaluation of the available information on alternatives, costs and benefits, the Committee concludes that a full ban of PFAS with an 18-month transition period (corresponding to RO1 in the Dossier Submitter's assessment) is likely not proportionate. Although RAC considers this restriction option an effective measure to minimise PFAS emissions and exposure of humans and the environment, SEAC finds that it does not sufficiently balance the associated benefits and costs, considering also the sufficiently strong evidence for low substitution potential for several of the (sub-)uses covered by the restriction proposal.

Instead, SEAC considers a ban with use-specific derogations where costs to society outweigh the benefits appropriate to ensure proportionality of the proposed restriction. SEAC has evaluated the available information on alternatives, costs and benefits to determine which derogations are justified to ensure the overall proportionality of a restriction. An overview of SEAC's conclusions regarding derogations is provided in section 3.4.3.2.5.8 of this opinion. It is important to note that any derogations that SEAC considers justified should be regarded as necessary to ensure that a restriction is proportionate, but not as sufficient on their own. Additional derogations may be required for certain (sub-)uses in order for a restriction to be proportionate. However, uncertainties in the available information for the assessed (sub-)uses, as well as unknown or unidentified (sub-)uses, prevent SEAC from specifying such additional derogations.

For the eight additional sectors for which the Committees did not carry out detailed sector-specific evaluations (see above), SEAC cannot conclude whether the derogations proposed by the Dossier Submitter for specific uses/applications within the scope of these sectors are justified, nor whether additional derogations for other uses/applications within these sectors would be justified. SEAC recommends that an evaluation of all uses/applications assessed by the Dossier Submitter within these specific sectors is performed as soon as possible. In the interim, SEAC recommends a time-limited derogation for all uses/applications within the scope of these specific sectors until such an evaluation has been performed and an appropriate decision can be made on proportionality. This would ensure that a decision on the

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need for derogations for uses/applications within the scope of these specific sectors is taken based on a detailed evaluation of the availability and technical and economic feasibility of alternatives, as well as socio-economic impacts. SEAC notes that RAC recommends the implementation of additional risk management measures to ensure PFAS emissions are minimised in case derogations are supported by the decision maker for these eight sectors.

SEAC notes and, in principle, supports RAC's recommendation to implement additional risk management measures – including site-specific PFAS management plans with monitoring of emissions, labelling, safe use and disposal instructions and effective supply chain communication – to ensure PFAS emissions are minimised in case derogations are supported by the decision maker. However, SEAC lacks the information to assess the associated impacts in terms of costs and benefits of these measures. Furthermore, SEAC has concerns about the enforceability of some of the specific measures proposed by RAC, although the Committee considers that these concerns could be mitigated through the elaboration of appropriate guidance. The same conclusion applies to the Dossier Submitter's proposed requirement for site-specific PFAS management plans, as SEAC also considers that there is insufficient information on the associated impacts and has concerns regarding the enforceability of such a requirement.

SEAC considers a reporting requirement to be a generally appropriate tool for monitoring the continued use of PFAS and the effectiveness of the proposed restriction. The Committee notes, however, that monitorability could be improved by extending the requirement to include information on emissions from derogated uses, as recommended by RAC. SEAC lacks information on whether the reporting requirement, either as proposed by the Dossier Submitter or extended to include emissions, would be proportionate in terms of costs and benefits. SEAC also notes that the reporting requirement would provide only limited added value for uses for which a 5-year derogation (following the general 18-month transition period) is proposed.

SEAC finds that the restriction as a whole, including appropriate derogations, is implementable, manageable and enforceable, although certain specific provisions may be more difficult to enforce. SEAC emphasises that the elaboration of appropriate guidance could help mitigate these enforceability concerns. Furthermore, an appropriate, practical and harmonised approach to enforcement at the EU/EEA level is considered a prerequisite to ensure enforceability. SEAC finds the proposed concentration limits appropriate considering the current state of analytical methods. SEAC also notes that, unlike the Dossier Submitter, RAC recommends mandatory prior degradation of precursors in the sample in order to check compliance with the 250 ppb limit since this would allow for the detection of additional PFAS (i.e. side-chain fluorinated polymers).

SEAC considers the proposed restriction to be monitorable. There are, however, challenges affecting monitorability which are linked to the enforceability of the proposed restriction, since enforcement will be the principal means of monitoring compliance and therefore effectiveness.

Overall, SEAC considers the proposed restriction, specifically a ban with use-specific derogations, to be the most appropriate Union-wide measure to address the identified risk while taking into account the proportionality of its socio-economic benefits to its socio-economic costs. It should be noted, however, that SEAC does not agree or cannot conclude on all the specific elements proposed by the Dossier Submitter, as detailed throughout the opinion. In addition, SEAC cannot conclude on the proportionality of the risk management measures recommended by RAC for derogated uses.

## 3. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

### 3.1. RISK ASSESSMENT

#### 3.1.1. Hazard(s)

**Relevant sections of the Background Document:**

See RAC Opinion.

**RAC conclusion(s):**

See RAC Opinion.

**Key elements underpinning the RAC conclusion(s):**

See RAC Opinion.

#### 3.1.2. Risk characterisation

**Relevant sections of the Background Document:**

See RAC Opinion.

**RAC conclusion(s):**

See RAC Opinion.

**Key elements underpinning the RAC conclusion(s):**

See RAC Opinion.

### 3.2. JUSTIFICATION THAT ACTION IS REQUIRED ON A UNION-WIDE BASIS

**Relevant sections of the Background Document:**

Main report, section 1.2.

**RAC conclusion(s):**

See RAC Opinion.

**Key elements underpinning the RAC conclusion(s):**

See RAC Opinion.

**SEAC conclusion(s):**

PFAS, as substances on their own or as part of mixtures or articles, are produced, placed on the market, transported and used throughout the EU in a variety of sectors, leading to transboundary pollution (meaning that one EU Member State may receive PFAS emissions released in another). Any action to address the risks/concerns identified by the Dossier Submitter, as confirmed by RAC, should therefore be taken on a Union-wide basis.

Based on the key principles of ensuring a high level of protection across the Union and of maintaining the free movement of goods within the Union, SEAC supports the view that any necessary action to address risks associated with PFAS should be implemented in all Member States.

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**Key elements underpinning the SEAC conclusion(s):**

Based on evidence provided by the Dossier Submitter, SEAC recognises that the manufacturing, placing on the market and use of PFAS takes place Union-wide.

The Dossier Submitter identified risks from the EU-wide use of PFAS that are not adequately controlled. A large variety of emission sources contribute to the exposure of humans and the environment to PFAS, with water and soil being the key receiving environmental compartments. Some PFAS were shown to be ubiquitous contaminants, for instance in arctic wildlife. Furthermore, the substantial amounts of emissions that reach the air can contribute considerably to transboundary pollution through atmospheric transport, emphasizing the need for EU-wide measures. RAC has confirmed the identified risk.

Continued emissions of PFAS, which are considered to be very persistent, are stated by the Dossier Submitter and RAC to lead to ever increasing amounts of PFAS until such levels are reached where adverse effects are likely<sup>3</sup>. Additionally, current releases of PFAS will become part of the environmental stock and would therefore continue to be a source of exposure for generations. The same holds true for emissions of existing technical stock<sup>4</sup> during the use and waste stage as well as PFAS-containing waste. This in turn will, over time, lead and has already led to irreversible adverse effects on the environment and on human health over time, giving rise to potentially significant social costs.

Exposure of humans, wildlife and the environment to PFAS occurs in all EU/EEA Member States. Removal of contamination is, if even possible at all, technically challenging, energy intensive, and thus costly. Additionally, loss of health (including costs of health care), loss of biodiversity, loss of ecosystem services and loss of property value need to be taken into account. Hence, any measure aiming to effectively reduce/address this risk and correct this market failure needs to be taken in all EU/EEA Member States.

Another argument showing the necessity of EU-wide action is the transboundary nature of PFAS pollution. One EU Member State may receive PFAS emissions released in other Member States. Furthermore, in this case, emissions taking place within the EEA may travel outside the EEA and vice versa. As such, an EU-wide action would not only have a positive effect on the final environmental PFAS stock and exposure levels in the EEA, but could also have this effect outside of the EEA.

The Dossier Submitter identified a large variety of sectors and applications where PFAS are used (Table A.1 in Annex A of the Background Document). Table 4 below presents an overview of the sectors or applications that were assessed in further detail by the Dossier Submitter.

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<sup>3</sup> See section 3.4.2.2.3 on benefits below for further detail regarding adverse effects for human health and environment.

<sup>4</sup> Technical stock of PFAS = defined by the Dossier Submitter as "PFAS in products already in use". Examples are fluorinated gases in heating, ventilation and (mobile) air conditioning equipment. When PFAS in technical stock are emitted they become part of the environmental stock.

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**Table 4: Overview of PFAS use by sector and/or application (ranked according to tonnage)**

1. PFAS manufacturing	2. Textiles, upholstery, leather, apparel and carpets (TULAC)	3. Applications of fluorinated gases
4. Transport	5. Sealing applications	6. Electronics and semiconductors
7. Construction products	8. Food contact materials and packaging	9. Medical devices
10. Lubricants	11. Energy	12. Technical textiles
13. Other medical applications	14. Military applications	15. Broader industrial uses
16. Metal plating and manufacture of metal products	17. Machinery applications	18. Cosmetics
19. Explosives	20. Printing applications	21. Consumer mixtures and miscellaneous consumer articles
22. Petroleum and mining	23. Ski wax	

*Note: Highest tonnage top left, lowest bottom right. Based on Table 3 in the main report of the Background Document (total PFAS, mid scenario).*

Even when only taking into account the sectors/applications in the table above, it becomes clear that PFAS use is widespread. Where information permitted or when socio-economic impacts within a sector or application and the feasibility and availability of alternatives were likely to vary substantially, further subdivisions were made by the Dossier Submitter. For example, TULAC was further subdivided in different uses (home textiles, consumer apparel, professional apparel, etc.) which were divided up even further (e.g. carpets and rugs, sportswear, personal protective equipment). This is however not the case for all sectors or applications.

From this table and the more detailed analysis of the different sectors/applications, SEAC concurs that PFAS have widespread and varied uses, which are targeted to industrial users, professionals and consumers across the EU. Union-wide action is therefore necessary in order to maintain a level playing field within the internal market. Union-wide action would also avoid potential national discrepancies between Member States regarding the definition of PFAS, or difference in scope, that could be a cause of trade and competition distortions and could delay the reduction in emissions of PFAS.

### 3.3. ANALYSIS OF ALTERNATIVES

#### 3.3.1. Availability and technical and economic feasibility of alternatives

##### Relevant sections of the Background Document:

Main report, section 2.4.1; Annex E.

##### SEAC conclusion(s):

SEAC finds the Dossier Submitter's approach for the analysis of alternatives to be appropriate, namely on a sector-by-sector and application-by-application basis. SEAC notes in this regard that information on alternatives varied considerably across sectors and applications, but the consultation on the Annex XV report complemented the analysis in the Background Document,

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even if it did not resolve important data gaps in many cases. Due to the specificities of sectors and (sub-)uses covered, no overall conclusion on the feasibility and availability of alternatives is possible.

SEAC also finds the use of the general “strength of evidence” approach applied by the Dossier Submitter in assessing alternatives appropriate, since it allows proper care to be taken in proposing derogations and providing a measured response to address the identified risk. However, SEAC notes that the Dossier Submitter has taken the non-existence of alternatives as the sole basis for proposing derogations. While an analysis of alternatives is a key element in deciding whether a derogation is warranted or not, the Committee considers that information on emissions as well as costs and benefits should also be taken into account. This would allow SEAC to fully assess the positive and negative effects associated with a lack of action on specific PFAS applications.

### **Key elements underpinning the SEAC conclusion(s):**

The Dossier Submitter approached the analysis of alternatives on a sector-by-sector and application-by-application basis in order to properly structure the Background Document and facilitate assessment of the impacts related to the use of PFAS. SEAC considers this appropriate for several reasons:

- While PFAS as a group have shared functional properties (which led to the shared concern), certain types of PFAS are used in different sectors/applications due to their specific characteristics. The Dossier Submitter categorised PFAS for impact assessment purposes as either 1) PFAAs and PFAA precursors (including short and long chain PFAAs)<sup>5</sup>, 2) Fluorinated gases, or 3) Polymeric PFAS<sup>6</sup>. Where information was available, alternatives were also assessed for smaller substance groups or even single substances.
- The specific characteristics linked to the different types of PFAS require a bespoke approach when it comes to finding alternatives.
- When considering potential loss of performance of alternatives, a bespoke approach is also necessary depending on the specific characteristics required for a specific use. Different levels of loss of performance can be considered acceptable for different applications. In other words, general criteria for “acceptable loss of performance” cannot and should not be defined. As an example, performance tolerances in safety-critical applications of PFAS alternatives in aviation are stricter than in consumer applications. SEAC assesses whether an alternative meets the level of performance required by stakeholders. This is not necessarily the same level of performance when compared to that achieved with the use of PFAS, and there might be some loss of performance<sup>7</sup>. Therefore, SEAC assesses “acceptable loss of performance” from a purely technical viewpoint. When information permitted, SEAC tried to include considerations in its evaluation of sector-/use-specific aspects relating to the base

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<sup>5</sup> PFAAs = Perfluoroalkyl acids (include side-chain fluorinated polymers).

<sup>6</sup> Includes fluoropolymers and perfluoropolyethers (PFPE).

<sup>7</sup> As a general example: a “product” is expected to perform during 20 000 “cycles” and the use of PFAS ensures the “product’s” performance during 40 000 cycles after which it no longer functions. The use of a PFAS-free alternative lowers the “product’s” performance to 35 000 cycles, but the required performance of 20 000 “cycles” is still met. As such, the PFAS-free alternative represents an “acceptable loss of performance” according to SEAC.

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functional performance necessary.

- Different sectors or applications are governed by different economic contexts.

The availability of information on alternatives varies considerably across sectors and applications. This in turn informed the level of detail the Dossier Submitter could go into for each sector and/or application. Furthermore, during the consultation on the Annex XV report a wealth of additional information was received to complement the analysis provided by the Dossier Submitter even if it did not resolve important data gaps in many cases.

The Dossier Submitter uses the “strength of evidence” as an important criterion in the analysis of alternatives and when proposing derogations and distinguishes between the following levels of evidence:

- **Sufficiently strong evidence:** Good evidence from one or more lines of evidence, where conflicting information can be explained and reconciled;
- **Weak evidence:** Insufficient information has been identified, or received from consultation, to establish a firm conclusion;
- **Inconclusive evidence:** Conflicting evidence from one or different lines of evidence, where conflicts cannot be explained and reconciled;
- **No evidence**

The Dossier Submitter also discusses the possible provenance of the evidence (e.g. literature, stakeholder consultations), the quality of the evidence (e.g. representativeness) and the extent to which evidence was available (e.g. multiple lines of evidence, consistency of evidence).

The above-described approach was applied by the Dossier Submitter in the analysis of alternatives and partly also in the socio-economic analysis. Additionally, the strength of evidence pointing to the non-existence of alternatives was the basis for determining if derogations were proposed or not by the Dossier Submitter:

- Only when there was **sufficiently strong evidence** for low substitution potential, a derogation was **proposed** by the Dossier Submitter.
- When there was **weak evidence** at the time of submission of the restriction dossier in January 2023, the Dossier Submitter indicated that a derogation could potentially be warranted but could only be supported if additional information from the six-month consultation on the Annex XV report sufficiently strengthens the evidence base. Where the Dossier Submitter concluded that the evidence remained weak after the Annex XV report consultation, no derogation was proposed.
- When there was **inconclusive evidence** or **no evidence**, a derogation was also not proposed by the Dossier Submitter.

SEAC finds the use of the general “strength of evidence” approach appropriate considering the type of risk the Dossier Submitter wishes to address, i.e. a risk related to exposure that may present delayed effects, is (practically) irreversible, will be carried forward into the future and affect future generations. The identified risk can therefore only be eliminated or reduced at the time of exposure, that is to say immediately (European Commission, 2000). As such, proper care needs to be taken when proposing derogations since these would lead to continued emissions and irreversible exposure to PFAS, resulting in the likelihood of harm persisting and increasing an environmental stock that is extremely difficult or (near-)

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impossible to deal with. The general “strength of evidence” approach used by the Dossier Submitter allows for such a measured response in addressing the risk.

However, SEAC does not find it appropriate that the Dossier Submitter chose to use the non-existence of alternatives as the sole basis for whether or not a derogation is justified or not. As stated earlier, derogations lead to continued emissions and irreversible exposure to PFAS. These continued emissions should therefore be taken into account when proposing a derogation. This would not only allow an examination of the costs and benefits of a proposed derogation by means of the “strength of evidence” approach, but more broadly also a scientific examination of the most likely positive or negative impacts of a lack of action for a certain PFAS application<sup>8</sup>. For this reason, SEAC’s analysis of the proposed derogations is based on the evaluation of the analysis of alternatives as well as the evaluation of associated emissions and socio-economic impacts (as discussed in the relevant sections of this opinion).

A more detailed evaluation of the analysis of alternatives performed by the Dossier Submitter is presented in separate documents containing SEAC’s evaluation of sector-/use-specific aspects.

### **3.3.2. Risk of alternatives**

#### **Relevant sections of the Background Document:**

See RAC Opinion.

#### **RAC conclusion(s):**

See RAC Opinion.

#### **Key elements underpinning the RAC conclusion(s):**

See RAC Opinion.

## **3.4. JUSTIFICATION THAT THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU-WIDE MEASURE**

### **3.4.1. Regulatory risk management options other than restriction**

#### **Relevant sections of the Background Document:**

Main report, section 2.2.

#### **RAC conclusion(s):**

See RAC Opinion.

#### **Key elements underpinning the RAC conclusion(s):**

See RAC Opinion.

#### **SEAC conclusion(s):**

As indicated in the RAC Opinion, a group restriction based on structural similarity and equivalent hazard will prevent regrettable substitution and future exposure to those PFAS

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<sup>8</sup> European Commission (2000)

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which are not currently in use. As such, the group-approach taken for the proposed restriction is considered more effective than regulating PFAS individually, especially when considering the high number of PFAS.

SEAC agrees that while currently applicable regulatory risk management measures (restrictions as well as other legislations) address some of the concerns associated with the use of certain PFAS, these cannot fully, appropriately and effectively address all risks from all PFAS uses (i.e. at the source). Specifically for active substances in Plant Protection Products (PPP) and Biocidal Products (BP), as well as active pharmaceutical ingredients (API) in human and veterinary Medicinal Products (MP), SEAC concludes that the Dossier Submitter has not justified the exclusion of these applications from the PFAS ban via a time-unlimited derogation.

SEAC therefore agrees that a broad restriction is the most appropriate risk management option to address the risks related to PFAS as a group considering their manufacture, uses and life cycle stages. In general, such an approach would allow tailoring the measure with regard to different uses as necessary in terms of use-specific conditions and transition times. SEAC notes that the concerns with PFAS are of a global nature and that as such, a global restrictive action on the manufacture, placing on the market and use of PFAS would be even more appropriate.

### **Key elements underpinning the SEAC conclusion(s):**

After having identified the risk associated with the manufacture, placing on the market and use of PFAS, the Dossier Submitter assessed several risk management options (RMOs) in order to propose the most appropriate option to address those risks (including two REACH restriction options identified as RO1 and RO2 as well as, in specific cases, alternative restriction options identified as RO3).

The Dossier Submitter's justification for the group-approach is in line with the scientific arguments presented in the Commission's Chemicals Strategy for Sustainability (CSS), and more specifically the Staff Working Document on PFAS (European Commission, 2020). Additionally, the grouping approach is found to be a good basis for risk assessment in the scientific literature<sup>9</sup>. The reasons detailing why it is appropriate to regulate PFAS as a group are stated to be:

- Concerns related to the high persistence of PFAS<sup>10</sup>, the lack of knowledge on chemical structures, properties, uses, and toxicological profiles of most PFAS currently in use.
- The growing evidence for adverse effects caused by exposure to highly fluorinated compounds (PFAS), the evidence for widespread occurrence of PFAS in water, soil, articles and waste.
- Precedents for regrettable substitution when only certain (sub-groups of) PFAS are banned which has in some cases led to higher emissions.
- Banning certain (sub-groups of) PFAS has in some cases not led to the elimination of their emissions (e.g. production of alternatives entails creation of banned PFAS as by-

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<sup>9</sup> Cousins et al. (2020b); Scheringer et al. (2022). SEAC notes that there also diverging opinions (e.g. Henry et al., 2018), but these do not take into account the full life cycle of PFAS (i.e. from the manufacturing to the waste stage).

<sup>10</sup> As a result of this the presence of PFAS in the environment is in many cases irreversible making certain natural resources unfit for use.

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products).

The Dossier Submitter additionally points out that a broad group-approach would also avoid the use of PFAS for new or unknown uses.

SEAC notes that RAC's opinion on regulating PFAS as a group is in line with the arguments presented by the Dossier Submitter. SEAC also finds the above-mentioned arguments to be convincing and consequently justify the use of a group-approach as being the most appropriate way to manage the identified risk.

The Dossier Submitter provides a brief overview of regulatory measures that are currently applicable to PFAS in the EU such as the POPs Regulation (Regulation (EU) 2019/1021) (implementing the Stockholm Convention and including PFOS, PFOA, PFHxS), REACH restrictions (TDFAs, C9-C14 PFCAs, etc.), SVHC identification (several PFCAs and PFSAs, etc.), the Ozone Depleting Substances Regulation (Regulation (EU) 2024/590) implementing the Montreal Protocol (covering for example CFCs and HCFCs for their ozone depleting properties), the F-gas Regulation (Regulation (EU) 2024/573) and Mobile Air Conditioning Directive (2006/40/EC) (e.g. HFCs), the Cosmetic Products Regulation (Regulation (EC) 1223/2009)<sup>11</sup>, the Drinking Water Directive (Directive (EU) 2020/2184), the Water Framework Directive (2000/60/EC) and the Food Contact Plastics Regulation (Commission Regulation (EU) 10/2011). Examples of regulatory action taken in non-EU countries such as the USA, Canada, New Zealand and Australia are also briefly discussed. SEAC finds that these more focussed measures (only targeting specific PFAS, specific concerns<sup>12</sup> and/or applications) and measures not addressing the concern at the source are less appropriate but can be complementary to the proposed restriction.

SEAC notes that using a restriction as an EU-wide measure to manage the risks posed by PFAS as a group is coherent with past actions taken for several PFAS substances. It can also be considered useful in terms of consistency of legislation, clarity of the measure to the affected parties, and overall improves the practicality and monitorability of the restriction<sup>13</sup>. Additionally, it adds value by ensuring the elimination of regulatory gaps, but as has been pointed out in the restriction dossier on PFAS in firefighting foams, there may be a need for the European Commission to reconcile the various restrictions at the decision-making phase. The present proposal also more clearly acts against regrettable substitution of one type of PFAS by other types of PFAS and avoids having to comply with several different restrictions of different PFAS, potentially with different transition periods and concentration limits.

The Dossier Submitter echoes arguments made by the Commission in the CSS for using a restriction as the most appropriate action to minimise emissions to the environment associated with the use of PFAS (see earlier). Additionally, the Dossier Submitter notes that a restriction also covers imported articles and indicated these to be a considerable source of PFAS emissions.

The Background Document also contains a brief discussion on measures that could be taken

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<sup>11</sup> Which only covers human health and not environment.

<sup>12</sup> Such as the Global Warming Potential (GWP) in case of the F-gas Regulation or the fact that the Mobile Air Conditioning Directive is limited to the use of fluorinated gases in air conditioning systems in cars and vans. Both legislations also do not target all PFAS (i.e. F-gases with "low" GWP values are not covered).

<sup>13</sup> Learnings from other restrictions can also be applied here and efficiency gains can be expected both from a compliance and enforcement perspective.

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under REACH and other EU legislations and why measures other than a REACH restriction were not considered appropriate. This discussion and SEAC's evaluation can be found in Table 5 below.

**Table 5: SEAC's assessment of RMOs other than REACH restriction**

Regulatory approach	Summary of reasons why SEAC does not find this option appropriate
REACH authorisation (including SVHC identification)	<p>The authorisation process works on a substance-by-substance basis and can as such not immediately address the common concern associated with all PFAS covered by the proposed restriction. The inclusion of thousands of PFAS in the Authorisation List (via the Candidate List) is also not considered practically manageable. The Candidate List currently includes eleven different PFAS. In some cases, these listings also cover salts and isomers. The Authorisation List contains no PFAS.</p> <p>The authorisation process can also not regulate imported articles which the Dossier Submitter indicated to be a considerable source of PFAS emissions. Uses where PFAS are intentionally added in concentrations below 0.1% would also not be covered.</p>
Harmonised classification and labelling (CLH) and/or self-classification	<p>The main concern for PFAS is their high persistence. While PBT/vPvB and PMT/vPvM properties have been added to the Classification, Labelling and Packaging (CLP) Regulation (Regulation (EC) 1272/2008), persistence as a stand-alone classification is not among the classification criteria for CLP. CLH would only be applicable for (certain groups of) select PFAS with additional hazardous properties that warrant classification.</p> <p>Furthermore, harmonised classification and labelling is not necessarily an incentive for substitution and would therefore not eliminate emissions (efficiently and effectively).</p>
Water Framework Directive	<p>These legislative approaches are not capable of preventing PFAS from ending up in the environment, as they are mostly relying on elimination of chemicals from the environment after emissions have taken place. Furthermore, they only legislate a specific aspect related to the PFAS concern.</p> <p>SEAC acknowledges that several of these initiatives have mechanisms to reduce or eliminate emissions of listed chemicals (i.e. Water Framework Directive and Industrial Emissions Directive), but they are much less effective, efficient and more uncertain at addressing the identified risk than the one provided by a restriction under REACH.</p> <p>Considering the information SEAC has on the availability, performance and cost of existing remediation techniques (based on the Background Document, Annex XV report consultation input and also information submitted in the course of evaluation of earlier restriction cases on PFAS substances), as well as taking into account the broad scope of the proposed restriction, the Committee concludes that minimising PFAS emissions at the source (which can be achieved via a restriction) is a more appropriate approach.</p> <p>SEAC notes, however, that actions under these legislations, in conjunction with the proposed restriction, can create synergies and raise the overall effectiveness of the proposed measure under REACH (especially for sectors/uses subject to derogations).</p>
EU soil health law	
Drinking Water Directive	
Sewage Sludge Directive (86/278/EEC)	
Waste legislation	
Industrial Emissions Directive (2010/75/EU)	
Volatile Organic Compounds Directive (1999/13/EC)	<p>While these legislations can tackle the emissions of PFAS at the source, measures taken would only apply to part of the concern that was identified by the Dossier Submitter. A restriction can cover food contact materials and all other uses as well.</p>
EU legislation on (plastic) materials intended to come into contact with food	
EU legislations on PPP, BP and MP	<p>Action taken under these legislations would not address the concerns associated with PFAS that have other applications than as active substances in PPP, BP and MP. See more detailed discussion below.</p>

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The assessment in the Background Document does not go into further detail (except for active substances, see below), and SEAC finds this logical, considering previous practices in regulating certain types of PFAS and the objectives and actions set out in the CSS.

The Dossier Submitter has explicitly excluded PFAS used as active substances<sup>14</sup> in **Plant Protection Products (PPP) and Biocidal Products (BP)**, as well as active pharmaceutical ingredients (API) in human and veterinary **Medicinal Products (MP)** by proposing a time-unlimited derogation from the ban on manufacturing, placing on the market and use. According to the Dossier Submitter this is justified due to there being a specific regulatory regime for these uses which includes an evaluation and approval process that could potentially deal with risks of persistent substances. However, since the Dossier Submitter acknowledges that PPP, BP and MP contribute to the releases of PFAS, they propose reporting requirements for manufacturers and importers of PFAS active substances and APIs. These reporting requirements are discussed later in this opinion, together with the reporting requirements proposed for certain use-specific derogations.

While SEAC agrees that certain PFAS used as active substances in PPP, BP and MP can play a vital role in our society and banning them could lead to significant impacts, for example on human health in case of MP, the Committee finds that excluding these applications from the PFAS ban via a time-unlimited derogation is not justified and inconsistent for several reasons:

- The Dossier Submitter acknowledges that these applications lead to significant emissions which are on par with some other uses of PFAS.
  - Volumes used of PFAS APIs for human use is estimated to be higher than 500 tonnes per year.
  - The use of PFAS active substances in PPP is roughly estimated to be 5 500 tonnes per year.
  - No information on volume is available for PFAS APIs in veterinary medicine and active substances in BP.
- The Dossier Submitter treats the use as active substances inconsistently when compared with the rest of the restriction proposal (i.e. where derogations were proposed by the Dossier Submitter based on an analysis of alternatives and an assessment of socio-economic impacts of a ban was provided).
- The Dossier Submitter points out that the predominant concern intended to be addressed by the proposed restriction (i.e. high persistence) is not sufficiently taken into account during the approval process for PPP, BP and MP. The mere existence of a form of environmental risk assessment as part of the authorisation/approval process is not sufficient to conclude that the risks associated with the use of PFAS in PPP, BP and MP are sufficiently addressed.
  - Likewise and more generally speaking, the mere existence of a specific regulatory regime for PPP, BP and MP does not automatically indicate that the risks with their use are sufficiently addressed under those sectoral legislations (see discussion on “Applications of fluorinated gases”).
- The Dossier Submitter indicates that trifluoroacetic acid (TFA) is one of the possible

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<sup>14</sup> SEAC notes that this proposed derogation does not cover co-formulants. Excipients, immediate packaging and drug delivery devices are assessed in the Background Document under “Other medical applications”.

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major metabolites/degradation products for PPP, BP and MP. TFA is known to be extremely persistent in the environment and has a harmonised classification for causing severe skin burns and eye damage, being harmful if inhaled and being harmful to aquatic life with long lasting effects. Other metabolites and/or degradation products which are extremely stable and hazardous can also be formed. Currently, a proposal to classify TFA as Acute toxic 3 (H331) and Reproductive toxicity cat 1B (H360Df), as well as PMT (H450) and vPvM, (EUH451), is under evaluation by RAC.

Since these applications were a priori proposed for a time-unlimited derogation, no risk and impact assessment was performed by the Dossier Submitter and as such there is no further information available for SEAC to assess what the socio-economic consequences would be of a ban on PFAS used as active substances or APIs, and whether this would be appropriate and proportionate. As such, SEAC concludes that the Dossier Submitter has not properly justified the exclusion of these applications from the ban on PFAS via a time-unlimited derogation. SEAC notes that RAC considers that current legislations on PPP, BP and MP do not fully address the concern associated with PFAS emissions to the environment and that RAC considers it important that measures to minimise emissions from the use of PFAS as active substances in PPP, BP and MP are incorporated into the respective sector-specific regulations in case derogations are granted for these uses.

The CSS also indicates that the Commission will complement a general restriction of PFAS, which limits emissions at the source, with actions under other legislative frameworks (water, food, industrial emissions, waste, sustainable products initiative) and non-legislative initiatives (soil). Specific measures that have been identified are, for example, to improve reporting of PFAS releases into the environment (via the Industrial Emissions Directive and the European Pollutant Release and Transfer Register), address PFAS via international fora such as the Stockholm Convention and establish financial support for research and innovation of PFAS alternatives as well as remediation practices. While a general restriction of PFAS is considered the most appropriate EU-wide measure, SEAC considers that the use of complementary measures (see above) could enhance the efficacy and effectiveness of the proposed restriction and already limit/reduce the risks for those applications where a derogation from the PFAS ban is proposed. These complementary measures can, for example, prove helpful in limiting the negative effects related to the proposed derogations (as well as provide better mapping of impacts related to these), reduce economic impacts related to substitution or address risks of PFAS on a more global level. An assessment of interactions between the proposed restriction and possible other legislative measures has not been performed by the Dossier Submitter and is therefore not evaluated by SEAC.

In addition to the above, where relevant, sector-specific considerations regarding regulatory risk management options other than restriction are discussed in the documents containing SEAC's evaluation of sector-/use-specific aspects.

### **3.4.2. Restriction options**

#### **Summary of the restriction options proposed by the Dossier Submitter:**

The Dossier Submitter assessed the following restriction options:

- Restriction option 1 (RO1): Full ban with an 18-month transition period; and
- Restriction option 2 (RO2): Ban with use-specific and (mainly) time-limited derogations.

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- For specific sectors, a third restriction option (RO3) was introduced by the Dossier Submitter, which foresees additional conditions for specific (sub-)uses instead of a ban or to complement a time-limited derogation. The conditions mainly relate to emission control and reporting measures for (sub-)uses where derogations are foreseen. RO3 was introduced only after the Annex XV report consultation, based on information provided by stakeholders, for the following sectors: i) PFAS manufacturing, ii) Transport, iii) Electronics and semiconductors, iv) Energy, v) Sealing applications, vi) Machinery applications and vii) Technical textiles. Depending on the sector affected, the design of RO3, as well as its conditions, differ.

The restriction proposed by the Dossier Submitter (see Table 1) corresponds to RO2 for all sectors except for PFAS manufacturing, for which RO3b<sup>15</sup> is proposed.

The conditions of the proposed restriction also include reporting requirements (for derogations with a 12-year derogation period or time-unlimited and all applications of fluorinated gases), labelling requirements (for certain plastic articles or complex objects) and the establishment of site-specific PFAS management plans (for manufacturers, importers and downstream users of fluoropolymers and perfluoropolyethers making use of a derogation). Further details on the proposed restriction are given in Table 1 of this opinion.

### **3.4.2.1. Effectiveness in reducing the identified risk(s)**

#### **Relevant sections of the Background Document:**

See RAC Opinion.

#### **RAC conclusion(s):**

See RAC Opinion.

#### **Key elements underpinning the RAC conclusion(s):**

See RAC Opinion.

### **3.4.2.2. Socio-economic analysis**

#### **3.4.2.2.1. Approach**

#### **Relevant sections of the Background Document:**

Annex E, section E.2.

#### **SEAC conclusion(s):**

SEAC notes that the scope of the PFAS restriction proposal is complex and broad (in terms of substances covered and sectors/(sub-)uses affected). Most of the sectors and (sub-)uses assessed in the Background Document lack robust socio-economic information, which hampers a proper (quantitative or qualitative) evaluation of the socio-economic impacts related to the restriction options discussed. SEAC emphasises that in such broad and complex restriction proposals, a well-elaborated approach, which is consistently applied across all sectors and (sub-)uses covered, is necessary to assess and conclude on the socio-economic

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<sup>15</sup> RO3b corresponds to a ban with a time-unlimited derogation for the manufacturing of PFAS conditional upon emission limits.

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impacts, regardless of whether the data allow for a quantitative or merely a qualitative assessment. Such an approach allows evaluating and comparing impacts (e.g. costs) across the sectors and (sub-)uses assessed and drawing conclusions in spite of data and information gaps. SEAC acknowledges the Dossier Submitter's effort to present a thought-through approach that tackles this challenge in a stepwise and transparent manner. SEAC finds the approach outlined by the Dossier Submitter, in principle, a good foundation upon which the assessment of socio-economic impacts can be built.

However, SEAC noticed that there are shortcomings in both, the design of some steps of the approach (i.e. the proportionality assessment) as well as the actual implementation of the approach, which hampered SEAC's ability to evaluate the socio-economic impacts of the restriction options assessed.

SEAC's view on the specific details of each step of the approach is presented in the sections on costs, benefits and proportionality further below in this opinion.

### **Key elements underpinning the SEAC conclusion(s):**

The Dossier Submitter assesses on a sector basis mainly qualitatively the positive (benefits) and negative (costs) impacts related to the two restriction options RO1 (full ban) and RO2 (ban with use-specific derogations) and, where relevant, RO3 (restriction options proposing conditions in case of continued use or to complement a time-limited derogation, discussed for specific sectors only). The impact assessment approach outlined in the Background Document covers the following steps<sup>16</sup>:

1. **Baseline:** this step covers information (where available) on the types of PFAS used in each sector, annual use volumes between 2020 and 2070 as well as associated emissions, and assumptions on expected growth rates over the assessment period, for which the Dossier Submitter chose a timeframe of 30 years.
2. **Analysis of alternatives:** this step includes information on the technical and economic feasibility of alternatives, their availability, their human health and environmental hazard profile, as well as the time required for transitioning to an alternative. The analysis of alternatives is discussed in more detail in section 3.3 of this opinion.
3. **Assessment of environmental impacts:** this step covers the environmental impact assessment for both restriction options RO1 (full ban) and RO2 (proposed restriction, ban with derogations) over an assessment period of 30 years. For RO2, the approach distinguishes between two possible scenarios: where quantitative emission data are available, the emissions due to a derogation are quantified. For many sectors, however, emission data at (sub-)use level are not available. In those cases, the Dossier Submitter approximated additional emissions due to the proposed derogations through expert judgement. On the basis of the emission reduction potential, the effectiveness of each restriction option is derived and is categorised into 5 levels ranging from very low to very high. Where relevant and possible, environmental impacts are also assessed for RO3.
4. **Assessment of economic and other impacts:** this step comprises the cost assessment performed by the Dossier Submitter on a sector and/or (sub-)use basis,

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<sup>16</sup> The approach to the impact assessment is in detail explained in section E.2 of Annex E to the Background Document. The above only provides a summary of the Dossier Submitter's approach.

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covering economic and other impacts, where relevant. While for some sectors/(sub-)uses covered, limited quantified cost figures are available, the assessment provided is largely qualitative. The Dossier Submitter considers different cost components (for details see the cost section below and the documents containing SEAC's evaluation of sector-/use-specific aspects) covering e.g. costs for companies (due to substitution or business closure), costs for customers (due to increasing prices of goods), welfare losses and/or costs resulting from changes in the characteristics (changes in quality and/or lifetime) or the absence of a good, and costs due to employment losses. In order to facilitate a comparison within and across sectors, costs are categorised into five qualitative categories, ranging from very low costs to very high costs. The Dossier Submitter's approach to determine each cost level is described in section 3.4.2.2.2 (costs) below.

5. **Summary of the cost and benefit assessment:** to present the outcome of the alternatives, cost and benefits assessment, as well as the relevant derogations proposed, tables with the aforementioned information (steps 1 to 4) are included.
6. **Proportionality assessment:** the last step comprises a comparison of the level of costs (economic costs or other impacts) with the effectiveness (emission reduction) of the restriction options at sector level. The Dossier Submitter presents the assigned effectiveness and cost levels in a matrix to allow an evaluation of the potential proportionality of the assessed restriction options at sector level. This approach is further explained in section 3.4.2.2.5 (proportionality) below.

SEAC notes that the above proportionality assessment is only available on a sector-specific basis but not for the different restriction options overall.

### **3.4.2.2.2. Costs**

#### **Relevant sections of the Background Document:**

Main report, sections 2.1 and 2.4.1; Annex E.

#### **SEAC conclusion(s):**

SEAC notes that the Dossier Submitter **did not conclude on the overall costs** associated with the restriction options RO1, RO2 and RO3 (discussed for specific sectors only) and, consequently, also not for the proposed restriction (which corresponds to RO2 for all sectors, except for PFAS manufacturing, for which RO3b is proposed). Instead, a cost assessment was performed on a sector- and/or (sub-)use-level for the sectors addressed in the Background Document. SEAC's evaluation of the sector-based cost assessment is provided in the respective documents containing SEAC's evaluation of sector-/use-specific aspects. Furthermore, SEAC notes that the main basis for the Dossier Submitter's cost assessment is the outcome of the analysis of alternatives, which is a relevant factor but generally not sufficient on its own to conclude on the magnitude of costs expected to result from a restriction.

For the restriction options and the proposed restriction overall, SEAC **cannot conclude on the magnitude of costs** due to a general lack of data and partly substantial shortcomings in the cost assessment provided in the Background Document (see key elements section below as well as the documents containing SEAC's evaluation of sector-/use-specific aspects).

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However, based on the information available to the Committee, SEAC finds that the costs associated with a **full ban of PFAS (= RO1) are likely significant**. Whilst SEAC finds that **costs associated with RO2 and RO3 and, therefore, the proposed restriction are mitigated** due to the derogations and conditions proposed allowing the continued use of PFAS for specific (sub-)uses and/or applications (in many cases with a time limit), the magnitude of the mitigation is unknown.

**Key elements underpinning the SEAC conclusion(s):**

- **Qualitative approach:**

In general, SEAC prefers a robust quantitative and monetised assessment of costs, which allows for a meaningful comparison of costs and benefits of a restriction proposal as well as between evaluated restriction options. However, SEAC acknowledges that there are cases where a quantitative assessment is not possible or proportionate. In such cases, the Dossier Submitter needs to clearly document the systematic efforts made towards a quantitative assessment and the reasons why any such assessment was not regarded feasible or proportionate. SEAC notes that in the current case, which is very broad as far as the scope is concerned (grouping of substances as well as covering a wide variety of sectors and (sub-)uses), a full quantitative assessment is a challenging and probably impossible task. However, SEAC notes that at least for sectors and uses where the impacts are considered to be considerable, attempts should be made to provide quantified cost estimates. If still regarded impossible by the Dossier Submitter, a detailed description of the attempts made and a justification for failure in sufficient detail is required by SEAC, as pointed out in the paper on SEAC's evaluation of qualitative assessments in restriction reports (ECHA, 2022).

In order to account for the approach outlined in the aforementioned SEAC paper and to allow comparability of costs within and across sectors, the Dossier Submitter introduced the following approach in the Background Document:

The Dossier Submitter's qualitative cost assessment comprises five categories: costs are classified as very low, low, moderate, high or very high, based on specific criteria applied. The criteria are mainly related to the availability and feasibility of alternatives and the expected magnitude of costs:

- a. **Very low** costs, if:
  - i. Technically and economically feasible alternatives are available; and
  - ii. The impact assessment indicates that the costs are close to zero, e.g. if only a small number of companies and/or users are affected, and each to a limited extent.
- b. **Low** costs, if:
  - i. Technically and economically feasible alternatives are available; and
  - ii. They do not fall into the very low or moderate cost categories.
- c. **Moderate** costs, if:
  - i. Technically and economically feasible alternatives are available; and
  - ii. The impact assessment indicates that substitution costs will not be low, e.g. due to a large number of firms and/or end users affected (despite limited impacts at company or individual level), and/or complicated substitution processes.

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- d. **High** costs, for all other cases, i.e.:
- i. Where feasible alternatives are not available;
  - ii. But the implications are not as severe as in the cases for which costs are classified as “very high”.
- e. **Very high** costs, if:
- i. Substantial social costs due to health and safety implications are expected; and/or
  - ii. Severe impacts on the competitiveness of the EEA industry are expected. As examples can be mentioned: i) PFAS are only relevant for the manufacturing stage of products and not contained in the final product and a ban would thus not affect imports; ii) market growth is expected to be high at the global level and the price is expected to play a role that is beyond average in determining customers’ purchasing decisions (with a very limited possibility for EU companies to compete in such markets based on quality arguments).

Furthermore, the Dossier Submitter uses the “strength of evidence” approach for assessing costs. However, whilst this was done by the Dossier Submitter for some sectors, it was not applied consistently for all sectors covered by the assessment of the restriction proposal. The concept is already explained in detail in section 3.3.1 on the analysis of alternatives above and distinguishes between the following levels of evidence:

- **Sufficiently strong evidence:** Good evidence from one or more lines of evidence, where conflicting information can be explained and reconciled;
- **Weak evidence:** Insufficient information has been identified, or received from consultation, to establish a firm conclusion;
- **Inconclusive evidence:** Conflicting evidence from one or different lines of evidence, where conflicts cannot be explained and reconciled;
- **No evidence**

Evidence can consist of information from literature, stakeholder information provided in the call for evidence, the stakeholder consultations performed by the Dossier Submitter or the consultation on the Annex XV report, precedence, principles, consistency arguments, defaults and expert judgement. A detailed description of what is understood by the aforementioned aspects is provided in the Background Document, section 2.4.1.1 (main report).

SEAC acknowledges the Dossier Submitter’s effort to develop an approach that allows a structured qualitative cost assessment across the sectors covered by the Background Document. Such an approach, in principle, enables consistency and comparability of (the results of) the cost assessment for different sectors. The Committee, however, notes differences in the approach to and quality of the assessments provided for different sectors. Furthermore, neither of the aforementioned concepts have been applied consistently across all sectors assessed; both aspects hampering the comparability of the results and the achievement of a complete picture of costs for the restriction options RO1, RO2 and RO3 as well as the proposed restriction overall. Furthermore, SEAC notes that even though the cost qualifiers (very low, low, moderate, high, very high) have been used for concluding on costs for all sectors assessed, the criteria established in order to arrive at a conclusion have not

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always been consistently and/or transparently applied so that in several cases SEAC lacks information why a specific conclusion has been drawn/a specific qualifier has been used. In its own evaluation, SEAC accounts for the aforementioned differences with a nuanced wording: where the Committee is confident with the sector-based assessment provided in the Background Document and is able to evaluate it, the cost qualifiers established by the Dossier Submitter are also used by SEAC (i.e. very low, low, moderate, high, very high). For sectors where SEAC is less confident with the assessment and conclusions presented in the Background Document, other qualifiers such as “(likely) significant”, “(likely) not insignificant”, “(likely) insignificant, and others are used, if the information available to the Committee allowed to do so. These qualifiers are used for sectors where some information was provided but the information base for assessing costs – e.g. the number of companies affected, the number of (sub-)uses/applications/products affected, the most likely reaction to a restriction (e.g. relocation and/or shutdown of business or substitution) – is unknown/unclear or very limited and/or the cost assessment is of low quality so that high uncertainties exist. This means that even if SEAC cannot conclude on the magnitude of costs, the Committee tried to provide the decision maker with an indication of the potential impacts related to a restriction option. SEAC notes that these qualifiers are to be seen as indications and do not correspond to a fixed scale or strictly defined criteria. The limited information available to SEAC as well as the differences in regard to the level of detail across the Dossier Submitter’s sector-specific cost assessments did not allow the Committee to systematically apply a fixed scale or strictly defined criteria. SEAC emphasises that for several sectors also the information provided by stakeholders in the Annex XV report consultation was utilised by the Committee to reach its conclusion on costs.

- **Sector-/use-specific approach:**

The Dossier Submitter approaches the cost assessment on a per-sector/per-(sub-)use basis. For this approach, 23 sectors, including PFAS manufacturing, were identified and further divided into uses and sub-uses. This further differentiation was regarded necessary, as socio-economic impacts differ among the different uses (as was the case for the analysis of alternatives). SEAC agrees with the Dossier Submitter’s approach to perform the cost assessment on a per-sector/per-(sub-)use level. However, SEAC notes that the cost assessment differs across sectors/(sub-)uses in terms of the approach, detail and quality, which hampers the comparability across sectors. SEAC notes that whilst for some sectors the cost assessment is very well structured and detailed and assumptions are well explained and substantiated by supporting evidence (e.g. the TULAC sector), for other sectors, the discussion and conclusion is brief and rather generic (e.g. the food contact materials and packaging sector). For sectors falling into the second category, SEAC notes that instead of a robust cost assessment (i.e. defining non-use scenarios which reflect the actual situation under a ban/restriction and assessing the related cost impacts), the discussion in the Background Document mainly consists of a listing of possible scenarios without defining and assessing the most likely scenario(s) and consequently, the related costs. Whilst SEAC understands that this is mainly due to a lack of (relevant) information, it hampers SEAC’s ability to evaluate and draw conclusions on costs. SEAC emphasizes that a similar basic approach consistently applied for all sectors, accompanied by an extended level of detail as applicable and as information allows, would have facilitated the overall assessment of and conclusion on costs as well as comparability of (the magnitude of) costs across sectors.

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- **Evaluated cost components:**

*On a per-sector/per-(sub-)use basis*

Depending on the specific situations of sectors and (sub-)uses and the information available, the Dossier Submitter generally considered **costs to industry** (e.g. costs for manufacturers or downstream users of PFAS-containing products due to closure of business or substitution), **costs to consumers** (e.g. as a result of changes in product prices), **welfare losses** (due to changes in the characteristics of goods (e.g. quality) or the fact that certain products are no longer available on the EU-market), as well as **social costs of unemployment**. SEAC agrees that these cost components are relevant for the proposed restriction. SEAC's view on the Dossier Submitter's assessment of these cost components is provided in the respective documents containing SEAC's evaluation of sector-/use-specific aspects.

*Overall for the proposed restriction*

In SEAC's view, a discussion on **enforcement costs** should in general comprise **administrative** and **analytical or testing costs** in relation to the proposed restriction, including incremental costs for staff salaries, materials, equipment and overhead costs as well as costs for developing testing methods and conducting tests for products affected by the proposed restriction. SEAC notes that no actual assessment of enforcement costs was provided by the Dossier Submitter. Instead, to account for **administrative** enforcement costs, a reference to the generic estimate of €55 000 annual average enforcement costs per restriction, as established by ECHA (2017)<sup>17</sup>, is provided in the Background Document. SEAC considers this approach feasible because of the lack of other available estimates, as stated by the Dossier Submitter, and due to the fact that this approach was also applied to other/comparable restriction cases, such as the restriction dossier on intentionally added microplastics. For the latter, the aforementioned estimate of €55 000 was not applied for the proposed restriction overall, but for each of the sectors affected in order to reflect the broad scope covering several sectors and uses. In line with this approach, the Dossier Submitter accounts for the enforcement costs with €55 000 for each sector. SEAC basically agrees that similarities between the present restriction case and the intentionally added microplastics case allow for a similar approach to assess enforcement costs. Furthermore, SEAC agrees with the Dossier Submitter that the approach could constitute an overestimation of enforcement cost, as e.g., several substances and uses covered by the restriction proposal are already targeted by existing restrictions within the POPs Regulation and the REACH Regulation and synergies with enforcing these restrictions exist. SEAC notes that only very limited information was provided by the Dossier Submitter on **analytical and testing costs**, stating costs of €100 per sample for a standardised targeted LC-MS/MS analysis in commercial laboratories up to significantly higher costs for more complex analysis, such as non-target screenings, which are rather to be performed by high-end commercial laboratories, research institutes and/or universities. No cost information on analytical and testing costs was provided in the consultation on the Annex XV report. SEAC therefore cannot conclude on their magnitude for the restriction proposal overall.

The Dossier Submitter further discusses **administrative costs for authorities** in relation to the **certification** of products based on alternatives. Where certification/requalification of

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<sup>17</sup> ECHA has estimated the incremental administrative costs for restrictions at approximately €55 000 per year using the fixed budget approach (i.e. that enforcement authorities have a limited budget for enforcement, which they allocate to enforcing restrictions on the basis of the expected risk of non-compliance).

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products lead to costs for companies, these are discussed in the documents containing SEAC's evaluation of sector-/use-specific aspects. SEAC notes that no information on the magnitude of costs to authorities have been provided by the Dossier Submitter, neither was any such cost information provided in the consultation on the Annex XV report. SEAC therefore cannot conclude on these costs.

SEAC notes that no information on costs associated with the proposed **reporting requirements, labelling requirements** and the proposed establishment of site-specific PFAS **management plans**, when making use of specific derogations, is provided in the Background Document. As such, the actual costs for companies to collect the required information, prepare the reporting, and/or establish a PFAS management plan remain unclear to SEAC. SEAC acknowledges that assessing any such costs is difficult, e.g. as the number of companies making use of a derogation, which would induce the aforementioned requirements, is unknown until the restriction enters into force. Regarding the reporting requirements, the Dossier Submitter provides a brief discussion on what needs to be reported, which (already established) formats could be used, which actors are involved and refers to reporting requirements and the related developed procedures within other REACH restrictions, specifically the restriction of synthetic polymer microparticles in Entry 78 of Annex XVII. SEAC, however, notes that for both requirements, the discussion is focussed on practicality rather than on any estimation of costs (e.g. one-off costs, recurring costs). Overall, SEAC cannot conclude on the costs associated with the reporting and labelling requirements as well as the establishment of site-specific PFAS management plans as proposed by the Dossier Submitter or as recommended by RAC and additional measures proposed by RAC<sup>18</sup> due to a lack of assessment as well as a general lack of data. Still, SEAC finds that costs associated with these requirements could potentially be significant due to the broad scope of the restriction proposal and the potentially high number of companies being affected. SEAC notes that the lack of information adds to the already existing uncertainties related to the magnitude of costs on a sector level as well as the proposed restriction overall.

### **3.4.2.2.3. Benefits**

#### **Relevant sections of the Background Document:**

Main report, sections 1.1.4, 2.1, 2.4.2 and 2.4.3; Annex B; Annex E.

#### **SEAC conclusion(s):**

SEAC notes RAC's conclusion on the **very persistent** property of PFAS as well as the supporting concerns. The latter include (eco)toxicity, mobility, bioaccumulation, long-range transport and global warming potential. While these properties vary between different PFAS, RAC considers the very persistent property of PFAS in combination with other, although diverging, hazards present grounds for a significant concern for human health and for the environment. Considering RAC's opinion on the very persistent property of PFAS or their transformation products, SEAC notes that present emissions continuously contribute to the build-up of the already existing environmental stock, which is technically and economically (nearly) impossible to clean up and, even if possible, remediation techniques are known to be very costly. Furthermore, elimination of present emissions does not necessarily lead to a

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<sup>18</sup> Detailed information on SEAC's evaluation of the Dossier Submitter's proposal as well as RAC's evaluation and recommendation is provided in section 3.4.3.2.6 below.

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decrease in exposure, as PFAS will continue to be released from articles in use or those remaining on the shelves (technical stock), as well as PFAS emissions from articles in the waste stage, both contributing to the environmental stock.

SEAC notes that RAC concurs with the Dossier Submitter that PFAS should be treated as non-threshold substances for the purpose of risk assessment in a similar manner to PBT/vPvB substances, whereby releases are taken to be a proxy for risk and ultimately, that releases should be minimised. Analogously to the evaluation of previously established and submitted restriction reports for persistent substances, the Dossier Submitter uses avoided emissions as a proxy for the risk reduction capacity of the restriction options assessed. Based on RAC's conclusion, SEAC regards this as an appropriate approach as this is well in line with the approach taken in previous restriction reports such as the one on intentionally added microplastics or other PFAS restriction proposals. However, SEAC notes a shortcoming when translating the emission reduction into the benefits of a restriction. SEAC agrees with the Dossier Submitter that this approach would only consider the pollution flow into the environment, but not the accumulation of pollution over time and any related long-term impacts and damage due to the persistence of PFAS. SEAC notes that the effects of such accumulation are unpredictable in the long-term. Even an immediate elimination of releases will not necessarily result in a measurable reduction in exposure due to the already existing stock in the environment as well as due to the technical stock. As the use of emission estimates as a proxy for risk does not reflect the accumulation of stocks of persistent substances in the environment, this approach will therefore likely underestimate the benefits of the proposed restriction. Nevertheless, considering SEAC's approach for evaluating persistent substances (ECHA, 2023), SEAC notes that benefits of regulatory measures adopted on persistent chemicals can be approximated by estimates of the avoided stock in the environment. Therefore, **SEAC agrees with the Dossier Submitter's approach to estimate benefits of each restriction option through the emission reduction potential.**

SEAC notes RAC's conclusion that **RO1**, i.e. a full ban for all uses of PFAS, is an effective measure to minimise PFAS emissions and exposure of humans and the environment. RAC calculated a total emission reduction potential of **96%** (excluding uses not evaluated in detail), corresponding to approximately 3.3 million tonnes of avoided emissions over the 30-year assessment period. Also, SEAC notes RAC's conclusion that the effectiveness of the **proposed restriction option** (which corresponds to RO2 for all sectors, except for PFAS manufacturing, for which RO3b is proposed) is reduced to **76%** due to the proposed use-specific derogations, corresponding to approximately 2.6 million tonnes of avoided emissions over the 30-year assessment period. As such, the proposed restriction option is estimated to induce additional emissions of around 700 000 tonnes compared to RO1 (excluding uses not evaluated in detail) and results in an uncontrolled risk. Further details are provided in section 3.4.2.1 of the RAC Opinion.

**In conclusion, SEAC takes note of the emission reduction potential as calculated by RAC and emphasises that this leads to manifold benefits associated with each unit of reduced emissions such as health impacts, environmental impacts and reduced remediation costs** as detailed below. SEAC notes that these **benefits are reduced under the proposed restriction** (which corresponds to RO2 for all sectors, except for PFAS manufacturing, for which RO3b is proposed) due to the additional emissions associated with the use-specific derogations. SEAC also notes that benefits would be reduced in case companies implement alternatives that are of comparable concern to PFAS. Further

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information on the risk of alternatives is provided in the sector-specific evaluations of RAC and SEAC.

**Key elements underpinning the SEAC conclusion(s):**

• **Concern identified and benefits associated with emission reduction:**

Considering RAC's conclusion on the **very persistent** property of the substances covered by the scope, SEAC notes that any emissions can stay in the environment for decades or longer, i.e. in case of continued emissions, the global environmental stock will be increasing continuously, leading to irreversible and continuing contamination. Furthermore, SEAC notes RAC's conclusion on supporting concerns related to specific PFAS covered by the scope, including **bioaccumulation, mobility, (eco-)toxicity**, their **long-range transport potential** as well as their **endocrine activity** (more information is provided in the RAC Opinion). RAC concluded that the exposure to PFAS may lead to numerous health and environmental effects. Therefore, SEAC notes that a reduction of PFAS emissions will lead to a number of benefits as detailed below:

- **Human health effects:** SEAC highlights that continuous emissions of PFAS lead to unavoidable exposure of humans and related negative effects on human health. Such negative effects are detailed in section 3.1.1 of the RAC Opinion and include, for instance, effects on liver and serum cholesterol levels, developmental effects such as birth weight and neurodevelopmental effects, effects on immune function including reduced antibody response after vaccination and reduced ability to fight against infections. Furthermore, SEAC notes that the list of adverse health effects has been confirmed (e.g. comments #7146, #7642, #9560) and even added to (e.g. comments #9228, #9560) by stakeholders in the consultation on the Annex XV report. The comments address, among others, decreased immune response to vaccines as well as various childhood illnesses, including endocrine disrupting effects, thyroid function and risk of obesity, distributed timing of puberty, impaired fertility, neurodevelopment alterations and numerous rare diseases as detailed in the Background Document. SEAC notes that the before-mentioned effects are associated with high costs such as welfare losses due to illness and reduced quality of life as well as high health care costs. Due to the high variety of PFAS types and characteristics and the lack of data with regards to specific health care costs directly to be linked to PFAS exposure, SEAC agrees with the Dossier Submitter that it is impossible to place a quantitative value on the health benefits of the proposed restriction. However, in SEAC's view, a restriction of PFAS will result in a reduction of the otherwise continuous and increasing exposure to PFAS. As such, a restriction will lead to benefits for human health through a reduction of any related negative human health effects. The Dossier Submitter substantiated the high cost of inaction with regards to health effects with a report by the Nordic Council of Ministers (Goldenman et al., 2019) that estimates the annual health costs of exposure to PFAS in all EEA countries to amount to €52-84 billion. SEAC notes that the health costs assessed in the report are associated with PFAS substances already restricted, such as PFOS and PFOA, and notes RAC's opinion on the large differences in the human health hazards of different PFAS. However, SEAC notes RAC's conclusion on the human health effects of numerous other PFAS substances emitted into the environment some of which are comparable to the concerns associated with PFOS and PFOA (see section 3.1.1 of the RAC Opinion). Furthermore, SEAC notes that a recent study by the European Commission (2026)

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confirms the substantial health costs associated with continuous emissions of and increasing human exposure to PFAS. The same study points out that health costs do not significantly decrease even if the limit values set by the Drinking Water Directive are met through expensive remediation and water treatment because drinking water only accounts for a small fraction of human exposure. Whilst no quantitative and monetised benefits assessment was performed by the Dossier Submitter for the proposed restriction, the results of these reports represent strong supporting evidence that a restriction of PFAS is expected to lead to substantial benefits for human health.

- **Environmental effects:** The Dossier Submitter provided an in-depth analysis of information available on hazards including ecotoxicity and other environmental impacts (Annex B and section 1.1.4 of the main report of the Background Document) and SEAC points to RAC's evaluation thereof (section 3.1 of the RAC Opinion). SEAC therefore notes the benefits associated with a reduction of PFAS emissions due to a reduction of adverse effects observed in various environmentally relevant species with potential relevance at the population level as confirmed by RAC. While the impacts of PFAS emissions on the environment were not monetized by the Dossier Submitter, the broader implications resulting from both human health and environmental effects such as loss of ecosystem services and the degradation of natural resources are further addressed below.
- **Particle emissions:** SEAC notes RAC's opinion on the concerns related to micro- and nano-sized fluoropolymer particles forming from fluoropolymers which are extensively used in several sectors assessed in this restriction proposal. Evidence indicates that micro- and nano-sized fluoropolymer particles can form during product use or at the waste stage and subsequently enter the environment, where they may become bioavailable and cause ecotoxicological effects. SEAC notes RAC's concern that data specific to fluoropolymer particles remain scarce but notes that RAC points out that particularly sub-micron particles (0.1-0.2 µm) may penetrate cells and potentially lead to adverse effects in organisms. Such effects induced by PTFE microparticles were reported to include oxidative stress and inflammation in human cell lines or impaired sperm quality. In addition, SEAC notes RAC's opinion on the long-range transport potential of fluoropolymer particles, which have been detected in diverse ecosystems, including remote regions. This long-range transport potential does not only concern the fluoropolymer particles themselves but also suggests a significant contribution to transboundary pollution through particle-facilitated transport of non-polymeric PFAS. Furthermore, SEAC emphasizes that similar concerns formed the basis for the restriction of synthetic polymer microparticles. However, that restriction does not address the concerns posed by fluoropolymers as the unintentional abrasion and degradation of any synthetic polymer microparticles is not covered by the scope of that restriction.

Although a quantification of polymeric particle emissions by RAC and a subsequent evaluation of socio-economic impacts by SEAC for either restriction option was not possible, SEAC points out that a restriction would tackle these above-described concerns to a certain extent leading to benefits for human health and the environment. SEAC notes that in case where fluoropolymers are substituted by other types of polymers that can emit microplastic particles unintentionally into the environment, a ban on fluoropolymers would not address the issue of polymer

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particle emissions.

- **Broader implications:** The Dossier Submitter notes that the environmental contamination with PFAS is associated with broader effects such as a loss of ecosystem services and the degradation of natural resources, which could be (partially) prevented by the proposed restriction. Although no monetized values of ecosystem services lost could be provided, SEAC notes that the Dossier Submitter provides compelling arguments with respect to the loss of natural resources supported by evidence from stakeholders in the Annex XV report consultation. The issues that were raised concern the following aspects:
  - i. the contamination of drinking water resources: increasing numbers of water bodies, especially surface water bodies, were shown to require treatment before safe for drinking, noting that removal processes are often either incomplete, very costly or bear negative environmental side effects with overall serious impacts on affordability of water services (e.g. Annex XV report consultation comments #6185, #7146, #7331, #7642, #8385, #9367, #9561, #9583). Furthermore, SEAC notes that a recent study by the European Commission (2026) has estimated costs for PFAS removal from drinking water resources required to meet limit values set by the Drinking Water Directive without reducing PFAS emissions into the environment. The study estimates costs for water treatment and soil remediation that could rise to €0.3-153.4 billion/year in 2050 with an additional €14-15 billion/year if the Drinking Water Directive's limit value for the sum of PFAS were applied to TFA. SEAC notes that to date no limit values for TFA exist but acknowledges the growing attention leading to proposals for so far non-binding or advisory limits for TFA by several Member States;
  - ii. effects on recovery and use of nutrients and materials: the presence of PFAS was shown to jeopardise nutrient and material recovery from wastewater and sewage sludge due to insufficient or too costly removal techniques of PFAS from such complex matrices. These were argued to lead to a substantial loss of the agricultural benefits that recovered wastewater or sewage sludge can offer, including financial losses as well as risking food security (e.g. Annex XV report consultation comments #7146, #7828, #9137, #9161, #9362, #9583);
  - iii. effects on food production: several instances are reported where governments and authorities already advised against the consumption of food grown on contaminated land as well as the consumption of sea food and regional wildlife due to the exceedance of safety limit values. These values were not specifically reported and could not be verified by SEAC, but the arguments were supported by stakeholders in the consultation on the Annex XV report and evidence was provided that bioaccumulation of PFAS in farm animals can lead to the exceedance of PFAS limits in food (e.g. comments #7146, #7871, #9561, #9583). Further arguments were provided in a recent study by the European Commission (2026) indicating that ecosystem service impacts from PFAS exposure may include effects on pollinators, poultry, livestock and aquaculture and thereby on food provisioning;
  - iv. other costs: loss of property value in polluted areas and loss of recreational

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value were mentioned but not analysed in detail in the Background Document. SEAC acknowledges further effects on ecosystem services related to non-use values (such as existence and bequest values) but notes that these are, even though not negligible, difficult to assess. Furthermore, the Background Document addresses the contribution of fluorinated gases to global warming (e.g. Annex XV report consultation comments #9137, #9561). SEAC notes that the F-gas Regulation restricts the use of those F-gases with the highest global warming potential (GWP) but points out that the regulation prioritizes F-gases with GWP above 150. SEAC points out that even a GWP below 150 constitutes a multiple of the GWP of CO<sub>2</sub> (GWP=1) and hence can lead to effects that are noteworthy in the context of the proposed PFAS restriction. Further details on overlaps between the restriction proposal and the F-gas Regulation as well as regulatory gaps are discussed in the document containing SEAC's evaluation of sector-/use-specific aspects regarding applications of fluorinated gases.

The aspects listed above are in detail described in the Background Document and were substantiated by comments from stakeholders from the consultation on the Annex XV report as specified above. SEAC notes that no EU-wide cost estimate could be provided that monetizes overall environmental costs and loss of resources for each of these aspects incurred through emissions of PFAS. However, SEAC notes that, where possible, cost figures were provided in the Background Document, especially for points i)-iii) above, which illustrate and support the arguments made.

- **Avoided remediation costs:** SEAC notes that the Dossier Submitter has estimated high remediation costs for sites contaminated with PFAS. Remediation of PFAS contaminated sites is particularly challenging due to technical difficulties arising from the specific properties of PFAS. For example, their high mobility challenges the potential for adsorptive removal, and their high persistence inhibits in-situ degradation. SEAC agrees that if remediation is at all (technically) possible, it comes with a high cost. Despite continuous technological advances, the scale and the widespread nature of PFAS contamination across highly diverse environmental compartments that require remediation, make large-scale remediation activities unfeasible, leading to very high costs. For the purpose of an estimation of a cost benchmark, the Dossier Submitter refers to examples of past remediation attempts and contaminated sites management in Belgium, Italy and the Netherlands. Each of the reported remediation attempts already incurred costs that amount to millions of euros, which are projected to increase if emissions continue. In addition to remediation costs through continuous emissions, legacy contamination of past emission continues to cause high costs as well. While past emissions are outside the scope of this restriction proposal, SEAC notes that this demonstrates that a delay in putting in place a restriction will cause remediation costs for many generations to come. Overall, a total amount of non-health impacts of PFAS including remediation costs in the case of continued PFAS emissions were estimated to amount to €821 million to €170.8 billion over a 20-year period in the EEA (Goldenman et al., 2019). A more recent study based on the forever pollution project calculated costs for the removal of current and future PFAS releases through remediation and treatment of soil, drinking water, wastewater and biosolids and landfill leachate. Their conservative estimate assuming only the

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remediation of the most contaminated sites amounts to €2 trillion<sup>19</sup> over a period of 20 years (Ling, 2025). Considerable costs were further demonstrated in a recent study by the European Commission (2026). The study estimates costs up to €21.6-712.9 billion/year in 2024 (albeit with decreasing trend) assuming full compliance with the Drinking Water Directive and Environmental Quality Standards. SEAC notes that the latter are still under negotiation but overall describe a realistic scenario. While the exact figures could not be confirmed by SEAC and figures cannot be used by SEAC for a quantitative socio-economic analysis for this restriction proposal, they clearly provide an important indication of the magnitude of impacts. Therefore, the Committee agrees that the intrinsic properties of PFAS are expected to result in substantial remediation costs that could (partially) be avoided by a restriction.

- **Environmental impact assessment:**

Each unit of emissions reduced is associated with several of the benefits elaborated above. Using the emissions as proxy for risk, the Dossier Submitter assessed the benefits of a restriction option in terms of emission reduction potential in Step 3 of the impact assessment approach presented in section 3.4.2.2.1 above. It covers the assessment of environmental impacts on a sector level and serves as a basis for the benefits and proportionality assessment. This assessment considers both the avoided emissions in case of a full ban (RO1) and the additional emissions resulting in case of a ban with use-specific derogations (RO2). Furthermore, where relevant and possible the Dossier Submitter has also provided a quantitative assessment of avoided emissions for RO3. For all sectors covered by the assessment and for all restriction options quantitatively assessed, the assessment period is 30 years (2025-2055). Based on the sector assessments, the Dossier Submitter also provides estimates of the total avoided emissions under RO1 and RO2 across all sectors, excluding PFAS manufacturing.

For the **environmental impact assessment of RO1**, the Dossier Submitter provides quantified estimates of avoided emissions at sector or, where data permits, at (sub-)use level. In general, SEAC agrees that the benefits of a full ban of PFAS (RO1) can be approximated by estimates of the avoided stock in the environment. However, the amount and quality of data on emissions varies between sectors assessed and SEAC's view is presented in the documents containing SEAC's evaluation of sector-/use-specific aspects.

For the **environmental impact assessment of RO2**, the Dossier Submitter distinguishes between two situations: i) quantitative emission data for certain PFAS uses within a sector are available and quantification is possible also for proposed derogations and ii) emission data are lacking and additional emissions of a proposed derogation are approximated through expert judgement considering e.g. information about the environmental release factors applied to certain PFAS groups or information about the relevance of a certain application in a sector.

With this, the Dossier Submitter assessed (in general on a sector basis) the effectiveness of RO1, RO2 and, where relevant and possible, RO3 and assigned corresponding effectiveness levels from very low to very high (see Table 6). More details are provided in section 2.4.3.1

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<sup>19</sup> Out of these, costs for remediation of legacy contamination are estimated to amount to €95 billion assuming immediate cessation of emissions and only the remediation of legacy PFAS that are partly already regulated.

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(main report) and section E.2 (Annex E) of the Background Document.

**Table 6: Effectiveness levels of restriction options**

Effectiveness of the restriction option in terms of emission reduction	Effectiveness qualifier
≥ 99%	Very high
90 – 98%	High
80 – 89%	Moderate
70 – 79%	Low
< 70%	Very low

SEAC notes the limitation of this approach raised by the Dossier Submitter that the assessment of effectiveness is implicitly driven by the delineation of sectors. A proposed derogation leading to an effectiveness of e.g. 90% in a high-tonnage sector may in absolute terms still cause much higher emissions than a proposed derogation leading to an effectiveness of e.g. only 30% in a low-tonnage sector. In both cases emission estimates are determined in relation to total emissions under the baseline in the *particular sector*. Therefore, the Dossier Submitter considers the effectiveness of RO2 (ban with derogations) in the first case still high but would assume it is very low in the second case. In SEAC's view this can lead to inconsistent conclusions among different sectors as has been shown to be the case, for example, when comparing conclusions on effectiveness and the resulting proportionality between the transport sector and the sector on applications of fluorinated gases (see section S-4.2 in the document containing SEAC's evaluation of sector-/use-specific aspects for the transport sector for further details). Hence, SEAC points out that the discussion on benefits and proportionality of a restriction option for a specific sector needs to be based on emission reduction in absolute terms. Accordingly, in the documents containing SEAC's evaluation of sector-/use-specific aspects, the Committee focuses on absolute emission reduction rather than relative effectiveness.

Furthermore, to be able to compare the impact of each proposed derogation, additional emissions resulting from these derogations alongside the corresponding effectiveness are presented and discussed in those documents.

Nevertheless, SEAC acknowledges that a restriction needs to be effective to address the identified risk. SEAC notes that a restriction option may be effective overall, even though it may not be effective for individual sectors. **It is therefore of higher relevance to assess the effectiveness of each restriction option overall to ensure that a restriction covering all sectors (with or without derogations) is an effective measure to reduce the identified risk.**

SEAC notes that RAC recalculated the emission reduction potential and, consequently, the effectiveness of the restriction options assessed by the Dossier Submitter. SEAC notes that RAC has provided corrected emission estimates as well as emission reduction estimates (for fluoropolymers, RAC has only taken into account the non-polymeric emissions and RAC applied a different set of waste-stage release factors compared to the Dossier Submitter). Also, RAC has provided overall emission reduction estimates for a full ban (RO1) as well as the restriction proposed by the Dossier Submitter (i.e. RO2, except for PFAS manufacturing for which RO3b is proposed), excluding the uses not evaluated in detail. SEAC emphasises

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that it bases its related evaluation of benefits and proportionality on the emission reduction estimates as provided by RAC but adds below, for the sake of completeness, also the Dossier Submitter's calculated figures.

According to the Dossier Submitter's assessment, the effectiveness of RO1 amounts to 96% while the effectiveness of RO2 amounts to 83%<sup>20</sup>. SEAC notes that RAC calculates a total emission reduction potential of 96%<sup>21</sup> under a full ban (i.e. RO1) and of 76%<sup>22</sup> for the restriction option ultimately proposed by the Dossier Submitter (i.e. RO2, except for PFAS manufacturing, where RO3b is proposed), both figures excluding uses not evaluated in detail. Although there is no specific threshold agreed upon by SEAC above which a restriction is seen as effective enough, SEAC notes that the effectiveness of both restriction options corresponds to the range of previous restriction proposals such as the restriction of synthetic polymer microparticles (85-95%), D4-D6 (90%), or PFAS in firefighting foams (84-93%). SEAC therefore concludes that both a full ban and the restriction proposed by the Dossier Submitter will contribute to the reduction of PFAS emissions, leading to the associated benefits for the environment and human health as detailed above. However, SEAC notes that the benefits under the proposed restriction are significantly reduced. According to RAC, a full ban for all uses of PFAS is an effective measure to minimise PFAS emissions and exposure of humans and the environment whereas the proposed restriction leads to additional emissions of approximately 700 000 tonnes compared to a full ban and, therefore, results in an uncontrolled risk. SEAC further notes that RAC recommends the implementation of additional risk management measures to ensure PFAS emissions are minimised in case derogations are supported by the decision maker. Further details regarding these are discussed in section 3.4.3.2.6 below. The extent to which such measures contribute to emission reduction is unknown to SEAC.

For RO3, the Dossier Submitter did not provide an estimate of overall effectiveness. SEAC's assessment of RO3 is therefore presented in the documents containing the evaluation of sector-/use-specific aspects. SEAC notes RAC's conclusions in the relevant sectors that include a third restriction option: in all such cases, RAC finds that emissions under RO3 are higher than under RO1, and consequently, the benefits of RO3 are lower than those of RO1. Whether RO2 is preferable to RO3 depends on the specific measures proposed in each sector; as this varies across sectors<sup>23</sup>, such a comparison is not addressed at the level of the restriction as a whole.

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<sup>20</sup> Effectiveness figures do not include emissions from PFAS manufacturing. For PFAS manufacturing, the restriction proposed by the Dossier Submitter (see Table 1) relates to an additional restriction option (RO3b) and not to RO2.

<sup>21</sup> 96% emission reduction potential corresponds to approximately 3.3 million tonnes of avoided emissions over the 30-year assessment period for RO1, excluding uses not evaluated in detail.

<sup>22</sup> 76% emission reduction potential corresponds to approximately 2.6 million tonnes of avoided emissions over the 30-year assessment period for the proposed restriction (i.e. RO2, except for PFAS manufacturing, where RO3b is proposed), excluding uses not evaluated in detail.

<sup>23</sup> In some sectors, RO3 includes operational conditions and risk management measures **in addition to** the derogations as proposed under RO2 whereas in other sectors, operational conditions and risk management measures are discussed **instead** of the derogations under RO2.

#### **3.4.2.2.4. Other relevant impacts**

##### **Relevant sections of the Background Document:**

The following aspects are covered by SEAC in this section (relevant sections of the Background Document indicated in parentheses):

- Second-hand articles (Annex E, section E.3.2)
- Spare parts (Annex E, section 3.3)
- Impacts on recycling and circular economy (Annex E, section E.3.4)
- Cumulative impacts (main report, section 2.4.1.1)
- Overarching impacts on trade and competitiveness (Annex E, section 2.4.1.1)
- Derogated uses lost due to low market volumes
- Upstream supply chain for derogated uses (main report, Explanatory notes)
- Scientific Research and Development (SR&D) (main report, Explanatory notes)
- Product and Process Oriented Research and Development (PPORD) (main report, Explanatory notes)

##### **SEAC conclusion(s):**

SEAC concurs with the Dossier Submitter's conclusion that a derogation for **second-hand articles** is likely justified based on sustainability and practicality aspects: a restriction of second-hand articles would be difficult to enforce, would likely have negative impacts on several of the European Union's sustainability initiatives and legislations and would lead to likely significant economic impacts, although their magnitude is unknown.

SEAC agrees that a derogation for PFAS-containing **spare parts** is necessary and justified for specific uses to avoid premature obsolescence of articles and complex objects. SEAC could, however, not single out those uses where a derogation is or is not justified. Furthermore, SEAC cannot support the derogation as it is currently phrased, mainly because it is not bound to the non-availability of alternatives. In addition, some uncertainties remain regarding the definition of spare parts vs. consumable and in relation to the justification of the proposed 20-year period during which PFAS-containing spare parts could still be supplied. SEAC furthermore agrees that a derogation is justified to ensure compliance with legal obligations regarding the use of specific spare parts.

The available information on the **impacts on recycling and circular economy** is limited and its representativeness often uncertain. Despite this, SEAC concludes that there are clear indications that at entry into force the proposed concentration limits cannot be met for recycled plastics, paper and board, and textiles. A ban on PFAS above the proposed concentration limits would therefore lead to significant negative impacts related to the recycling of these three waste streams. As such, SEAC finds that time-limited derogations could be justified to ensure proportionality of a restriction as a whole. SEAC can, however, not conclude on the length of the necessary derogation period due to uncertainties linked to i) the ability of recyclers to meet the proposed concentration limits, ii) the actual magnitude of economic impacts in cases where the concentration limits cannot be met, and iii) the lack of information on additional emissions in case of a derogation. SEAC finds that no derogation is warranted for recycled metals since there is sufficiently strong evidence indicating that the concentration limits can be met at entry into force and therefore that no negative impacts

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related to metal recycling are expected.

For other specific aspects discussed by the Dossier Submitter in the Background Document, the information base as well as the assessment is very brief so that SEAC cannot properly evaluate these and, consequently, assess and conclude on potential related impacts. This is valid for **cumulative impacts, overarching impacts on trade and competitiveness**, a potential for **derogated uses lost due to low market volumes** as well as for derogations in the **upstream supply chain for derogated uses**. Whilst SEAC notes that these are relevant issues to be discussed for the restriction proposal at hand, the Committee cannot provide a robust conclusion on the magnitude of impacts. SEAC's detailed view is provided in the key elements section below.

It is unclear to SEAC whether "*diagnostic laboratory testing*" (including in vitro diagnostic medical devices) and "*calibration of measurement instruments and as analytical reference materials*" are fully covered by the **SR&D** exemption as stated by the Dossier Submitter. SEAC also finds it unclear whether the use of fluoropolymers as materials in equipment and instruments in research-related activities will be covered under the same exemption. The Background Document and the comments submitted in the consultation on the Annex XV report do not contain information that would justify specific derogations for the use of PFAS in applications linked to but not covered by SR&D (as defined under REACH).

SEAC concludes that the justification provided by the Dossier Submitter and stakeholders in the consultation on the Annex XV report does not warrant a generic derogation for all **PPORD** activities. SEAC also questions the utility of a potential derogation on PPORD activities related to applications that will only be derogated for 5 or 12 years (following the general 18-month transition period). SEAC can however envision that unwanted circumstances might arise if PPORD activities are no longer allowed when these can be linked to applications for which a time-unlimited derogation is proposed by the Dossier Submitter.

**Key elements underpinning the SEAC conclusion(s):**

**A. Second-hand articles:**

The Dossier Submitter proposes a time-unlimited derogation for the placing on the market of articles, which were already in end-use in the Union (so-called second-hand articles) before the expiration of the relevant transition periods (i.e. 18 months, 6.5 years and 13.5 years, depending on the article concerned). This derogation does not cover other articles that have already been placed on the market, e.g. stocks of intermediate and finished products. The purpose of this derogation is the extension of the service-life of articles already manufactured and to address the difficulties that sellers of such articles and enforcement authorities face, i.e. not knowing whether PFAS are present in these products.

SEAC notes that the Dossier Submitter's assessment is based on information provided by stakeholders in the Annex XV report consultation (e.g. comments #4266, #4436, #5927, #6395, #6559, #7044, #7145, #7285, #8072, #8102, #8587, #8695, #9148). These comments have been provided by industry and/or industry associations from inside and outside the EU/EEA and mainly refer to **sustainability** aspects<sup>24</sup> as well as **practicality**

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<sup>24</sup> EU goals on circular economy, the European Green Deal and its initiatives as well as different legislations, e.g. the Ecodesign for Sustainable Products Regulation (Regulation (EU) 2024/1781), the End of Life Vehicles Directive (2000/53/EC), the IEC 63077:2019 Good refurbishment practices for medical imaging equipment, and the Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS) Directive (2011/65/EU).

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aspects<sup>25</sup>. Also, other already implemented PFAS restrictions are mentioned that include a derogation for second-hand articles<sup>26</sup>. Some stakeholders also provide information on potential economic impacts related to a restriction of second-hand articles, mainly providing information about the market size and value of second-hand markets for the automotive sector, for smartphones, textiles as well as refurbished goods and reuse rates in the energy sector. Due to a lack of robust information, SEAC is not able to qualitatively or quantitatively assess the costs and benefits (in terms of emission reduction) of granting or not granting a derogation for the second-hand market. However, noting RAC's conclusion that additional emissions related to second-hand articles are considered negligible to low, SEAC concurs with the Dossier Submitter's conclusion that a derogation for the second-hand market is likely justified based on sustainability and practicality aspects: a restriction of second-hand articles would be difficult to enforce, would likely have negative impacts on several of the European Union's sustainability initiatives and legislations and would lead to likely significant economic impacts, although their magnitude is unknown. This conclusion is supported by the information provided by stakeholders in the Annex XV report consultation.

### **B. Spare parts:**

The Dossier Submitter addresses the role of spare parts to prevent the premature obsolescence of complex objects already in use as an overarching issue that concerns several sectors and (sub-)uses. Where substances or mixtures could be seen as spare parts due to their role in maintenance and repair of complex objects (e.g. lubricants), these are addressed in the relevant sector-specific assessments and use-specific derogations are proposed by the Dossier Submitter, where deemed necessary. For example, in analogy to derogation 4f concerning spare parts, the Dossier Submitter proposes derogation 5n for fluorinated gases so that existing HVACR, fire-suppressing and switchgear equipment can be used until the end of service life to avoid premature redundancy of the equipment. The Dossier Submitter also proposes a 12-year derogation (following the general 18-month transition period) for PFAS in industrial and professional uses of lubricants. The overarching discussion on spare parts in the Background Document is therefore focused on articles or complex objects used for the maintenance and repair of another article or complex object.

As detailed below, the Dossier Submitter provides several economic, ecological and political arguments to justify the continued use of PFAS-containing spare parts.

In REACH, the importance of spare parts has previously been addressed in the context of authorisations. Commission Implementing Regulation (EU) 2021/876<sup>27</sup> states that an application for authorisation needs to demonstrate that a substance is either necessary for the production of the relevant spare part or necessary for the repair of articles or complex products no longer produced. As noted in the regulation's preamble, the aim is to prevent premature obsolescence of articles or complex objects. Although not directly transferrable,

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<sup>25</sup> Difficulties with enforcing second-hand market products due to the challenges related to the identification and testing of these articles that might contain PFAS and consequently to comply with proposed threshold values.

<sup>26</sup> E.g. REACH Annex XVII, entry 68 on perfluorocarboxylic acids containing 9 to 14 carbon atoms in the chain (C9-C14 PFCAs), their salts and C9-C14 PFCA-related substances and entry 79 on undecafluorohexanoic acid (PFHxA), its salts and related substances.

<sup>27</sup> Commission Implementing Regulation (EU) 2021/876 of 31 May 2021 laying down rules for the application of Regulation (EC) No 1907/2006 as regards applications for authorisation and review reports for the uses of substances in the production of legacy spare parts and in the repair of articles and complex products no longer produced and amending Regulation (EC) No 340/2008.

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SEAC agrees that a similar rationale can be applied to the current restriction proposal.

The Dossier Submitter also states that the aim to prevent premature obsolescence is in line with the goal of the EU's Circular Economy Action Plan (less waste through maintenance and repair of existing articles and complex objects), the Ecodesign for Sustainable Products Regulation (Regulation (EU) 2024/1781) (requirements set out for durability and circularity), the Right-to-Repair Directive (2024/1799/EU) (promoting repair and setting out rules for spare parts), or the End of Life Vehicles (ELV) Directive (2000/53/EC)<sup>28</sup> (granting exemptions for hazardous substances if needed in spare parts).

The costs associated with a ban with or without a derogation for PFAS-containing spare parts are argued to depend on the availability of alternatives and to what extent these can be installed in complex objects directly or after modification of the complex object. The Dossier Submitter points out that in case alternatives are available or where adaptations to a complex object to accommodate a new PFAS-free spare part are possible, societal costs are likely moderate and a derogation for spare parts may not be justified. In contrast, where no PFAS-free alternatives are available or an adaptation of the complex object to PFAS-free alternatives is not possible or impeded by certification requirements, premature obsolescence was deemed to be a major concern and/or related costs were projected to be substantial. A quantification of the related costs for the proposed restriction overall or on a sector basis could not be provided by the Dossier Submitter. However, the examples provided in the Background Document showcase the order of magnitude of costs, were a restriction implemented without a derogation covering PFAS-containing spare parts. Related costs are estimated to amount to several billion euros by both individual companies and industry associations according to information provided through the Annex XV report consultation (e.g. comments #7144, #7145, #7571, #8097). Further costs that were not quantified but mentioned generically include the considerable production of excess waste as well as health and safety implications, e.g. where sealing applications fail. SEAC agrees that costs in specific (sub-)uses, as pointed out by stakeholders in the Annex XV report consultation, are likely significant. However, SEAC notes that the available data lack the granularity for the Dossier Submitter to determine the availability of alternatives and readiness of the respective complex objects to accommodate PFAS-free spare parts for all sectors and (sub-)uses. Accordingly, the information provided in the Background Document and in the Annex XV report consultation does not allow SEAC to distinguish the costs of a ban across the affected sectors and (sub-)uses. Therefore, SEAC points out that while costs related to the non-availability of PFAS-containing spare parts are likely significant for some (sub-)uses, this conclusion likely does not apply throughout all sectors and (sub-)uses of the restriction proposal.

SEAC furthermore notes that the use of PFAS in spare parts and hence emissions related to the proposed derogation were not quantified. Therefore, SEAC notes that it is not possible for RAC to estimate volumes of spare parts needed and related emissions. In addition, SEAC notes RAC's projection that since the need for spare parts containing PFAS will decrease with time, related emissions will also gradually decrease after the restriction enters in force.

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<sup>28</sup> The End of Life Vehicles Directive (2000/53/EC) was reviewed in 2021 and the Commission made a proposal for a new regulation in 2023. A provisional agreement was reached between the Council and the Parliament in December 2025. The End of Life Vehicles Regulation is expected to be adopted by summer 2026.

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- Derogation 4e<sup>29</sup>:

Overall, SEAC agrees that a **derogation for PFAS-containing spare parts is necessary and justified for specific (sub-)uses**. However, SEAC **cannot support the derogation as it is currently phrased** due to several aspects:

1. The proposed derogation does not only cover specific industries or sectors but every application where PFAS-containing spare parts may be used.
2. The proposed derogation is independent of the availability of alternatives.
3. The distinction between spare parts and consumables may not be clear enough.
4. The proposed 20-year period during which PFAS-containing spare parts could still be supplied is only partly justified.

Ad 1: The Dossier Submitter points out the examples of the restrictions for decaBDE and Dechlorane Plus where a similar derogation for spare parts was granted for 20 years under the POPs Regulation. However, SEAC wants to stress that in both cases the derogation was not granted broadly for any sector or application where spare parts may be used. This derogation was only applicable for specific sectors where the non-availability of drop-in alternatives would lead to significant impacts for health and safety and functioning of applications (for instance heavy machinery, aircraft or certain electronic equipment). While the analysis of the comments in the consultation on the Annex XV report showed the likelihood of significant costs associated with a ban on PFAS-containing spare parts, the Background Document does not contain a specific assessment that could single out those uses where a derogation is or is not justified.

Ad 2: The derogation as proposed covers all sectors and applications where PFAS-containing spare parts may be used. It therefore also covers articles for which the Dossier Submitter and/or SEAC have identified technically and economically feasible alternatives. Although the Background Document explicitly states that the “purpose of the derogation is to extend the service-life of articles already manufactured when there are no technically or economically feasible PFAS-free spare parts available”, the availability of alternatives is not reflected in the wording of the proposed derogation. Therefore, the proposed derogation 4e introduces the possibility that some of these uses for which a derogation does not seem justified can be continued if they are applied as spare part in an article or complex object. SEAC acknowledges that for those uses where the available alternatives would require a redesign of the complex object leading to its premature obsolescence, a derogation for PFAS-containing spare parts can avoid significant amounts of waste and costs to industry and society. However, for those uses, where alternatives are available and the use of PFAS-free spare parts would not require a (significant) redesign of the article or complex object that would lead to its premature obsolescence, the proposed derogation 4e would open the possibility to continue the use of PFAS-containing spare parts without the necessity to do so. In SEAC’s view, this possibility leads to the continuation of PFAS uses that can be avoided. Although the respective volumes and associated emissions are not known to SEAC, the Committee points out RAC’s opinion that emissions of PFAS should be minimised.

Ad 3: The Dossier Submitter points out that the derogation for PFAS-containing spare parts

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<sup>29</sup> “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”.

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is not meant to cover consumables, such as, but not limited to, batteries, non-permanent filters or razor blades. For this purpose, the Dossier Submitter defines consumables as “materials or items that are regularly replaced because they are ‘used up’ during the normal operation/design of a product, and are not expected to (have a long lifetime)/last the product lifetime”. SEAC considers that the distinction between a spare part and a consumable may not always be entirely clear.

Definitions on what is considered a spare part or replacement part are provided in various pieces of EU legislation, e.g. in the Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS) Directive (2011/65/EU), in several implementing regulations of the Ecodesign Directive (2009/125/EC), the Ecodesign for Sustainable Products Regulation or the Medical Device Regulation (Regulation (EU) 2017/745). However, these directives and frameworks do not provide a legal definition of “consumable” that cleanly contrasts with “spare part”. Therefore, SEAC points out that in order to implement the Dossier Submitter’s intention to exclude consumables from this derogation, a definition of spare parts that clearly separates them from consumables needs to be ensured by the legislator.

Ad 4: SEAC acknowledges that the proposed timeline of 20 years during which PFAS-containing spare parts could still be supplied is anchored in the restrictions for decaBDE and Dechlorane Plus under the POPs Regulation and takes into account information from the consultation on the Annex XV report. In the latter, stakeholders report service lives of different products ranging from 10 to more than 50 years, including contractual agreements for ensuring the availability of spare parts over 20-30 years. SEAC notes in addition that other EU regulations contain requirements for the availability of spare parts such as Commission Regulation (EU) 2019/2023 for household washing machines and washer-dryers. For example, it requires manufacturers/importers to make certain spare parts available for at least 10 years after the last model unit is placed on market. Overall, SEAC points out that the service lives of different complex objects can vary substantially. SEAC notes that the service life of a certain proportion of articles and complex objects may end even before the end of the 20-year derogation period. However, SEAC does not have any information on the proportion of articles and complex objects that would exceed this timeline, where a ban at the end of the timeline would lead to their premature obsolescence and premature waste generation. SEAC, therefore, cannot conclude on the related socio-economic impacts of different timeframes of the derogation and on the exact timeframe required.

- Derogation 4f<sup>30</sup>:

SEAC finds that points 2 and 3 discussed for derogation 4e are also valid here, i.e. the assessment is independent of the availability of alternatives and the distinction between consumables and spare parts may not always be entirely clear.

In addition to this, SEAC notes that derogation 4f specifically targets spare parts for which the continued placing on the market until the end of service life of a complex object is a legal obligation. The Dossier Submitter bases this derogation proposal on stakeholder comments submitted in the Annex XV report consultation regarding recertification and approval procedures in several sectors such as electronics and semiconductors, transport<sup>31</sup>, and

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<sup>30</sup> “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”.

<sup>31</sup> E.g. aircraft within the scope of Regulation (EU) 2018/1139 or Commission Regulation (EU) 748/2012 (as pointed out by stakeholders, e.g. comment #9434).

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energy, which SEAC acknowledges as valuable arguments (e.g. comments #9434 and #8214 by industry associations).

SEAC notes that the proposed derogation 4f is consistent with the proposed derogation 6f(i)<sup>32</sup> dealing with transport vehicles specifically, since they both deal with legal obligations related to their placing on the market (e.g. lengthy and stringent type-approval procedures and/or requirement to supply spare parts during a certain period) and are not time-limited. For other sectors, similar derogations taking into account approval procedures for PFAS-containing articles were, however, not proposed by the Dossier Submitter. Since the need for derogations related to recertification and approval processes of PFAS-containing articles were not identified in other sectors, SEAC cannot conclude on the necessity of such a broad derogation under 4f. Nevertheless, SEAC can agree that this derogation offers a pragmatic way to cover all potential difficulties in relation to recertification and type approval that may not have been identified in the sector-specific assessments. SEAC notes that (partial) overlap might exist between this broad derogation for spare parts and the abovementioned derogation 6f(i) for transport vehicles.

### **C. Impacts on recycling and circular economy:**

The assessment provided by the Dossier Submitter in the Background Document is based on the comments received in the consultation on the Annex XV report. SEAC notes that comments were mostly submitted by industrial stakeholders and that the Committee has some (significant) concerns regarding the representativeness and robustness of the submitted data (especially in regard to the concentrations of PFAS in waste streams and costs). SEAC also notes that the assessment is almost exclusively focussed on the economic impacts of the ban on PFAS in recycled material. Only very limited (general) information is available on the related emissions/emission reduction and no environmental impact assessment was performed by the Dossier Submitter. SEAC notes RAC's conclusion that additional emissions related to some recycling activities are considered negligible to low. Even though the Dossier Submitter in general acknowledges that in case of a derogation PFAS emissions will continue and the effectiveness of a restriction is therefore reduced, proportionality of a potential ban on PFAS in recycled material is solely assessed based on economic considerations. Furthermore, the Background Document makes clear that the recycling market is growing both through higher recycling rates from existing waste streams and an increase in waste volume. As such, it can be expected that PFAS emissions from this economic activity<sup>33</sup> will grow in kind for quite some time (as compared to the baseline scenario without the proposed restriction).

Based on the submitted comments, the Dossier Submitter identified four waste streams that could be impacted by a restriction: plastics, paper and board, textiles, and metal. According to the Dossier Submitter the central question to ascertain if impacts from a ban on PFAS in recycled material can be expected, is whether the proposed concentration limits (see

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<sup>32</sup> Derogation for fluoropolymers and perfluoropolyethers in vehicle systems, components or separate technical units that are subject to EU vehicle type approval, where the type approval was obtained within 13.5 years after entry into force. For the full wording, see the draft Annex XVII entry proposed by the Dossier Submitter in Table 1. While the proposed derogation only refers to fluoropolymers and perfluoropolyethers, SEAC notes in its evaluation of sector-/use-specific aspects regarding transport that a broader scope covering all PFAS is considered justified. However, SEAC does not consider it necessary to extend the scope of derogation 4f as the use of substances on their own, or in mixtures for maintenance and repair is covered in the sector-specific assessments in the Background Document.

<sup>33</sup> Emissions both from recycling itself as well as from the use of recycled material.

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paragraph 2 in Table 1) can be met for the different waste streams. An assessment of this central question is performed based on the presence of PFAS in the relevant waste streams, the extent of recycling taking place, the recycling methods that are employed and evidence on PFAS concentrations in (articles made from) recycled material. SEAC finds the approach taken to identify whether impacts on recycling can be expected to be appropriate.

SEAC notes that the sector-specific assessments carried out by the Dossier Submitter as well as SEAC's evaluation thereof also have significant bearing on the magnitude of the impacts for the recycling sector and specifically how long these can be expected to last. Depending on the sector-/use-specific derogations that would be included in the final decision, it is conceivable that this might require an adjustment of the derogations for recycling. This might include changes to the scope and/or the derogation period since sector-/use-specific derogations will extend the period for which PFAS will remain in waste streams. Where possible, SEAC will try to mention relevant conclusions from their evaluation of sector-/use-specific aspects, but the Committee notes that an exhaustive discussion is not possible due to a lack of granularity in the information provided in the consultation on the Annex XV report.

SEAC's evaluation of the Dossier Submitter's assessment for the different waste streams can be found below.

- Plastics

Based on the information received from the consultation on the Annex XV report and the assessment of these comments performed by the Dossier Submitter, SEAC finds there to be sufficiently strong evidence that the plastic waste stream contains PFAS coming from a wide variety of sources (e.g. different types of packaging, plastics incorporated in electrical and electronic equipment, vehicles and aerospace). The Committee also notes the wide variability in service life of products entering this waste stream (e.g. drinking bottles and plastic films versus building and construction products). SEAC notes that the assessment focusses on the presence of PFAS in non-PFAS plastics (e.g. PET, PE, PP, PVC). The assessment does not discuss recycling of polymeric PFAS, which SEAC finds understandable since Conversio (2022) indicates that only 3% of fluoropolymers are actually recycled.

One comment from an industry association submitted during the consultation on the Annex XV report (#8689) contains some analytical data on PFAS concentrations in a variety of recycled materials coming from different input streams. While this data is limited and its representativeness for the whole sector is uncertain, it does show that in many instances (but not all), the proposed concentration limits are (significantly) exceeded. Other disparate information referenced in the Background Document also indicates that PFAS will be present at relevant concentrations in waste streams. In contrast to this, Pivato et al. (2024) also provide information on PFAS concentrations which indicates that from 613 observations only 2.17% exceeded the proposed 25 ppb concentration limit value (for PFOS), with no measurement exceeding the 25 ppb concentration limit value for PFOA, C9-C14 PFCAs, PFHxS or "other PFAS". While the Dossier Submitter correctly points out that this review only focussed on the 25 ppb limit (and not the 250 ppb and 50 ppm limits) and the waste data mainly refers to "*single-use plastic packaging, ELV plastic components and parts of household appliances*", the information contained in this review complicates answering the question whether the proposed concentration limits would prove to be problematic for (all) plastic waste streams. Additional factors to take into account are the differences in service life of the

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different products entering the waste stream<sup>34</sup> (e.g. drinking bottles and plastic films versus building and construction products), SEAC's conclusions from the evaluation of sector-/use-specific aspects for applications where polymeric PFAS or PFAS-containing plastics play a role (e.g. polymer processing aids in flexible plastic film extrusion<sup>35,36</sup> and inks, lacquers and waxes in FCM packaging<sup>35,37</sup>), and the fact that several bans on PFAS are already in effect<sup>38</sup>. Finally, there are also clear indications that different material streams correspond to different input streams<sup>39</sup> (waste source) with potentially different concentrations of PFAS<sup>40</sup>. SEAC therefore considers it likely that certain material streams might be able to comply with the proposed concentration limits earlier than others based on both the service life and the input stream (waste source). It is however impossible to determine at which time and for which material and/or input stream the proposed concentration limits might be able to be met.

While, overall, SEAC still finds it plausible that meeting the proposed concentration limits can prove challenging for the recycling of plastics (considering the widespread use, see Dossier Submitter's sector-specific assessments and SEAC's evaluation thereof), there are significant uncertainties associated with this conclusion. Especially since there are also some indications that for certain input streams (waste sources) the concentration limits might be met earlier than for others. There is however insufficient data on the different variables discussed above for SEAC to provide a more robust, granular and nuanced conclusion.

The Dossier Submitter discusses potential impacts for recyclers as well as for downstream users of recycled materials if the proposed concentration limits cannot be met for recycled plastics<sup>41</sup>. Also, sustainability aspects<sup>42</sup> and potential impacts on the compliance with other EU legislation are considered in the Background Document. The Dossier Submitter concludes that considerable impacts are expected to occur in case recovered materials cannot comply with the proposed concentration limits, regardless of whether use-specific derogations are proposed (under RO2 and RO3) or not (under RO1). This conclusion is based on disparate information provided by stakeholders in the Annex XV report consultation (e.g. comments

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<sup>34</sup> Geyer et al. (2017) modelled how long plastics are in use before they reach the end of their useful lifetimes and found average lifetimes of: 0.5 years for packaging, three years for consumer and institutional products, five years for textiles, eight years for electrical and electronic equipment, 13 years for transportation, 20 years for industrial machinery and 35 years for building and construction.

<sup>35</sup> See SEAC's evaluation of sector-/use-specific aspects regarding "Food contact materials (FCM) and packaging".

<sup>36</sup> Weak evidence for low substitution potential for applications where the structural integrity of the packaging is critical for human health and safety, and insufficient and/or insufficiently substantiated evidence on alternatives for all other applications. SEAC notes that the information available to the Committee on cost and benefits does not allow drawing a conclusion on whether a derogation is justified in order to ensure proportionality for the sector.

<sup>37</sup> SEAC considers there to be evidence that no derogation is needed.

<sup>38</sup> Including REACH restrictions, a ban on PFAS in food contact packaging under the Packaging and Packaging Waste Regulation (Regulation (EU) 2025/40) and a ban on PFAS under the new Toy Safety Regulation (Regulation (EU) 2025/2509).

<sup>39</sup> E.g. PET recycling mainly processes (food contact) bottles from deposit return schemes and/or household waste, LDPE/HDPE mainly from household waste, PVC and PU mostly from building and demolition activities.

<sup>40</sup> The limited quantitative data, as well as the qualitative discussion in the Background Document provides credence to this assumption.

<sup>41</sup> SEAC notes that Dossier Submitter states that impacts on consumers as well as wider economic impacts are not expected. The Dossier Submitter makes this statement without any further assessment.

<sup>42</sup> E.g. EU goals on circular economy, the European Green Deal and its initiatives as well as different legislations.

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#4600, #7608, #7702, #8195, #8689, #8784, #9166). SEAC notes that the disparate figures provided by stakeholders point towards the economic impacts being significant.

Given the aforementioned aspects, the Dossier Submitter concludes that complying with the concentration limits proposed in the Background Document is not deemed proportionate for recycled plastic. However, this conclusion is subject to major uncertainties for the following reasons:

- No in-depth assessment is provided in the Background Document based on the figures provided by stakeholders.
- The provided figures lack sufficient granularity and there are significant concerns regarding their representativeness as the reported data<sup>43</sup> is not sufficiently substantiated (e.g. neither information on the assumptions taken, nor the calculations are available to the Committee).
  - The provided figures seem to assume that all plastic recycling activities would be affected equally (both in duration and across waste streams). SEAC's assessment of the information in the Background Document on whether the recycling sector can meet the proposed concentration limits does however indicate that certain material streams might be able to comply with the proposed concentration limits earlier than others, depending on both the service life and the input stream (waste source). This type of nuance and granularity is not reflected by stakeholders when presenting their figures.
- The Dossier Submitter's conclusion that complying with the proposed concentration limits is not proportionate for recycled plastics is solely based on the consideration of economic impacts, while the relevant environmental impacts were not assessed.

SEAC notes that several pieces of EU legislation (will) set mandatory requirements for the use of recycled content for certain specific applications (e.g. Packaging and Packaging Waste Regulation (Regulation (EU) 2025/40), Single-Use Plastics Directive (Directive (EU) 2019/904)). In case recycled material for the relevant applications would not be able to meet the proposed concentration limits, compliance with the different mandatory targets might be jeopardised. SEAC can however not determine to what extent compliance might become problematic due to a lack of data on this issue. It is however clear to the Committee that not being able to meet the mandatory requirements set out in EU legislation will add to the potential impacts mentioned above.

The Dossier Submitter proposes a derogation for plastic articles containing recovered material, with the exception of food contact material and food contact packaging and toys as defined in the Toy Safety Directive (2009/48/EC)<sup>44</sup>, until 23.5 years after entry into force. Additionally, suppliers of plastic articles or complex objects falling under the scope of the Waste Electrical and Electronic Equipment (WEEE) Directive (2012/19/EU) or ELV Directive as well as suppliers of PVC articles listed in paragraph 18 (a to f) of Commission Regulation

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<sup>43</sup> One stakeholder states that 700 recycling facilities would be affected (#6198), another assumes 350 (#8689). The latter mentions a loss of market value of between €80-150 million for polyolefins, €2.8 billion for PET, €1 billion for PVC.

<sup>44</sup> The Toy Safety Directive (2009/48/EC) was evaluated in 2015 and the Commission made a proposal for a new regulation in 2023. The new Toy Safety Regulation (Regulation (EU) 2025/2509) was adopted on 26 November 2025 and entered into force on 1 January 2026.

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(EU) 2023/923 on lead and its compounds in PVC, would be subject to labelling requirements and, upon request by national enforcement agencies, providing documentary evidence on the origin of recovered material.

Based on its evaluation of the available information and considering mandatory requirements for the use of recycled content for specific applications, **SEAC concludes that a time-limited derogation as defined by the Dossier Submitter<sup>45</sup> could be justified to ensure proportionality** of the restriction overall. SEAC can, however, not conclude on the length of the necessary derogation period due to the following uncertainties: i) the extent to which the proposed concentration limits can already be met by recyclers and for which plastic waste streams, ii) the actual magnitude of economic impacts in cases where the concentration limits cannot be met, as well as iii) the lack of information on additional emissions related to the proposed derogation for recycled plastics<sup>46</sup>.

SEAC also highlights some uncertainties on whether the wording of the proposed derogation would allow the addition of PFAS to plastic articles outside of the PFAS already present in the recovered plastic material. It is clear to SEAC that in order to avoid making it possible to circumvent the intention of the proposed derogation, the PFAS present in plastic articles containing recovered material should only be allowed to originate from the recovered material. Similarly, there is also a potential for the introduction of PFAS-containing recovered plastic into articles or complex objects where previously no PFAS were used or needed (circumventing the ban for certain applications<sup>47</sup>). Additionally, the wording of the proposed derogation could also lead to the use of higher amounts of PFAS-containing recovered material since it does not contain concentration limits. The Dossier Submitter's proposal to provide documentary evidence of the origin of recovered material would then allow enforcement agencies to check compliance with the proposed derogation and whether the PFAS present in the plastic article or complex object were added intentionally or originate from the recovered material. As such, SEAC supports this proposal, but notes that Forum has identified concerns regarding enforceability of this requirement (i.e. there not being a concentration limit).

Additionally, the Dossier Submitter proposes a labelling requirement analogous to an existing one for recycled lead in PVC (Commission Regulation (EU) 2023/923). Labelling under the currently proposed restriction would only be required for plastic articles or complex objects falling within the scope of the WEEE Directive and ELV Directive as well as for PVC articles listed in paragraph 18 (a to f) of Commission Regulation (EU) 2023/923 on lead and its compounds in PVC. SEAC considers that a labelling requirement should further facilitate the separate collection (and appropriate treatment) already mandated for these waste streams by the above-mentioned pieces of legislations. While there is no specific assessment of extending the labelling requirement to all plastic articles containing recovered material (i.e. covering the whole scope of the proposed derogation for recycled plastics), SEAC finds it plausible that such a requirement would have less added value and be less practical than for highly specific technical plastic waste streams already covered by specific legislation. SEAC

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<sup>45</sup> Covering plastic articles containing recovered material but excluding food contact materials and toys since PFAS are already banned in these applications according to the corresponding sector regulations.

<sup>46</sup> Overall, RAC considers that since in the majority of cases the PFAS levels in recyclates seem to be below the concentration limits, the overall emissions are likely to be minimal and are decreasing further as a result of the phase-out of PFAS from products.

<sup>47</sup> Virgin materials would need to comply with the concentration limits, but a small addition of recovered material would ensure that the derogation applies.

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notes that, unlike Commission Regulation (EU) 2023/923, the currently proposed restriction does not set clear boundaries for the use of recovered/recycled PFAS-containing plastic<sup>48</sup>.

- Paper and board

Based on the information received from the consultation on the Annex XV report and the assessment of these comments performed by the Dossier Submitter, SEAC finds there to be sufficiently strong evidence that the paper and board waste stream contains PFAS coming from a wide variety of sources (a majority of which seems to relate to packaging<sup>49</sup>). SEAC also notes that the available information indicates that while there is variation in the average service life of paper and board products, overall, the service life can be considered short.

Submissions from many stakeholders<sup>50</sup> provide clear indications that PFAS concentrations in paper and board (waste and recycled material) in many instances exceed all proposed concentration limits (i.e. 25 ppb, 250 ppb and 50 ppm). SEAC does however note that the submitted data is limited and its representativeness for the whole sector is uncertain. This is also acknowledged by the Dossier Submitter: *“data on PFASs in paper and board is scattered, that variability in reported concentrations is significant, and many PFASs are not analysed regularly and/or not detectable with commercially available equipment.”* A review by Pivato et al. (2024) gathered concentration data on products in the paper and board waste stream<sup>51</sup> and compared these to the proposed 25 ppb concentration limit for individual PFAS. Based on 2 680 observations, 6.51% exceeded the 25 ppb limit for PFOA, 5.35% for C9-C14 PFCAs, 0.65% for PFOS, 5.35% for PFHxS and 6.98% for “other PFAS”.

SEAC agrees with the Dossier Submitter that even though the data submitted in the consultation on the Annex XV report shows that there is significant variability in PFAS concentrations in paper and board products, there are clear indications that, at entry into force, PFAS will be present at concentrations above the proposed concentration limits in feedstocks for paper and board recycling as well as products made of recycled material. It is however also likely that compliance with the proposed concentration limits might occur faster after entry into force than for the plastic waste stream considering the short service life of paper and board products and the state of alternatives for paper and board packaging (which the assessment mostly relates to). There are however significant uncertainties associated with this conclusion.

The Dossier Submitter concludes that considerable impacts are expected to occur in case the proposed concentration limits cannot be met for recycled paper and board, regardless of whether use-specific derogations are provided (under RO2) or not (under RO1). Stakeholders providing comments in the Annex XV report consultation (e.g. comments #8399, #9009, #9154, #9291) generally indicated that the proposed concentration limits could make paper and board recycling impossible. As limited information on the paper and board waste and

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<sup>48</sup> Commission Regulation (EU) 2023/923 essentially creates a closed loop system for certain specific PVC applications since recovered PVC from the categories listed in paragraph 18 (a to f) can only be used for the production of new articles of the same categories (e.g. multi-layer pipes, fittings and certain profiles and sheets).

<sup>49</sup> Transport, industrial, food, feed, pharma, medical devices, cosmetics, and semiconductor packaging or food-contact materials.

<sup>50</sup> E.g. #5885, #6177, #7549, #7555, #7563, #7590, #7803.

<sup>51</sup> Analysed products included disposable food contact materials (e.g. bowls, paper table wares, beverage cups, paper bags, etc.), several dedicated to substitute single use plastics, and disposable fast food packaging materials (e.g. fast food wraps, pop-corn bags, boxes for French fries, etc.).

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recycling market was provided during the Annex XV report consultation, the Dossier Submitter's assessment is mainly based on information from one stakeholder (Confederation of European Paper Industries, CEPI), who represents the European pulp and paper industry. The Dossier Submitter discusses profit and employment losses for recyclers as well as impacts related to the non-availability of raw materials/products and related costs for downstream users of recycled materials as well as for consumers. The assumption that the proposed concentration limits might not be consistently achieved across the paper and board recycling sector in combination with information on the amount of paper recycled in the EU (tens of millions of tonnes) lead the Dossier Submitter to the conclusion that, overall, economic impacts are expected to be considerable. Additionally, price increases for paper and board products are expected due to a shortage of supply which could trigger wider economic impacts<sup>52</sup>. Also, sustainability issues are briefly discussed, such as an increased demand for wood and the risk of increased deforestation with wider adverse impacts on climate regulation and biodiversity services provided by forests if the huge share of feedstock for paper and board production would need to be replaced.

Given the aforementioned aspects, the Dossier Submitter concludes that complying with the concentration limits proposed in the Background Document is not deemed proportionate for recycled paper and board. It is important to note however that this conclusion is based on economic considerations only, not considering emissions associated with the recycling of PFAS-containing paper and board. Whilst SEAC agrees with the Dossier Submitter that economic impacts are to be expected in case of a ban, their magnitude is unknown. SEAC has identified the following uncertainties affecting the Dossier Submitter's assessment and conclusions:

- The qualitative assessment and the related conclusions on impacts drawn are not substantiated by supporting evidence.
  - SEAC's evaluation of the information in the Background Document shows that compliance with the proposed concentration limits might occur faster after entry into force than for the plastic waste stream considering the short service life of paper and board products and the state of alternatives for paper and board packaging.
- The Dossier Submitter's conclusion that complying with the proposed concentration limits is not proportionate for recycled paper and board is solely based on the consideration of economic impacts, while the relevant environmental impacts were not assessed.

SEAC notes that several pieces of EU legislation (will) set mandatory requirements for the use of recycled content for packaging and paper and board in general (e.g. Packaging and Packaging Waste Regulation). In case recycled material would not be able to meet the proposed concentration limits, compliance with the different mandatory targets might be jeopardised. SEAC can however not determine to what extent compliance might become problematic and for how long due to concerns regarding the representativeness of the limited information on this issue and the overall short service life of paper and board products. SEAC

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<sup>52</sup> The Dossier Submitter concludes that the resulting price increases for paper and board products could trigger price increases in other parts of the EU economy, e.g. increased packaging prices might impact delivery fees for e-commerce or prices for food providers, potentially resulting in price increases for supermarket products and of food delivery services.

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additionally notes its conclusion on paper and board packaging as part of its evaluation of sector-/use-specific aspects regarding “Food contact materials and packaging” (i.e. SEAC considers there to be evidence that no derogation is needed). It is however clear to the Committee that not being able to meet the mandatory requirements in EU legislation will add to the potential impacts mentioned above.

The Dossier Submitter proposes an indefinite derogation for paper and board articles containing recovered material, with the exception of food contact material and packaging. The Dossier Submitter indicates that a time-unlimited derogation is justified in order to align with their evaluation of printing applications (e.g. inks and toners) where the continued use of PFAS in certain printing applications is proposed. As such, the Dossier Submitter considers that a derogation for paper and board recycling needs to take into account the prolonged presence of PFAS in this waste stream from printing applications. Additionally, suppliers of paper and board articles would be subject to, upon request by national enforcement agencies, providing documentary evidence on the origin of recovered material.

Based on its evaluation of the available information and considering mandatory requirements for the use of recycled content for specific applications as well as sustainability considerations, **SEAC concludes that a derogation for paper and board articles containing recovered material (excluding food contact material and packaging) could be justified to ensure proportionality** of the restriction overall. SEAC does, however, not agree with the proposal to have a time-unlimited derogation. SEAC notes that an alignment between derogations for printing applications and paper and board recycling does not take into account that the recycling process as described by the Dossier Submitter explicitly includes a “de-inking” stage to increase the purity of the paper pulp and therefore separates printing inks and other contaminants from the pulp. As such, the use of PFAS in printing applications need not impact the presence of PFAS in recycled paper and board. Additionally, paper and board articles have a shorter service life than plastic articles, alternatives are in general farther along than for plastic articles and can in any case not be recycled indefinitely. SEAC cannot conclude on the length of the necessary derogation period due to the following uncertainties: i) at what time after entry into force the proposed concentration limits could be met by recyclers, ii) the actual magnitude of economic impacts in cases where the concentration limits cannot be met, as well as iii) the lack of information on additional emissions related to a derogation for recycled paper and board<sup>53</sup>.

SEAC also highlights some uncertainties on whether the wording of the proposed derogation would allow the addition of PFAS to paper and board articles outside of the PFAS already present in the recovered paper and board material. It is clear to SEAC that in order to avoid making it possible to circumvent the intention of the proposed derogation, the PFAS present in paper and board articles containing recovered material should only be allowed to originate from the recovered material. Similarly, there is also a potential for the introduction of PFAS-containing recovered paper and board into articles where previously no PFAS were used or needed (circumventing the ban for certain applications<sup>54</sup>). Additionally, the wording of the proposed derogation could also lead to the use of higher amounts of PFAS-containing

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<sup>53</sup> Overall, RAC agrees with the Dossier Submitter that recycling of paper and board is likely to result in additional PFAS emissions, which are however likely to decrease progressively as a result of the phase-out of PFAS in products made of virgin materials.

<sup>54</sup> Virgin materials would need to comply with the concentration limits, but a small addition of recovered material would ensure that the derogation applies.

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recovered material since it does not contain concentration limits. The Dossier Submitter's proposal to provide documentary evidence of the origin of recovered material would then allow enforcement agencies to check compliance with the proposed derogation and whether the PFAS present in the paper and board article were added intentionally or originate from the recovered material. As such, SEAC supports this proposal, but notes that Forum has identified concerns regarding enforceability of this requirement (i.e. there not being a concentration limit).

SEAC agrees with the Dossier Submitter that a labelling requirement would have no or only limited added value since there is no legislation governing the collection and treatment of highly specific paper and board waste streams as is the case for certain technical plastic streams (see earlier).

- Textiles

Based on the information received from the consultation on the Annex XV report and the assessment of these comments performed by the Dossier Submitter, SEAC finds there to be sufficiently strong evidence that the textile waste stream contains PFAS coming from a wide variety of sources (e.g. home textiles and consumer apparel, sportswear and footwear). The Committee also notes that the wide variability in service life of products entering this waste stream with specific applications having very long service lives (technical textiles).

SEAC finds that a ban on PFAS in recycled textiles with long service lives, among others technical textiles, is likely to have minimal impact on the recycling of textiles in general for the following reasons:

- Fluoropolymers are predominantly used in this application<sup>55</sup> and these materials have been omitted from the scope of the assessment on textile recycling by the Dossier Submitter. The assessment is solely focussed on the impacts of the proposed restriction on the recycling of non-PFAS textiles.
- Stakeholders<sup>56</sup> have indicated that a lot of applications falling under the moniker of technical textiles are not commonly recycled, e.g. vacuum cleaner filters, certain textiles used in operating theatres (due to contamination); and C6-treated technical textiles for professional and industrial uses are typically disposed via incineration. More generally, Conversio (2022) indicates that only 3% of fluoropolymers are actually recycled.

The Dossier Submitter indicates that during the consultation on the Annex XV report several stakeholders<sup>57</sup> provided quantitative information on PFAS concentrations in various textile waste streams. This data provides a mixed picture in that some of the tested samples exceed the proposed 25 ppb and 250 ppb concentration limits, but also that a lot of samples covering distinct applications (carpet, leather, as well as certain consumer products to treat textile) already comply. As such, SEAC agrees with the Dossier Submitter's statement that not all products entering recycling feedstocks contain PFAS. While SEAC notes that the submitted data is limited and its representativeness for the whole sector is uncertain, it does seem to be in line with the Dossier Submitter's assessment of alternatives for the TULAC sector and

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<sup>55</sup> Mid-scenario estimated volumes (2020 figures) for "Technical textiles" according to the Background Document (Annex A, section A.3.23.2): 4 605 t/y fluoropolymers versus 727 t/y PFAAs and PFAA precursors.

<sup>56</sup> E.g. #6395, #8910, #9032, #9478, #9512, #9534.

<sup>57</sup> E.g. #7549, #7555, #7563, #7564, #7830.

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SEAC's evaluation thereof (i.e. that alternative-based home textile and consumer/professional<sup>58</sup> apparel products are already widely available on the market<sup>59</sup>). While a review by Pivato et al. (2024) does not provide more clarity, it also does not contradict the findings discussed above. This review gathered PFAS concentration data on products in textile waste streams<sup>60</sup> from literature and compared these to the proposed 25 ppb limit for individual PFAS. Based on 1 488 observations, 2.97% of data exceeded the 25 ppb limit for PFOA, 0.87% for C9-C14 PFCAs, 7.41% for PFOS, 0.87% for PFHxS and 8.14% for "other PFAS". There is limited data on PFAS concentrations in recycled material, but since currently the most widely used recycling method is mechanical recycling, any PFAS in the feedstock will also be present in the recycled material.

SEAC agrees with the Dossier Submitter that even though the data submitted in the consultation on the Annex XV report on PFAS concentrations in textile products is limited and there are concerns surrounding its representativeness, there are indications that, at entry into force, PFAS can still be present at concentrations above the proposed concentration limits in feedstocks for textile recycling as well as products made of recycled material. It is however also likely that compliance with the proposed concentration limits might occur faster after entry into force than for other waste streams considering the state of alternatives for home textile and consumer/professional apparel products.

The Dossier Submitter discusses profit and employment losses for recyclers as well as impacts related to the non-availability of raw materials/products and related costs for downstream users of recycled materials as well as for consumers. Also, sustainability aspects are considered in the Background Document associated with a higher use of virgin materials<sup>61</sup>. The Dossier Submitter concludes that considerable profit and employment losses for recyclers<sup>62</sup> are expected to occur in case concentration limits cannot be met for recycled textiles, regardless of whether use-specific derogations are provided (under RO2 and RO3) or not (under RO1). The other impacts discussed in the Background Document are expected to be more limited. The Dossier Submitter's conclusion is based on information provided by stakeholders in the Annex XV report consultation (e.g. comments #6395, #7804, #9083, #9314, #9403).

Given the aforementioned aspects, the Dossier Submitter concludes that complying with the concentration limits proposed in the Background Document is not deemed proportionate for recycled textiles. It is important to note that this conclusion is based on economic

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<sup>58</sup> Excluding PPE.

<sup>59</sup> See SEAC's evaluation of sector-/use-specific aspects regarding "TULAC".

<sup>60</sup> Waste data mostly included "treated upholstery (both from houses, e.g. carpets, End-Life-Vehicles (ELV)) and treated apparels".

<sup>61</sup> The Dossier Submitter refers to a potential increase in greenhouse gas emissions associated with an increased use of virgin fibres; chemical recycling of synthetic fibres is, for example, expected to reduce CO<sub>2</sub>e emissions by 60-70% compared to the use of virgin fibres. Other examples are mentioned in the Background Document as well. While it is noted that determining the true CO<sub>2</sub>e emission reduction potential for the various textile recycling technologies requires a fibre-by-fibre comparison and some uncertainties prevail, an increase in greenhouse gas emissions cannot be ruled out.

<sup>62</sup> The Dossier Submitter mentions business closures as a reaction to a restriction (given the negative implications and risks of post-production batch testing for profitability), which would lead to considerable profit and employment losses for/in at least 17 European fibre-to-fibre recycling companies with a total annual fibre-to-fibre recycling capacity of 1.3 million tonnes per year.

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considerations only, not considering emissions associated with the recycling of PFAS-containing textiles. Whilst SEAC agrees with the Dossier Submitter that economic impacts are to be expected in case of a ban, their magnitude is unknown. SEAC has identified the following uncertainties affecting the Dossier Submitter's assessment and conclusions:

- The qualitative assessment and the related conclusions on impacts drawn are not substantiated by supporting evidence.
  - SEAC's evaluation of the information in the Background Document shows that compliance with the proposed concentration limits might occur faster after entry into force than for other waste streams considering the state of alternatives for home textile and consumer/professional apparel products.
- The Dossier Submitter's conclusion that complying with the proposed concentration limits is not proportionate for recycled textiles is solely based on the consideration of economic impacts, while the relevant environmental impacts were not assessed.

SEAC notes that while European legislation aims to promote higher levels of separate collection, recyclability and recycling of textiles, specific recycling targets for textiles have so far not been set. It is therefore unclear whether impacts from a ban on PFAS in recycled textiles would significantly affect meeting the aims of European legislation on sustainability.

The Dossier Submitter proposes a derogation for textile articles containing recovered material, with the exception of toys as defined in the Toy Safety Directive, until 13.5 years after entry into force. Additionally, suppliers of textile articles would be subject to, upon request by national enforcement agencies, providing documentary evidence on the origin of recovered material.

Based on its evaluation of the available information as well as considering sustainability considerations, **SEAC concludes that a time-limited derogation for textile articles containing recovered material (excluding toys) could be justified to ensure proportionality** of the restriction overall. SEAC cannot conclude on the length of the necessary derogation period due to the following uncertainties: i) at what time after entry into force the proposed concentration limits could be met by recyclers, ii) the actual magnitude of economic impacts in cases where the concentration limits cannot be met, as well as iii) the lack of information on additional emissions related to the proposed derogation for recycled textiles<sup>63</sup>.

SEAC also highlights some uncertainties on whether the wording of the proposed derogation would allow the addition of PFAS to textile articles outside of the PFAS already present in the recovered textile material. It is clear to SEAC that in order to avoid making it possible to circumvent the intention of the proposed derogation, the PFAS present in textile articles containing recovered material should only be allowed to originate from the recovered material. Similarly, there is also a potential for the introduction of PFAS-containing recovered textiles into articles where previously no PFAS were used or needed (circumventing the ban for certain applications<sup>64</sup>). Additionally, the wording of the proposed derogation could also lead to the use of higher amounts of PFAS-containing recovered material since it does not

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<sup>63</sup> According to RAC, the emissions may vary depending on the type of the recycling process. Emissions and levels of PFAS in recyclate are, however, likely to decrease gradually after the restriction enters in force

<sup>64</sup> Virgin materials would need to comply with the concentration limits, but a small addition of recovered material would ensure that the derogation applies.

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contain concentration limits. The Dossier Submitter's proposal to provide documentary evidence of the origin of recovered material would then allow enforcement agencies to check compliance with the proposed derogation and whether the PFAS present in the textile article were added intentionally or originate from the recovered material. As such, SEAC supports this proposal, but notes that Forum has identified concerns regarding enforceability of this requirement (i.e. there not being a concentration limit).

SEAC agrees with the Dossier Submitter that a labelling requirement would have no or only limited added value since there is no legislation governing the collection and treatment of highly specific textile waste streams as is the case for certain technical plastic streams (see earlier).

- Metals

Based on the information received from the consultation on the Annex XV report and the assessment of these comments performed by the Dossier Submitter, SEAC finds there to be sufficiently strong evidence that the metals waste stream contains PFAS coming from a wide variety of sources. PFAS are used in various products ranging from relatively simple articles (e.g. fluoropolymer-coated metal parts used in transport vehicles, machinery or construction products), to complex objects (e.g. electronic devices, fuel cells and batteries). The metals in these different products, such as steel, aluminium (and its alloys), lithium, cobalt, copper, nickel, cadmium, lead and platinum-group metals are frequently recovered/recycled at the end of the products' service life. SEAC notes that the average service life of metal-containing products varies depending on their application, with several applications having very long service lifespans (up to several decades in some rare cases).

The Dossier Submitter indicates that during the consultation on the Annex XV report several stakeholders<sup>65</sup> provided quantitative information on PFAS concentrations in various metals waste streams. A review by Pivato et al. (2024) also contains some information, but SEAC considers the scope too narrow (automotive shredder residues) for the results to be at all representative for the waste metal stream as a whole.

Based on the information in the Background Document it is clear to SEAC that PFAS will enter the metals waste stream. However, while the recycling methods for the other waste streams do not ensure that PFAS are no longer present in the recycled material (above the proposed concentration limits), this does seem to be the case for the metals waste streams. The Dossier Submitter provides a somewhat detailed discussion of the used recycling methods which indicates that during the recycling process PFAS are either completely degraded or can be separated from the metals fraction<sup>66</sup>. This is consistently confirmed by stakeholders<sup>67</sup>.

SEAC therefore agrees with the Dossier Submitter that compliance with the proposed concentration limits will be possible at entry into force. As such no impacts related to metal recycling are expected to occur.

In conclusion, and based on its assessment of the available information, SEAC agrees with

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<sup>65</sup> Relevant examples: coatings (e.g. #3986, #4139, #6009, #6043, #8144, #8734); electrical insulation of cables, connectors and other electrical equipment (e.g. #4479, #5991, #6473, #6642, #7264, #7491, #8144, #8398, #8584); components of batteries and electrolyser and fuel cell systems (e.g. #4114, #4254, #4445, #6059, #6121, #6142, #6478, #6587, #6904, #6913, #7652, #8771, #8910, #9217, #9246).

<sup>66</sup> The final fate of these separated PFAS-containing fractions is unknown to SEAC.

<sup>67</sup> E.g. #7038, #7052, #7145, #8680, #8771, #9078, #9311, #9410, #9534.

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the Dossier Submitter that a **derogation for recycled metals is not warranted**.

**D. Cumulative impacts:**

According to the Dossier Submitter, cumulative impacts can occur when multiple uses/products based on PFAS, when combined, lead to additional adverse effects on companies and/or sectors, and their ability to transition to alternatives to PFAS within the proposed timeframes for derogations. The Dossier Submitter describes two main scenarios where a cumulation of impacts could occur, especially where no suitable alternatives have been identified yet. Nevertheless, the Dossier Submitter concludes that the 12-year derogation periods (following the general 18-month transition period) proposed in such cases to be sufficient to transition to alternatives. The two scenarios described by the Dossier Submitter and SEAC's evaluation of these are as follows:

1. **The same company** uses PFAS in a variety of products for multiple downstream uses and in multiple sectors (e.g. Annex XV report consultation comment #3977). SEAC agrees with the Dossier Submitter's reasoning that such companies, whose portfolio depends in large part on the use of PFAS, are less resilient to a ban of PFAS than those that only need to focus on the substitution in a few applications. Generally, where such information was available on a company level, it was taken into account for the sector-specific cost assessments and SEAC's evaluation thereof. However, SEAC notes that it has no information on the proportion of companies that would be disproportionately affected by a ban compared to the proportion of "more resilient" companies in a sector and, therefore, also not on the overall magnitude of the related impacts.
2. The supply chain of **the same complex object** (e.g. a car or an airplane) depends on PFAS in a range of components, such as in sealings, textiles, metal plated parts, semiconductors and other electric components, lubricants, batteries, heat pumps, etc. (e.g. Annex XV report consultation comments #7145, #8945, #8974). Stakeholders argue that the interdependency of these components makes substitution likely infeasible and the Dossier Submitter recognizes that this interdependency makes the transition to alternatives more complex. In the Dossier Submitter's assessment of the specific sectors and the proposed derogations as well SEAC's evaluation thereof generally each (sub-)use and the related derogation is considered on its own. However, the discussion provided in the Background Document did not specifically address specific complex objects such as a car or a specific industrial machine. SEAC notes that even if alternatives were available for each single article within a complex object, cumulative impacts may still be significant (and render substitution for the complex object overall infeasible). Furthermore, despite the availability of alternatives for single components, cumulative impacts may occur where substitution processes have high interdependency. For example, in the electronics sector, certain devices may integrate other objects that may need to first undergo substitution before the complex object can be adapted. Such situations require strong communication within the supply chain and may induce lag time in alternatives development. Consequently, SEAC cannot conclude whether the 12-year derogations proposed by the Dossier Submitter on the basis of an assessment of isolated substitution processes do consider any cumulative impacts properly. Overall, SEAC notes that the number of complex objects for which companies will need to substitute more than just a few parts simultaneously may be significant.

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**E. Overarching impacts on trade and competitiveness:**

The Dossier Submitter qualitatively discussed potential impacts on trade and competitiveness. This was done based on information provided mainly by industry/trade associations in the Annex XV report consultation (e.g. comments #5390, #6362, #7993, #7996, #8199, #8587, #8748, #8912, #9023, #9262, #9314), from which the Dossier Submitter identified the following as the main issues for EU/EEA-based companies concerning trade and competitiveness in the global market. These are relevant for most, if not all sectors covered by the restriction proposal:

- **Increased costs, reduced product performance and/or higher product prices** and a **shorter product lifespan** due to using alternatives; differences in prices and functionalities could pose a challenge for EU/EEA-based companies to compete on the global market with the consequence of a potential loss of market share.
- Implications on **product innovation**, e.g. a crowd-out of other product innovation efforts due to a required transition to alternatives associated with the proposed restriction; also, declining profit margins due to increased costs and or/lower product performance could impact the capacity for innovation; and, lastly, PFAS themselves play an important role in product innovation in a wide range of sectors.
- Disruption of **critical supply chains** due to the collapsing of entire production processes if alternative materials are not yet available and/or fail to meet strict technical or safety standards<sup>68</sup>.
- Risk of **non-compliant products** distorting competition in case no standardised analytical methods and sufficient enforcement is available.

Overall, the Dossier Submitter agrees with the arguments brought forward by stakeholders but concludes that the concerns will largely be mitigated by comprehensive and well-designed derogations as presented in the sector-specific assessments. Also, the restriction proposal is regarded as practical and enforceable by the Dossier Submitter. Still, the Dossier Submitter acknowledges that some impacts on competitiveness in the global market will occur due to the aforementioned issues. The Dossier Submitter concludes that negative implications on trade and competitiveness might be partially mitigated if regulations on PFAS are introduced in other, non-EU/EEA-countries. In such cases, EU/EEA-based companies could potentially benefit from being early adopters of PFAS-alternatives.

Whilst SEAC finds that the issues brought forward by the Dossier Submitter are valid, relevant and important aspects, the Committee notes that no actual assessment was provided in the Background Document and no conclusion is drawn on the potential magnitude of these impacts and/or their mitigation. The assessment provided is largely a general listing of issues related to trade and competition, which are relevant for many restriction proposals, independently of the substances concerned. Also, whilst SEAC agrees that well-designed derogations can address several of the aforementioned impacts, no assessment is provided that would discuss and/or demonstrate this for the sectors covered by the restriction proposal. Furthermore, SEAC notes that the Dossier Submitter's sector-specific assessment is subject to large uncertainties in terms of the analysis of alternatives as well as the socio-economic impacts. Also, it is uncertain whether all PFAS (sub-)uses have been identified, assessed and properly discussed in the Background Document. These aspects make the Dossier Submitter's

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<sup>68</sup> This could be relevant for the use of PFAS in/as e.g. seals, refrigerants, coatings and lubricants.

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conclusion that negative implications on trade and competitiveness will overall be mitigated by the proposed derogations as well as an effective enforcement highly uncertain. Due to the lack of a (qualitative and/or quantitative) assessment as well as the high uncertainties related to the Dossier Submitter's conclusion, SEAC is unable to provide its view on the magnitude of any potential impacts on trade and competitiveness.

**F. Derogated uses lost due to low market volumes**

The Dossier Submitter, in the response to comments from the Annex XV report consultation, mentions the concern brought forward by a few stakeholders (e.g. #4115, #8521) that the supply of PFAS for (niche) applications proposed to be derogated may not be ensured due to a critical reduction in market size for some PFAS. Due to a lack of substantiated arguments neither the Dossier Submitter nor SEAC were able to assess the validity of this concern and its possible impact. SEAC notes the considerable cumulative tonnages of all uses proposed to be derogated by the Dossier Submitter, creating or maintaining a market for PFAS. Nevertheless, SEAC acknowledges that over time and especially when approaching the end of the different derogation periods, the market may change and the demand for PFAS for the remaining derogated uses may need to be satisfied through import.

**G. Upstream supply chain for derogated uses**

The Dossier Submitter clarifies that **starting materials and intermediates** in the manufacture of PFAS as well as the production of **PFAS-containing mixtures or articles** in the upstream supply chain for derogated uses<sup>69</sup> should also be derogated from a restriction. SEAC notes that this upstream supply chain derogation only applies to PFAS substances used in a derogated use, as well as the building blocks needed to produce this PFAS substance, i.e. starting materials and intermediates. It is important to emphasize that this derogation does not encompass the use of PFAS in, for example, equipment and instruments used to produce for the downstream derogated uses, or solvents and auxiliary chemicals, i.e. those that are not intentionally present in the end-product. SEAC supports this approach from a practicality point of view. However, SEAC emphasizes that no information related to the impacts of (not) granting a derogation for upstream supply chain uses is available to the Committee, i.e. any consequences in terms of cost and benefits are unknown.

**H. SR&D and PPORD**

According to REACH article 67, restrictions do not apply to **Scientific Research and Development (SR&D)** and a specific derogation is therefore not needed to exclude SR&D activities from the proposed restriction. SEAC does however note that the original Annex XV report included explicit derogations for "*diagnostic laboratory testing*" (including in vitro diagnostic medical devices) and "*calibration of measurement instruments and as analytical reference materials*". These derogations were subsequently deleted from the Background Document since the Dossier Submitter considers these uses to be covered by the SR&D exemption. More broadly the Dossier Submitter also considers the use of fluoropolymers as materials in equipment and instruments in research-related activities to be covered by the SR&D exemption. The Dossier Submitter does not provide further justification for this. The ECHA guidance on SR&D (and PPORD) only indicates that "*SR&D may include any experimental research or analytical activities at a laboratory scale such as synthesis and*

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<sup>69</sup> The derogation applies to uses listed under paragraphs 4, 5 and 6 of the restriction proposed by the Dossier Submitter (see Table 1).

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*testing of applications of chemicals, release tests, etc. as well as the use of the substance in monitoring and routine quality control or in vitro diagnostics at a laboratory scale under controlled conditions*". It is therefore unclear to SEAC whether "*diagnostic laboratory testing*" (including in vitro diagnostic medical devices) and "*calibration of measurement instruments and as analytical reference materials*" are fully covered by the SR&D exemption. SEAC also finds it unclear whether the use of fluoropolymers as materials in equipment and instruments in research-related activities will be covered under the same exemption. SEAC notes, however, that the use of PFAS as reference standards specifically is essential in ensuring compliance with and enforcement of the proposed restriction (i.e. for targeted PFAS analysis). The Background Document and the comments submitted in the consultation on the Annex XV report do however not contain information that would justify specific derogations for the use of PFAS in applications linked to but not covered by SR&D (as defined under REACH).

The Dossier Submitter included an explicit time-unlimited derogation for PFAS used in **Product and Process Orientated Research and Development (PPORD)**. The justification for a derogation for PPORD activities provided in the Background Document is based on comments from stakeholders<sup>70</sup> active in the field of pharmaceuticals, but also in the field of energy and electronics. According to the Background Document, the stakeholders indicate that "*the need for a derogation is to allow all stages in the development of a product in the EU/EEA before market introduction for derogated uses*". The Dossier Submitter also notes specifically that "*the absence of an exemption for clinical trials in paragraph 4(b) of the REACH restriction for synthetic polymer microparticles (Annex XVII entry 78, also known as the Microplastic restriction) is currently being addressed by the European Commission. The Commission services are currently preparing a Correcting Act to change the wording of this paragraph so that the placing on the market of medicinal products used in clinical trials is included in the derogation*". While SEAC agrees that according to REACH article 67(1) a restriction should specify whether it applies to PPORD (and specify the maximum quantity if it does), the justification provided by stakeholders and the Dossier Submitter needs to be nuanced for several reasons:

- The derogation proposed as part of the PFAS restriction is worded in such a way as to apply regardless of the application and therefore makes no distinction between whether a time-limited or time-unlimited derogation was proposed, or no derogation at all. The Dossier Submitter does however indicate that this proposed derogation would in practice only have any utility for derogated uses.
- In contrast, the Correcting Act to the microplastics restriction mentioned by the Dossier Submitter is aimed at rectifying an oversight for a specific time-unlimited derogation.
- The microplastics restriction derogates "*medicinal products within the scope of Directive 2001/83/EC and veterinary medicinal products within the scope of Regulation (EU) 2019/6 of the European Parliament and of the Council*", while the proposed PFAS restriction only proposes to derogate "*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*".
- SEAC concluded that specifically for active substances in Plant Protection Products (PPP) and Biocidal Products (BP), as well as active pharmaceutical ingredients (API) in human and veterinary Medicinal Products (MP), the Dossier Submitter has not properly

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<sup>70</sup> E.g. #4041, #4455, #4503, #6436, #6708, #7142, #7281, #7756, #7875, #8804, #9063, #9365, #9453.

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justified the exclusion of these applications via a time-unlimited derogation.

SEAC therefore concludes that the justification provided by the Dossier Submitter and stakeholders in the consultation on the Annex XV report does not warrant a generic derogation for all PPORD activities. SEAC also questions the utility of a potential derogation on PPORD activities related to applications that will only be derogated for 5 or 12 years (following the general 18-month transition period). SEAC can however envision that unwanted circumstances might arise if PPORD activities are no longer allowed when these can be linked to applications for which a time-unlimited derogation is proposed by the Dossier Submitter. More specifically, if the decision maker would find a time-unlimited derogation for the use of PFAS as active substances in medicinal products to be warranted despite SEAC's reservations, then a derogation for PPORD activities could likely also be necessary (based on a similar experience in the microplastics restriction). There is no information available to SEAC to assess whether such a PPORD derogation could also be necessary for the use of PFAS as active substances in Plant Protection Products (PPP) and Biocidal Products (BP) if the decision maker decided to derogate these applications.

### **3.4.2.2.5. Proportionality**

#### **Relevant sections of the Background Document:**

Main report, section 2.4.4; Annex E.

#### **SEAC conclusion(s):**

SEAC notes that due to lack of quantitative cost data, a cost-effectiveness analysis to evaluate proportionality is not possible for the restriction options RO1, RO2 and RO3 as well as the proposed restriction (which corresponds to RO2 for all sectors, except for PFAS manufacturing, for which RO3b is proposed) overall; the same applies for almost all sectors/(sub-)uses covered by the proposed restriction. Therefore, the Dossier Submitter provided a proportionality assessment according to step 6 of the impact assessment approach established for the restriction proposal (see section 3.4.2.2 of this opinion). SEAC has several concerns regarding the applicability of this approach as pointed out in the key elements section below. However, SEAC notes that (mainly qualitative) information on costs and benefits as well as information on the substitution potential is available for several sectors and/or (sub-)uses, allowing for an evaluation according to SEAC's approach to qualitative assessments in restriction reports (ECHA, 2022).

SEAC notes that the Dossier Submitter **did not specifically conclude on the overall proportionality** of the three restriction options (RO1, RO2 and RO3) discussed in the Background Document and, consequently, also not for the proposed restriction (which corresponds to RO2 for all sectors, except for PFAS manufacturing, for which RO3b is proposed). Instead, proportionality is assessed and concluded on a sector-basis only. SEAC's conclusion on proportionality for the specific sectors is provided in the documents containing SEAC's evaluation of sector-/use-specific aspects. SEAC, however, notes that RO2 is the restriction option, which is proposed by the Dossier Submitter for the draft Annex XVII entry text (except for PFAS manufacturing, for which RO3b is proposed) and found preferable over RO1 due to lower costs.

Based on the information available to the Committee, SEAC concludes that **RO1**, i.e. a full ban, is **likely not proportionate**. Even though RAC considers RO1 to be an effective measure to minimise PFAS emissions and exposure of humans and the environment and calculates a

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total emission reduction potential of 96%<sup>71</sup> (excluding uses not evaluated in detail) for this restriction option, SEAC considers that RO1 does not sufficiently balance benefits and costs, considering also the sufficiently strong evidence for low substitution potential for several of the (sub-)uses covered by the restriction proposal. In such cases, i.e. if neither PFAS can be used, nor technically and economically feasible alternatives are already available, substantial societal costs can additionally be expected where a ban of a (sub-)use would lead to health and safety implications, e.g. in sectors such as medical devices, transport, energy and others. Further information is provided in the documents containing SEAC's evaluation of sector-/use-specific aspects.

In general, SEAC considers a ban with use-specific derogations where costs to society outweigh the benefits appropriate to ensure proportionality of the proposed PFAS restriction. Derogations that are considered justified by SEAC are highlighted in the respective documents containing SEAC's evaluation of sector-/use-specific aspects and are also summarised in section 3.4.3.2.5.8 below. SEAC emphasises that due to the lack of assessment available to the Committee as well as the overall lack of information, these derogations are understood to be necessary but not sufficient on their own to ensure proportionality for a restriction. The general lack of data as well as uncertainties in the available information on the assessed (sub-)uses, as well as unknown or unidentified (sub-)uses, **prevent SEAC from concluding on the proportionality** of restriction options **RO2 and RO3 as well as the proposed restriction** overall.

In addition to the comparison of the emission reduction potential and costs associated with the restriction options assessed, SEAC emphasises the accumulation of pollution over time and the related long-term environmental impact potential associated with PFAS as a result of the very persistent property of these substances. As pointed out in section 3.4.2.2.3 on benefits, this is not reflected in the emission reduction potential. SEAC agrees with the Dossier Submitter that the accumulation of pollution over time and any related impacts are important aspects to consider for the conclusion on benefits as well as proportionality in addition to the emission reduction potential of a restriction. Also, these are important aspects for the decision maker to consider when deciding on the actual conditions of a PFAS restriction, specifically in the absence of a robust qualitative and/or quantitative proportionality assessment.

### **Key elements underpinning the SEAC conclusion(s):**

- **Quantitative vs. qualitative analysis:** As pointed out previously in this opinion, SEAC prefers a robust quantitative assessment of impacts, also when it comes to the evaluation of/conclusion on proportionality. A CEA is recognized by SEAC to be currently an appropriate method for assessing proportionality of restrictions of persistent substances since safe concentration levels cannot be derived for these substances (ECHA, 2023). Therefore, for the present restriction proposal, a CEA is regarded by SEAC as an appropriate tool to assess proportionality. However, SEAC acknowledges that there are cases where a quantitative assessment is not possible. In such cases, the Dossier Submitter needs to clearly document the systematic efforts made towards a quantitative assessment and the reasons why such an assessment was not regarded feasible or proportionate, as outlined in the paper on SEAC's evaluation of qualitative assessments in restriction reports (ECHA, 2022). SEAC notes

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<sup>71</sup> 96% emission reduction potential corresponds to approximately 3.3 million tonnes of avoided emissions over the 30-year assessment period for RO1, excluding uses not evaluated in detail.

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that in the current case, due to its very broad scope (both, in terms of substances and scope), a full quantitative assessment is a challenging and probably impossible task. From the cost assessment performed by the Dossier Submitter, SEAC notes that for most sectors and (sub-)uses no quantified cost estimates could be established. Consequently, no CEA can be performed. SEAC notes that only for very few (sub-)uses (i.e. cosmetics, greaseproof paper) a quantitative cost-effectiveness analysis (CEA) was possible; the main reason is lack of quantitative cost data. Also, while quantified figures for emissions and emission reduction potential for most sectors would be available to conduct a quantitative CEA, SEAC notes RAC’s conclusion that in some cases significant uncertainties are associated with these estimates. If a CEA were to be conducted on this basis, its robustness may be limited in these cases. Hence, the available quantitative information is insufficient to conclude on the overall proportionality of the restriction options discussed based on CEA.

- **SEAC’s view on the proportionality assessment according to the stepwise impact assessment approach<sup>72</sup>:** Step 6 of the Dossier Submitter’s impact assessment approach covers a proportionality assessment, which is based on the effectiveness (the emission reduction potential) as well as the costs (mainly qualitatively assessed economic costs and/or other impacts) of the restriction options on a sector basis. The Dossier Submitter established a matrix, comparing these two aspects to assess proportionality (see Table 7 below). Whilst this has been done on a sector basis, no assessment of proportionality is done for the assessed restriction options overall, as information on total costs at the restriction option level is lacking. The results of the matrix allow the Dossier Submitter to conclude on whether a combination of different cost and effectiveness levels is considered proportionate, likely proportionate, likely not proportionate or not proportionate. There are also situations, i.e. combinations of cost levels and effectiveness levels, where no conclusion is drawn as the situations are regarded either i) not effective enough to achieve the desired goal or ii) where costs are so high that it is recommended to look for a restriction option associated with lower costs. Although the approach cannot be regarded as quantitative cost-effectiveness analysis (CEA), SEAC acknowledges the Dossier Submitter’s attempt to compare costs and effectiveness in a qualitative manner using gradation scales, as depicted in Table 7 below.

**Table 7: Dossier Submitter’s matrix for assessing proportionality**

Effectiveness: emission reduction [%]	Economic costs or other impacts of a restriction option				
	Very low	Low	Moderate	High	Very high
Very Low (<70%)	Not effective enough to achieve the desired minimum effectiveness level				
Low (70 – 79%)	Proportionate	Likely proportionate	Likely proportionate	Not proportionate	Not proportionate
Moderate (80 – 89%)	Proportionate	Likely proportionate	Likely proportionate	Likely not proportionate	Likely not proportionate
High (90 – 98%)	Proportionate	Proportionate	Likely proportionate	Likely not proportionate	Likely not proportionate
Very high (≥ 99%)	Proportionate	Proportionate	Proportionate	Likely proportionate	Very effective, very high costs

<sup>72</sup> For further details on the impact assessment approach established by the Dossier Submitter, see section 3.4.2.2.1 of this opinion.

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SEAC agrees that the comparison of effectiveness against the associated costs supports the conclusion on proportionality. However, SEAC raises some concerns regarding the set-up of the matrix, its applicability for assessing proportionality and the interpretation of the related conclusions. The following aspects are the main reasons why SEAC does not take forward the Dossier Submitter's matrix to conclude on proportionality:

- The Dossier Submitter's conclusion on costs (very low to very high) for each sector is mainly based on a qualitative assessment which, as pointed out in section 3.4.2.2.2 above, differs in terms of detail and quality. For some sectors, SEAC cannot verify the Dossier Submitter's conclusion on costs, as the cost assessment is very limited, the criteria established for the assessment have not been (transparently) applied and the related conclusion is unclear to SEAC, i.e. SEAC cannot take the Dossier Submitter's cost conclusion forward to the proportionality assessment. Additionally, the results of the cost assessments are, in SEAC's view, not comparable across sectors, which hampers an assessment of the overall costs of a restriction on a sector-basis and for the restriction options RO1, RO2 and RO3 as well as the proposed restriction overall.
- The effectiveness level only takes the emission reduction relative to the baseline of a sector into account without considering the absolute tonnage of remaining emissions. An effectiveness of e.g. 90% in a high-tonnage sector may in absolute terms still result in much higher remaining emissions than an effectiveness of e.g. only 30% in a low-tonnage sector. Similarly, a proposed derogation causing high additional emissions may result in different levels of effectiveness depending on whether a high-tonnage or low-tonnage sector is considered.
- The outcome of the proportionality assessment based on the Dossier Submitter's approach is dependent on the delineation of sectors/(sub-)uses and the level of aggregation at which the assessment is performed. Furthermore, the effectiveness of a restriction option at (sub-)use level is dependent on the chosen frame of reference, i.e. whether the emission reduction is compared to the baseline emissions of i) the relevant (sub-)use, ii) the relevant sector or iii) the restriction overall. The level of aggregation and frame of reference influence the effectiveness. The qualitative cost assessment in combination with the dependency of the effectiveness on the level of aggregation and frame of reference used could lead to ambiguous outcomes of the proportionality assessment.
- The Dossier Submitter considers an effectiveness of <70% too low to achieve the desired goal of a restriction even if associated costs are very low. Whilst SEAC takes note of the reasoning of the Dossier Submitter for choosing this indicative benchmark, i.e. a respective reduction of PFAS emissions to the environment, SEAC notes that there is currently no agreed benchmark for a minimum effectiveness level for concluding on proportionality. Furthermore, SEAC notes that also effectiveness levels below 70% contribute, in certain cases substantially (depending on whether a high- or a low-tonnage sector is considered), to the goal of a restriction.

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- **SEAC's approach to assess proportionality (sector-basis as well as restriction options and proposed restriction overall):** SEAC's *sector-specific* proportionality assessment is based on the outcome of the analyses of alternatives as well as the available information on costs and benefits. The Committee's evaluation focuses on whether there is enough and sufficiently transparent information, whether the qualitative assessment is consistent and transparent, and whether the conclusions reached by the Dossier Submitter are justified. Also, information provided by stakeholders in the Annex XV report consultation is considered by SEAC.

The aforementioned sector-specific assessment forms the basis for SEAC's evaluation and conclusion on the proportionality of the **restriction options RO1, RO2 and RO3 as well as the proposed restriction overall**. SEAC notes that the sector-based assessment indicates for several sectors that RO1, i.e. a full ban of PFAS, is likely not proportionate, given the available information on alternatives, costs and benefits. Consequently, SEAC concludes that RO1 overall is likely not a proportionate restriction option as it does not sufficiently balance costs and benefits. Due to a lack of information and limitations in both, the analysis of alternatives and the socio-economic analysis, SEAC is not able to conclude on the proportionality of RO2 and RO3 for most sectors; hence SEAC is not able to conclude on the proportionality for the restriction options RO2 and RO3 as well as the proposed restriction overall. However, for several (sub-)uses, SEAC has identified the need for derogations to ensure the proportionality of a restriction overall and in a specific sector. These are highlighted in the respective documents containing the evaluation of sector-/use-specific aspects and are summarised in section 3.4.3.2.5 below. SEAC emphasizes that any derogation that the Committee considers justified should be regarded as necessary to ensure that a restriction is proportionate, but not as sufficient on their own. Additional derogations may be required for certain (sub-)uses in order for a restriction to be proportionate. However, uncertainties in the available information on the assessed (sub-)uses, as well as unknown or unidentified (sub-)uses, prevent SEAC from specifying such additional derogations.

- **Additional aspects to consider for the proportionality assessment:** SEAC's detailed view regarding the accumulation of pollution over time and the related long-term environmental impact potential associated with PFAS as a result of the very persistent property of these substances is provided in section 3.4.2.2.3 on benefits above. This section also contains a detailed qualitative evaluation of the benefits associated with the emission reduction of PFAS as well as recent findings (in qualitative and partly also quantitative terms) concerning the overall effects due to emissions of and exposure to PFAS.

### **3.4.2.3. Practicality, including enforceability**

#### **Relevant sections of the Background Document:**

Main report, section 2.5; Annex E, section E.4.

#### **RAC conclusion(s):**

See RAC Opinion.

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**Key elements underpinning the RAC conclusion(s):**

See RAC Opinion.

**SEAC conclusion(s):**

While the proposed restriction certainly poses challenges in regard to its implementation and enforceability, especially when it comes to analytical methods, SEAC considers that the restriction as a whole (including appropriate derogations) is implementable, manageable and enforceable even though certain specific components/provisions are (more) difficult to enforce. A more granular discussion can be found in the key elements section.

Generally speaking, SEAC does however note the following:

- Due to the broad scope of the proposed restriction, guidance should be provided to all stakeholders needing to comply with the proposed restriction. As was the case for the restriction on synthetic polymer particles (the “microplastics restriction”) this will increase the manageability and implementability of the proposed restriction. In this guidance, specific attention should be paid to the interplay between the proposed concentration limits and the already available analytical methods/strategies to show compliance. Additionally, particular attention should also be paid to a clear understanding of what applications are or are not covered by potential derogations.
- An appropriate, practical and harmonised approach to enforcement needs to be elaborated at the EU/EEA level by inspectors (e.g. within the Forum for Exchange of Information on Enforcement, hereafter referred to as “Forum”). This is considered a prerequisite to ensure enforceability.
- Continued investments and/or support by/from the Commission and Member States in the development of (standardised) analytical methods are needed, especially for total fluorine methods, to increase the enforceability further.
- The proposed concentration limits are appropriate considering the state of play on analytical methods.
- While the scope is clear overall, careful drafting of the wording for potential derogations will increase the implementability, manageability and enforceability of the proposed restriction.
- The reporting requirement as proposed by the Dossier Submitter is considered enforceable. The same conclusion is valid for the reporting requirement as proposed by RAC.
- As proposed and worded by the Dossier Submitter, SEAC considers the requirement to elaborate a site-specific PFAS management plan to be difficult to enforce based on concerns raised by Forum and SEAC itself. The elaboration of appropriate guidance might mitigate concerns related to enforceability.
- As proposed and worded by RAC, SEAC considers the requirement to elaborate a site-specific PFAS management plan to be difficult to enforce. The elaboration of appropriate guidance might mitigate concerns related to enforceability.
- Supply chain communication: While SEAC is in favour of effective supply chain communication, SEAC finds RAC’s proposal difficult to enforce. The elaboration of appropriate guidance might mitigate concerns related to enforceability.

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- Risk management measures for professional/consumer uses: SEAC finds RAC's proposal difficult to enforce. The elaboration of appropriate guidance might mitigate concerns related to enforceability.
- General labelling requirement: SEAC finds this requirement to be enforceable, but does note that concerns raised on analytical methods might pose challenges for enforcement agencies and companies.

### **Key elements underpinning the SEAC conclusion(s):**

#### **A. Scope of the proposed restriction**

In its advice, the Forum<sup>73</sup> proposes to reformulate **paragraph 2 of the restriction wording** in order to make clear that the ban does not cover the use of PFAS in another substance, mixture and/or an article<sup>74</sup> when these products have already been placed on the market at entry into force. SEAC agrees that making this explicit in the restriction wording would avoid potential misinterpretations.

Forum has also indicated that the wording of paragraph 2 should indicate how the specific **concentration limits** apply to articles consisting of other articles (i.e. **complex articles**) and therefore whether the concentration limits apply to the final (complex) article as a whole or also to its parts. SEAC notes that previous PFAS restrictions also did not specify whether the final (complex) article or also its parts are covered, but the Committee nonetheless supports Forum's proposal considering the wide-reaching and complex nature of the current restriction proposal.

SEAC notes that the Dossier Submitter has also clearly indicated that the restriction proposal not only covers PFAS as substances on their own, in mixtures and articles, but also as a constituent, including as impurity or additive.

#### **B. Derogations**

SEAC refers to the documents containing its evaluation of sector-/use-specific aspects for a more detailed discussion on potential use-specific derogations and specific practicality aspects discussed for:

- PFAS manufacturing (in relation to the practicality/implementability of the proposed emission limits)
- Transport (in relation to RO3)
- Electronics and semiconductors (in relation to RO3)
- Lubricants

Furthermore, practicality aspects are also discussed in section 3.4.2.2.4 above in relation to second-hand articles, spare parts, recycling, and upstream supply chain for derogated uses.

To ensure the implementability, manageability and enforceability of the proposed restriction, a clear understanding of what is covered (or not) by potential derogations is needed. This

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<sup>73</sup> Forum for Exchange of Information on Enforcement, Advice on enforceability of the Annex XV restriction proposal regarding "Per- and polyfluoroalkyl substances (PFAS)": <https://echa.europa.eu/documents/10162/c77815fb-d3b8-38f3-ca2d-de7fdd155e60> [Accessed 26/08/2025]

<sup>74</sup> As is, for example, the case for entry 68 of Annex XVII of REACH, the PFHxS restriction and the PFHxA restriction proposal.

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needs to be ensured through appropriate wording of the final legal text as well as by elaborating and providing clear guidance to all stakeholders (e.g. similar to the “microplastics restriction”).

**C. Reporting requirements and site-specific PFAS management plan**

Both requirements are discussed in more detail in section 3.4.3.2.6 below.

From an enforceability standpoint, SEAC considers the **reporting requirements**<sup>75</sup> as proposed by the Dossier Submitter and RAC to be clear in terms of what needs to be provided to ECHA, by which date and under which circumstances.

SEAC considers there to be several concerns regarding the requirement to elaborate a **site-specific PFAS management** plan as proposed by the Dossier Submitter (in paragraph 8 of the proposed restriction wording):

- It is unclear what is considered to be an appropriate “*justification for the use*” and how this should be assessed by enforcement agencies.
- It is unclear what is considered to be sufficient “*details on the conditions of use and safe disposal*”.

In its advice Forum has also raised a concern regarding the scope of products proposed to be covered under paragraph 8 (substances, mixtures, articles). Forum indicates that is not clear enough for which importers and downstream users the requirement shall apply. For example, an importer of a fluoropolymer is clearly in the scope once the fluoropolymer is a substance. However, it remains unclear to which extent the importer of mixtures or articles containing fluoropolymers above 50 ppm is affected by the provisions of paragraph 8, creating legal uncertainty for companies and inspectors. Also, companies who refill substances or mixtures and which are considered as downstream users, will in most cases not have the information necessary to draft a “site-specific PFAS management plan”. SEAC agrees with these points raised by the Forum. More information can be found in the Forum advice.

As such, while SEAC finds that this type of measure can in principle contribute to ensuring the proper management of PFAS, the Committee considers the provisions on the elaboration of a site-specific PFAS management plan as proposed by the Dossier Submitter to be difficult to enforce. The elaboration of appropriate guidance might mitigate concerns related to enforceability.

RAC has proposed their own version of the requirement to elaborate site-specific PFAS management plans for those uses where (time-limited or time-unlimited) derogations are supported by the decision maker. These requirements are as follows:

- a justification for the use of PFAS (including an assessment of the technical feasibility of alternatives);
- report the conditions of use and disposal of PFAS used on site to minimise emissions to the environment and direct and indirect human exposure (including plans for the treatment and appropriate disposal of PFAS-containing wastes arising in production, routine cleaning and maintenance of equipment etc.);

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<sup>75</sup> These reporting requirements relate to both active substances (paragraph 4 of the restriction wording proposed by the Dossier Submitter) and derogated uses (paragraph 7 of the restriction wording proposed by the Dossier Submitter).

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- report the results of monitoring activities<sup>76</sup> on PFAS presence on site to assess the potential emissions and concentrations into the environment (e.g. air emissions, waste, wastewater, soil);
- regularly review the site-specific PFAS management plan (at least annually) and keep it available for inspection by enforcement authorities on request.

Furthermore, RAC considers that:

- This requirement should apply to industrial uses of PFAS with high emission potential and in particular to PFAS manufacturing and industrial downstream uses of PFAS and PFAS-containing mixtures (e.g. formulation of mixtures, production of articles, etc.) that will be allowed to continue (e.g. derogated) once the transition period comes to an end.
- PFAS management plans should cover all types of PFAS and should not be restricted to fluoropolymers and PFPE, as proposed by the Dossier Submitter.

While this proposal provides some detail on what is expected to be included in the management plans, all of the concerns related to the Dossier Submitter's proposal are also applicable here, as well as additional concerns:

- It is unclear what is considered to be an appropriate "*justification for the use*" and how this should be assessed by enforcement agencies.
- It is unclear what is considered to be an appropriate "*assessment of technical feasibility of alternatives*" and how this should be assessed by enforcement agencies.
- It is unclear what is considered to be sufficient "*details on the conditions of use and safe disposal of PFAS on site to minimise emissions*".
- It is unclear what is considered to be an appropriate "*report of the results of monitoring activities on PFAS presence on site to assess the potential emissions and concentrations into the environment*" and how this should be assessed by enforcement agencies.

As such, while SEAC finds that this type of measure can in principle contribute to ensuring the proper management of PFAS, the Committee considers the provisions on the elaboration of a site-specific PFAS management plan as proposed by RAC to be difficult to enforce. The elaboration of appropriate guidance might mitigate concerns related to enforceability.

### **D. Additional conditions considered by RAC**

- Supply chain communication:

RAC considers this essential to ensure minimisation of emissions in all relevant stages of the life cycle. RAC indicates that effective communication can be done through safety datasheets/technical datasheets, labels (see below) or product passports. RAC indicates that it should be introduced for manufacturers and importers of PFAS and PFAS-containing mixtures and articles for all derogated industrial uses, with the exception of materials/articles produced from recycled/recovered plastics, textiles or paper and board, or articles which were already in end-use in the Union (reuse of articles).

While SEAC is in favour of effective supply chain communication, SEAC has the following

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<sup>76</sup> RAC notes that the results of monitoring activities should also be reported to the Agency.

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concerns with RAC's proposal:

- It is unclear what is considered to be appropriate "*Instructions for safe use and disposal explaining to industrial and professional users and the general public how to prevent releases of PFAS to the environment*" and how this should be checked by enforcement agencies.
- As already indicated for the site-specific PFAS management plans, the categorisation used by the Dossier Submitter in the Background Document (i.e. into sectors and/or uses) does generally not allow disentanglement of uses into industrial, professional or consumer uses.

As such, SEAC finds RAC's proposal difficult to enforce. The elaboration of appropriate guidance might mitigate concerns related to enforceability.

- Risk management measures for professional/consumer uses:

RAC does not consider site-specific PFAS management plans nor supply-chain communication as discussed above to be effective in reducing associated emissions for professional and consumer uses. RAC instead proposes a labelling requirement, similar to the microplastics restriction, to inform professionals and consumers on the presence of PFAS and recommend disposal practices to minimise emissions.

SEAC notes that RAC does not specify what they consider to be industrial, professional and consumer uses in the context of this restriction. SEAC notes that the categorisation used by the Dossier Submitter in the Background Document (i.e. into sectors and/or uses) does generally not allow disentanglement of uses into industrial, professional or consumer uses. As such, SEAC finds RAC's proposal difficult to enforce. The elaboration of appropriate guidance might mitigate concerns related to enforceability.

- Labelling requirements:

Separate from labelling requirements as part of the additional measures discussed above, RAC recommends a general labelling obligation for all PFAS-containing products independently of whether PFAS are present as the result of impurities from the production process (e.g. use of polymerisation aids) or have been intentionally added. RAC considers this labelling requirement not to be practical for derogated recovered materials and articles containing recovered material, or for reuse of articles already in end-use in the Union.

SEAC finds this requirement to be enforceable but does note that the concerns raised in the section below on analytical methods might pose challenges for enforcement agencies and companies.

### **E. Analytical methods**

The Dossier Submitter bases much of what is in the Background Document on three reports that were commissioned by the Nordic Council of Ministers:

1. Analytical Methods for PFAS in Products and the Environment (NCM, 2022)
2. Analysis of needs for enforcement of PFAS in articles and chemical products (NCM, 2024)
3. A Systematic Workflow for Compliance Testing of Emerging International Classwide Restrictions on PFAS (Vestergren et al., 2024)

The Dossier Submitter indicates that only 40-60 PFAS can currently be quantified, but that

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the research is evolving rapidly. As such, the Dossier Submitter contends that it would not be appropriate to include specific analytical methods in the restriction proposal since these would be supplanted by new or improved methods already in the short term. SEAC agrees with the Dossier Submitter's conclusion and also recommends not to include specific methods in the legal text of the restriction since developments in PFAS analytical methods is a fast-moving field.

The Background Document does contain a detailed description of the currently available and known methods and their performance<sup>77</sup>. Furthermore, the aforementioned 2022 Norwegian study (NCM, 2022) also discusses the availability and appropriateness of analytical methods per sector<sup>78</sup>. The more recent 2024 study commissioned by the Nordic Council of Ministers provides an even more detailed and structured discussion on the currently available analytical methods (including advantages, disadvantages, specific use scenarios, etc). While clear progress has been made since the 2022 report, many of the challenges associated with enforcement of PFAS in articles and chemical products remain. These challenges include sampling, sample preparation, analytical method development, analyte complexity, low detection limits are required, sample matrix effects (causing interference during analysis), limited availability of reference standards, non-targeted screening methods are still evolving, labour-intensive and complex data interpretation, need for high-end analytical instrumentation, background contamination. Most of these challenges are also echoed by Forum in their advice.

A number of accredited methods are present for different matrices, but these don't cover the complete range of matrices. Table 8 lists, on an application-by-application basis, whether methods for commercial use are available (e.g. CEN, ISO) or if suitable methods are listed in literature<sup>79</sup>.

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<sup>77</sup> Appendices E.4.1 and E.4.2.

<sup>78</sup> Categorisation is as follows in the NO study: Packaging material; FCM & food & feed processing equipment; F-gases and refrigerants including blowing agents; Ski Wax; Medical devices and medicinal products; Consumer products; Flame retardants & resins; Fire Fighting Foams; Cosmetics; Textiles; Waste treatment of PFAS articles & industrial waste; Lubricants; Oil, Gas, and mining; Construction products; Metal plating; Production of PFAS, including polymers; Transportation, Automotive, Aircraft, Space and Ships; Electric and electronic equipment including semiconductors; Human and environmental samples for monitoring.

<sup>79</sup> This table is based on a more detailed table (Table 8, page 138) from the NCM (2024) report.

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**Table 8: Availability of methods for commercial use or identified in literature**

Consumer products	Textiles, leather, carpets	Food Contact Material
Cosmetics	Ski Wax	Metal plating
Medical devices and medicinal products	Electric and electronic components	Chemical products
Energy sector	Transport	Firefighting foams <sup>80</sup>
Flame retardants and resins	F-gases	Construction products
Lubricants	Petroleum and mining	Waste

Note: green cells = method for commercial use available, orange cells = method identified in literature, blank cells = no methods available for commercial use or identified in literature (NCM (2024) report indicates that methods for other sectors might be useful as well).

The Dossier Submitter discusses the following categories of PFAS analysis:

1. Target analysis (relevant for the proposed 25 ppb and 250 ppb concentration limits):

Targeted methods are used to quantify levels of specific PFAS in various matrices. In general, targeted methods involve chromatography hyphenated to mass spectrometry (LC/GC-MS). For quantification an appropriate reference standard is necessary which are only available for certain PFAS. Target analysis of PFAS is well established and advantageous in that it provides an accurate PFAS concentration, and the achievable 1-2 ng/L (1 000 ppt) reporting limit meets the regulatory standards. However, as this analytical technique only applies to a limited subset of PFAS it is not sufficient to provide a comprehensive indication of the total PFAS that may exist in contaminated soils, water or any other sample. SEAC notes that, unlike the Dossier Submitter, RAC recommends mandatory prior degradation of precursors in the sample in order to check compliance with the 250 ppb limit since this would allow for the detection of a wider array of PFAS including side-chain fluorinated polymers.

2. Total fluorine (organic fluorine) methods (relevant for the 50 ppm concentration limit):

Total fluorine (TF) is the sum of Inorganic Fluorine (IF) and Organic Fluorine (OF) or Total Organic Fluorine (TOF). The Dossier Submitter indicates that in common products inorganic fluorine is usually not present and the total fluorine can often be assumed to be organic fluorine. Total fluorine methods can also be used to look at extractable organic fluorine (EOF) and adsorbable organic fluorine (AOF).

An advantage of total fluorine methods compared to targeted PFAS analysis or TOPA (see below), is that they detect and quantify PFAS for which no reference standards exist, including polymeric PFAS. An additional advantage of total fluorine methods is that they are significantly faster and cheaper than targeted analyses. Hence, the use of total fluorine methods to quantify PFAS, e.g. for compliance and enforcement purposes, is practical as they are more compatible with the scope of

<sup>80</sup> Covered by a separate restriction: <https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1856e8ce6> [Accessed 26/08/2025]

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the restriction proposal (which encompasses all PFAS). There are currently no standard methods for total fluorine. The US EPA is however developing standard methods for Total Organic Fluorine (TOF).

A significant disadvantage of the total fluorine methods is that also non-PFAS fluorine (i.e. not intended to be restricted) is included in the measurement. To address this the Dossier Submitter proposes an obligation for companies to disclose information about the fluorine content of a product, i.e. when the measured total fluorine in a product exceeds 50 mg F/kg during enforcement, the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFAS or non-PFAS. SEAC agrees that this obligation can increase the enforceability, but notes that in the case of complex supply chains providing this information might prove difficult for companies (especially downstream users).

### 3. Non-target analysis, suspect screening and total oxidizable precursor assay (TOPA)

Non-targeted screening (NTS) is used for a broad screening purpose and allows detection and identification of unexpected or previously unknown PFAS. The methods require a high degree of labour, are time-consuming and require a high degree of analytical expertise.

During a suspect screening analysis (SSA) the accurate mass, isotope pattern and fragmentation pattern of molecular features obtained from HR-MS (High Resolution Mass Spectrometry) are compared to databases with known PFAS.

The Total Oxidizable Precursors Assay (TOP assay or TOPA) is a method to identify PFAA precursors. Currently there is no standard method for TOPA available, but TOPA is already offered by some commercial laboratories and the US EPA is developing a standard method for TOPA for environmental samples. Drawbacks of TOPA are that precursors are determined indirectly and therefore their chemical identity is unknown. Furthermore, the method is comparatively labour intensive.

SEAC acknowledges that there are significant challenges linked to the current state of play of PFAS analysis. As such the Committee concludes that there are also significant challenges related to the enforceability of the proposed restriction. SEAC does however note the following:

- Research on analytical methods is evolving rapidly. As such, challenges that currently exist, will be alleviated and resolved the longer the restriction will be in force.
- Analytical capacity, both in volume and technological sophistication, within private and public test centres will rise the longer the restriction will be in force.

As such, SEAC does not find the proposed restriction to be unenforceable. The Committee does recommend continued investments and/or support by/from the Commission and Member States in the development of (standardised) analytical methods, especially for total fluorine methods, since this is a major hurdle in the short-term for the efficient enforcement of the proposed restriction. SEAC also refers to the “needs and proposals” formulated in the NCM (2024) report<sup>81</sup> for further action that can be undertaken by Member States and the Commission to increase enforceability.

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<sup>81</sup> Table 9, page 157 of the report.

## **F. Strategy and approach to enforcement**

SEAC agrees that enforcing a broad restriction such as the one that is proposed, is complex and challenging. While SEAC acknowledges that only a relatively limited amount of PFAS can be determined, identified and/or quantified and only a few standard methods are available, the Committee concludes that a well-thought-out enforcement strategy can allow inspection services to monitor compliance already at entry into force.

The Dossier Submitter discusses a possible **analytical strategy** taken from a paper by Koch et al. (2020). In that paper the authors propose a top-down approach enabling a comprehensive assessment of organic fluorine. Total (/extractable/adsorbable organic) fluorine methods are used for an initial analysis after which targeted analysis can be performed on samples of interest to determine specific organic fluorine content. Using these results, fluorine mass balance calculations can then be done to obtain the unquantifiable organic fluorine which can be further identified using approaches such as a total oxidisable precursor assay, suspect and non-target screening. Depending on resources, level of prior information on products or prioritisation, only elements of this plan can be used instead of going through the full analysis.

Another generic approach to analyse PFAS levels at a reasonable cost is proposed in the Nordic Council of Ministers report from 2024 (NCM, 2024):

1. **Administrative assessment without chemical analysis:** This can be done by using routines, datasheets and chemical management systems of industries combined with interviews about chemical content and technologies used in chemical products and articles.
2. **Fast screening methods to determine the total amount of fluorine (TF) in the sample:** Ideally, these methods are inexpensive, require little sample preparation and can be used for the screening of both chemical products and articles. Total amount of fluorine can be determined directly in the field without any sample preparation.
3. **Targeted analysis of selected samples identified by the screening methods:** Many commercial laboratories can perform these methods, although not all PFAS can be measured by targeted methods (e.g. fluoropolymers). For some matrices, standard protocols are already available for a limited number of PFAS compounds (40–60).
4. **Non-targeted or suspect screening:** This can deliver additional information where there is a large discrepancy between the total fluorine content and the PFAS identified by the targeted analysis.

A final method discussed by the Dossier Submitter is taken from Vestergren et al. (2024) and consists of similar steps as the two approaches discussed above:

1. **Screening for total fluorine (TF)** which provides a relatively fast and inexpensive way to assess whether PFAS may be present in a sample.
2. **Information from upstream manufacturers or importers** on potential content of inorganic fluorine or non-PFAS organic fluorine. If reliable information is not available, the presence or absence of CF<sub>2</sub> or CF<sub>3</sub> groups may be determined analytically.
3. **Targeted PFAS analyses** with analytical reference standards and compared with the 25 ppb and 250 ppb (sum) limit values.

Forum did not specifically address the proposed general enforcement strategy outlined above

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in their advice. SEAC does however consider that a strategy, such as the ones discussed above, is a prerequisite to efficiently and effectively enforce this complex restriction. SEAC also considers that such a strategy should be elaborated at the EU/EEA level by inspectors, for example within Forum.

REACH article 1 paragraph 3 indicates that "*manufacturers, importers and downstream users*" need "*to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment*". This implies that in order to comply with a restriction, each actor in the supply chain has a responsibility to know the composition of the products they manufacture, place on the market or use (i.e. according to the principles of good chemicals management). As such, SEAC considers paper-based enforcement to be an important part of an enforcement strategy, especially in order for a broad restriction such as this to remain manageable. As an example, the requirement to elaborate site-specific PFAS management plans for derogated uses as proposed by the Dossier Submitter, will aid enforcement agencies in identifying which products within a company contain fluoropolymers and perfluoropolyethers. SEAC considers this will allow for more targeted analytical testing and enforcement campaigns by inspection services for non-derogated uses.

### **G. Concentration limits**

Based on their analysis of available analytical methods, the Dossier Submitter proposes the following cumulatively applicable **concentration limits** for the placing on the market of PFAS in another substance as constituent, in a mixture or in an article:

- **25 ppb for any PFAS** as measured with targeted PFAS analysis (polymeric PFAS excluded from quantification).
- **250 ppb for the sum of PFAS** measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors.
- **50 ppm for total PFAS (polymeric PFAS included)**. If total fluorine exceeds 50 mg F/kg proof for the fluorine measured as content of either PFAS or non-PFAS shall be provided on request of enforcement authorities.

The Dossier Submitter indicates that since PFAS are non-threshold substances, concentration limits should be set at such a low level that no meaningful uses of PFAS are possible. From an enforceability perspective, technical limitations in regard to analytical methods do however need to be taken into account. As such a concentration limit set at zero is impractical and unenforceable.

Based on previous experiences (other PFAS restrictions) and an analysis of the analytical methods that are already available, the Dossier Submitter considers the **25 ppb** limit for an individual (non-polymeric) PFAS to be a practical and enforceable limit. After having reviewed the information provided by the Dossier Submitter and the scientific literature on analytical methods referenced in the Background Document, SEAC agrees with the conclusion that this concentration limit is practical and enforceable while also noting RAC's support for it. Forum does not explicitly discuss this concentration limit. SEAC does however agree with RAC that currently this concentration limit might be difficult to achieve for certain PFAS. SEAC notes that progress in PFAS analytical methods is evolving rapidly which indicates that current difficulties in meeting this concentration limit might already be resolved at entry into force of the proposed restriction and/or when the use-specific derogations expire.

The Dossier Submitter proposes a **250 ppb** concentration limit for the sum of (non-polymeric) PFAS as a means to address combination effects linked to several PFAS being present. SEAC

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agrees with this approach in general since it was already considered valid to regulate certain groups of PFAS in a similar fashion previously (e.g. PFHxS, C9-C14 PFCAs, PFOA, PFHxA). SEAC notes that the concentration limit that has been proposed is lower than in previous cases<sup>82</sup> and the Dossier Submitter provides no specific justification to set it at 250 ppb. SEAC does however find this concentration limit for the sum of (non-polymeric) PFAS to be appropriate considering the advances in analytical methods and 250 ppb is therefore a pragmatic choice in regard to enforceability. SEAC notes RAC's proposal to make prior degradation of precursors in the sample mandatory (when feasible) as this would allow for the detection of additional PFAS (i.e. side-chain fluorinated polymers). Guidance documents for the proposed restriction should specify which degradation methods are appropriate to use for a specific type of sample.

The Dossier Submitter proposes a **50 mg F/kg** total fluorine limit as a trigger for an information requirement to enforcement authorities. On request of enforcement authorities, manufacturers, importers or downstream users will have to prove which fluorine content in a given product originates from PFAS (including polymeric PFAS) or non-PFAS. While the Dossier Submitter states that this information requirement is similar to the one under the "microplastics restriction", SEAC considers the "proof of origin" of the fluorine content to be more complicated. As indicated earlier in the opinion (discussion on analytical methods), in the case of complex supply chains, providing this information might prove difficult for companies (especially downstream users). It is possible, but in certain instances resource-intensive, to conclusively determine the presence of a CF<sub>3</sub> or CF<sub>2</sub> group. The Dossier Submitter indicates that the 50 ppm limit was chosen pragmatically and matches the current sensitivity of total fluorine methods. For comparison, the proposed limit value is higher than the corresponding limit value for PFAS in fire-fighting foams (1 ppm), a matrix for which PFAS detection limits are lower. SEAC agrees with this approach and therefore also the proposed concentration limit.

Considering the fact that a lot of progress is being made in developing analytical methods for other matrices, the Committee recommends a periodic re-assessment of the proposed concentration limits to ensure that the risks associated with PFAS are always addressed in the most appropriate way. This would also be consistent with RAC's viewpoint that PFAS emissions should be (further) minimised whenever possible.

### **3.4.2.4. Monitorability**

#### **Relevant sections of the Background Document:**

Main report, section 2.5; Annex E, section E.4.

#### **RAC conclusion(s):**

See RAC Opinion.

#### **Key elements underpinning the RAC conclusion(s):**

See RAC Opinion.

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<sup>82</sup> 260 ppb for C14-C19 PFCAs; 1 000 ppb for PFHxA, PFHxS, PFOA.

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**SEAC conclusion(s):**

SEAC considers that the proposed restriction is monitorable even while noting there are considerable challenges associated with it. These challenges are linked to the enforceability of the proposed restriction since enforcement will be the principal means of monitoring compliance and therefore effectiveness. SEAC considers the proposed reporting requirements to improve the monitorability of the proposed restriction and could be further improved by also requesting information on (potential) emissions.

**Key elements underpinning the SEAC conclusion(s):**

According to the Dossier Submitter there are different approaches that can be taken to monitor the effectiveness of the proposed restriction in reducing the identified risk:

1. Enforcement of the concentration limits within each sector and for each application
2. Time trend monitoring of environmental and human samples
3. Monitoring of PFAS emissions in wastewater and waste streams

According to SEAC, the most appropriate approach to monitor the effectiveness of the proposed restriction is through the enforcement of the concentration limits within each sector and for each application. This approach presents the quickest route to monitoring whether the proposed restriction and/or parts thereof are performing as intended in reducing the identified risk.

Time trend monitoring performed on samples from the environment and humans should over time show a reduction in PFAS emissions. SEAC agrees with the Dossier Submitter that it may take a long time before such a decreasing trend may be observed. Furthermore, SEAC notes that it might be difficult to tell apart the effects from the proposed restriction from already existing PFAS restrictions.

SEAC notes that the reporting requirements proposed by the Dossier Submitter will increase the monitorability of the proposed restriction. The information that needs to be submitted to ECHA as part of this requirement will allow the decision maker to monitor use of PFAS in derogated uses and follow up with appropriate action to address potential residual risks. As indicated in section 3.4.3.2.6.1, SEAC considers that the reporting requirements and therefore also monitorability can be increased by also requesting information on (potential) emissions related to the relevant derogated uses.

SEAC notes that RAC concludes that labelling requirements are also expected to increase monitorability of the restriction and subsequently proposes to extend this requirement to all PFAS-containing materials/products covered by derogations. While SEAC agrees that labelling requirements might in principle aid in monitoring the effectiveness of the proposed restriction (i.e. the extent to which PFAS-labelled products disappear from the market over time), the Committee questions whether this will actually be the case for a restriction such as this (broad scope, wide variety of products covered across sectors, etc).

SEAC does not consider the Dossier Submitter's proposal and wording for a requirement to elaborate a site-specific PFAS management plan under certain conditions to significantly contribute to the monitorability of the proposed restriction as a whole since it will be difficult to enforce (even though the elaboration of guidance might mitigate this) and the management plan should only be kept available for inspection upon request. SEAC also finds this conclusion to be valid for RAC's proposal to expand the management plan requirement to all types of PFAS and not just fluoropolymers and PFPE.

### **3.4.3. Conclusion whether the suggested restriction is the most appropriate EU-wide measure**

#### **3.4.3.1. RAC conclusion(s)**

See RAC Opinion.

#### **3.4.3.2. SEAC conclusion(s)**

SEAC considers the proposed restriction, specifically a ban with use-specific derogations, to be the most appropriate Union-wide measure to address the identified risk while taking into account the proportionality of its socio-economic benefits to its socio-economic costs. It should be noted, however, that SEAC does not agree or cannot conclude on all the specific elements proposed by the Dossier Submitter due to a lack of data and a lack of a proper assessment for specific elements, as pointed out in detail throughout SEAC's opinion.

The different conclusions on the specific elements of the proposed restriction below are structured in line with the draft Annex XVII entry proposed by the Dossier Submitter (see Table 1). The parentheses next to each sub-heading below indicate where the specific element is reflected in the proposed draft Annex XVII entry.

##### **3.4.3.2.1. Substance scope (column 1)**

###### *i. PFAS definition*

The Dossier Submitter uses the commonly accepted OECD (2021) **PFAS definition** and categorization as the basis for describing what substances are generally considered to be PFAS (see column 1 of the Annex XVII entry proposed by the Dossier Submitter in Table 1). The OECD definition and categorization is based on structural properties of fluorinated substances and not on hazard properties or risk. SEAC considers the Dossier Submitter's approach of defining PFAS based on the OECD definition appropriate since it creates a harmonized understanding of the term and is consistent with the Chemical Strategy for Sustainability (European Commission, 2020).

###### *ii. Exclusion of PFAS from the scope*

With the proposed restriction the Dossier Submitter wishes to address concerns related to PFAS, especially the main concern of high persistence (due to the parent compounds and/or degradation/transformation products) but also supporting concerns (e.g. bioaccumulation, mobility, (eco)toxicological effects, long-range transport potential). Certain PFAS with specific structural elements were excluded from the scope by the Dossier Submitter since these were considered to be fully degradable and cannot form persistent PFAS arrowheads (see column 1 of the Annex XVII entry proposed by the Dossier Submitter in Table 1).

SEAC takes note and supports RAC's conclusions indicating (that):

- Structural similarities between PFAS trigger the concern on persistence for the whole group of PFAS.
- The need to consider the very persistent properties of PFAS together with other properties of concern.
- The exclusion of certain PFAS sub-groups from the scope on the grounds that they are

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fully degradable, is not justified.

During the consultation on the Annex XV report many stakeholders indicated that the definition (scope) of (the) PFAS (restriction proposal) is too broad<sup>83</sup> and that it contains a wide variety of substances with different hazards:

- *“Definition of PFAS is too broad”*: SEAC reiterates that the use of the OECD definition and categorization of PFAS is considered fully appropriate by the Committee for reasons that were explained earlier in this section.
- *“Scope of the restriction is too broad”*: SEAC notes that these comments refer to the breadth of applications covered by the proposed restriction. SEAC does not agree with these comments since the risks associated with the use of PFAS is not linked to specific applications, but to the use of PFAS across sectors and applications.
- *“Wide variety of substances with different hazards”*: SEAC notes that previous experience with regulating specific PFAS substances of subgroups has led to so-called regrettable substitution (e.g. long-chain with short-chain PFAS). See also the discussion on the risk management options in section 3.4.1 above.

One specific issue on the scope of the proposed restriction that was raised by many industry stakeholders is that they consider fluoropolymers to meet the OECD criteria for Polymers of Low Concern and as such these PFAS do not contribute to the identified risk. These stakeholders are therefore requesting the exclusion of fluoropolymers from the scope. RAC has evaluated the information provided by these stakeholders, the discussion in the Background Document as well as scientific literature on this issue and has concluded that the entire life cycle of polymeric PFAS needs to be considered and not only the use phase. As such RAC considers that polymeric PFAS (including fluoropolymers) should be included in the scope of the proposed restriction.

### **3.4.3.2.2. Scope of the proposed restriction (paragraphs 1 and 2)**

The restriction proposal bans the manufacture, placing on the market and use of PFAS as substances on their own and, above set concentration limits, the placing on the market of PFAS in another substance as constituent, in a mixture or in an article. SEAC agrees with the Dossier Submitter’s targeting since emissions can or will result from all these actions.

### **3.4.3.2.3. Concentration limits (paragraph 2)**

In line with other (proposed) restrictions on members of the PFAS substance group (PFHxA, PFHxS, C9-C14 PFCAs), but taking into account certain specificities of PFAS as a whole, the Dossier Submitter proposes the following **concentration limits** for the placing on the market of PFAS in another substance as constituent, in a mixture or in an article:

- **25 ppb for any PFAS** as measured with targeted PFAS analysis (polymeric PFAS excluded from quantification).
- **250 ppb for the sum of PFAS** measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors.

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<sup>83</sup> E.g. #9164, #9468, #9587.

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- **50 ppm for total PFAS (polymeric PFAS included)**. If total fluorine exceeds 50 mg F/kg proof for the fluorine measured as content of either PFAS or non-PFAS shall be provided on request of enforcement authorities.

SEAC notes the three concentration limits need to be met simultaneously or the mixtures and articles cannot be placed on the market. The proposed concentration limits are appropriate considering the state of play on analytical methods. SEAC notes that, unlike the Dossier Submitter, RAC recommends mandatory prior degradation of precursors in the sample in order to check compliance with the 250 ppb limit since this would allow for the detection of additional PFAS (i.e. side-chain fluorinated polymers). A full discussion on the practicality (including enforceability) of these concentration limits can be found in section 3.4.2.3 of this opinion.

#### **3.4.3.2.4. General 18-month transition period (paragraph 3)**

The Dossier Submitter indicates that a standard transition period of 18 months is deemed reasonable to allow companies with uses for which no derogation was warranted, to cease their use, switch to alternatives, sell off existing stocks of PFAS and PFAS-containing materials and implement the reporting requirements for certain derogated uses. In the response to comments submitted during the consultation on the Annex XV report, the Dossier Submitter indicates that the choice for an 18-month transition period is in line with decisions taken under several other REACH restrictions<sup>84</sup> and has commonly been considered appropriate for generic restrictions. The Dossier Submitter additionally notes that where it was demonstrated that technically and economically feasible alternatives were available at entry into force (termed “high substitution potential”) a “default” transition period of 18 months is considered practicable in terms of the selection, testing and implementation of the most appropriate non-PFAS alternatives. The Dossier Submitter also stresses that a transition period as short as practicable, whilst minimising supply chain disruptions, was important to prevent further PFAS emissions into the environment contributing to the existing environmental stock. SEAC notes that whilst shortening the general 18-month transition period would increase the benefits (in terms of emission reduction) of a restriction, it would also likely increase the costs due to companies having less time to react to a restriction (e.g. transitioning to alternatives) and vice versa. However, due to a lack of concrete cost-benefit information, the differences in impacts of a shorter or longer default transition period cannot be estimated by SEAC. Based on the justification provided by the Dossier Submitter and an analysis of the comments provided by stakeholders in the Annex XV report consultation<sup>85</sup>, SEAC finds the “default” 18-month transition period to be appropriate and sufficient to cease the use of PFAS, switch to alternatives, sell off existing stocks of PFAS and PFAS-containing materials and implement the reporting requirements for certain derogated uses.

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<sup>84</sup> E.g. PFHxA, its salts and related substances (Annex XVII entry 79); PFHxS, its salts and related substances (prior to its inclusion in the POPs Regulation), long chain (C9 to C14) PFCAs, their salts and related substances (Annex XVII entry 68) as well as perfluorinated silanes (Annex XVII entry 73).

<sup>85</sup> E.g. #6327, #7651, #8040, #8521, #8632, #8863, #9220, #9262.

#### **3.4.3.2.5. Derogations (paragraphs 4, 5 and 6)**

##### **3.4.3.2.5.1. Active substances (paragraphs 4a, 4b and 4c)**

While SEAC agrees that certain PFAS used as active substances in plant protection products, biocidal products and medicinal products can play a vital role in our society and banning them could lead to significant impacts, for example on human health in case of medicinal products, the Committee finds that excluding these applications from the ban on PFAS via a time-unlimited derogation is not justified and inconsistent with the rest of the restriction proposal (i.e. where derogations were proposed by the Dossier Submitter based on an analysis of alternatives and an assessment of socio-economic impacts of a ban was provided). See section 3.4.1 for more details.

##### **3.4.3.2.5.2. Second-hand articles (paragraph 4d)**

SEAC concurs with the Dossier Submitter's conclusion that a derogation for second-hand articles is likely justified based on sustainability and practicality aspects. See section 3.4.2.2.4 for more details.

##### **3.4.3.2.5.3. Spare parts (paragraphs 4e and 4f)**

SEAC agrees that derogation 4e is justified in cases where a continuing need exists (e.g. no alternatives available and/or significant redesign of object is necessary). Due to a lack of granular information, SEAC is unable to identify those uses where a continuing need exists.

SEAC agrees that derogation 4f represents a pragmatic way forward that avoids impacting legal obligations in regard to spare parts. As such SEAC supports this derogation. SEAC notes that a possible (partial) overlap may exist with derogation 6f(i).

SEAC finds that a clear definition of "spare parts" that does not cover "consumables", needs to be elaborated.

See section 3.4.2.2.4 for more details on spare parts.

##### **3.4.3.2.5.4. Upstream supply chain for derogated uses (paragraphs 4g and 4h)**

The information base as well as the assessment performed by the Dossier Submitter is such that SEAC cannot properly evaluate this issue and, consequently, conclude on potential related impacts. SEAC, however, supports the Dossier Submitter's proposal for a derogation from a practicality point of view. See section 3.4.2.2.4 for more details.

##### **3.4.3.2.5.5. Product and Process Related Research and Development (PPORD) (paragraph 4i)**

SEAC concludes that the justification provided by the Dossier Submitter and stakeholders in the consultation on the Annex XV report does not warrant a generic derogation for all PPORD activities. SEAC also questions the utility of a potential derogation on PPORD activities related to applications that will only be derogated for 5 or 12 years (following the general 18-month transition period). SEAC can however envision that unwanted circumstances might arise if PPORD activities are no longer allowed when these can be linked to applications for which a

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time-unlimited derogation is proposed by the Dossier Submitter. For this reason, SEAC considers a derogation justified for PPORD activities linked to time-unlimited derogations. See section 3.4.2.2.4 for more details.

### **3.4.3.2.5.6. Recycling (paragraphs 4j, 4k, 4l and additional requirements in paragraph 4)**

Despite the available information on the impacts on recycling and circular economy being limited and its representativeness often uncertain, SEAC concludes that there are clear indications that at entry into force the proposed concentration limits cannot be met for recycled plastics, paper and board, and textiles. A ban on PFAS above the proposed concentration limits would therefore lead to significant negative impacts related to the recycling of these three waste streams. As such, SEAC finds that time-limited derogations could be justified to ensure proportionality of a restriction as a whole. SEAC can, however, not conclude on the length of the necessary derogation period.

The Dossier Submitter's proposal to provide documentary evidence of the origin of recovered material for plastics, paper and board and textile products is supported by SEAC. SEAC also agrees with the Dossier Submitter that a labelling requirement has added-value for plastic articles or complex objects falling within the scope of the WEEE Directive and ELV Directive as well as for PVC articles listed in paragraph 18 (a to f) of Commission Regulation (EU) 2023/923 on lead and its compounds in PVC, but not for paper and board and textile products.

SEAC finds that no derogation is warranted for recycled metals since there is sufficiently strong evidence indicating that the concentration limits can be met at entry into force and therefore that no negative impacts related to metal recycling are expected.

See section 3.4.2.2.4 for more details.

### **3.4.3.2.5.7. Sector-/use-specific derogations (paragraphs 4m, 5 and 6)**

While assessing the different (sub-)sectors and (sub-)uses where PFAS are used, the Dossier Submitter identified several specific uses where **time-limited** and some **time-unlimited derogations** were considered appropriate<sup>86</sup>. The Dossier Submitter based their assessment of derogations on an analysis of alternatives for each (sub-)sector and (sub-)use. It is important to note that SEAC in general disagrees with the identification of derogations solely based on the availability of technically and economically feasible alternatives. While SEAC acknowledges that an analysis of alternatives should form the basis for any discussion on derogations (and transition/derogation periods), the Committee considers that a more comprehensive view of the associated emissions and the socio-economic impacts related to those derogations should be taken into account as well, i.e. including costs and benefits (i.e. avoided emissions as a proxy for risk reduction) associated with not implementing a specific derogation. As such, SEAC's analysis of the proposed use-specific derogations is based on the evaluation of the analysis of alternatives (as described in section 3.3.1 above) as well as the

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<sup>86</sup> Additionally, several potential derogations for reconsideration after the Annex XV report consultation were identified in the Annex XV report. For the PFAS uses in question, the Dossier Submitter considered that a derogation could potentially be warranted at the time of submission of the restriction dossier in January 2023, the available evidence was however considered insufficient to allow a firm conclusion. The Dossier Submitter does not propose derogations for uses where it is concluded that the evidence remains weak after the Annex XV report consultation.

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evaluation of socio-economic impacts (as described in section 3.4.2.2 above). Section 3.4.3.2.5.8 below provides an overview of SEAC's evaluation of the various sector-/use-specific derogations proposed by the Dossier Submitter. SEAC refers to the documents containing its evaluation of sector-/use-specific aspects for a more detailed discussion on potential use-specific derogations.

The determination of the **appropriate transition/derogation period** (18 months + 5 years or 18 months + 12 years) was also done based on the analysis of alternatives and more specifically the strength of the evidence available for there being suitable alternatives.

When there is sufficiently strong evidence for either of the following, a 5-year derogation period on top of the standard 18 months is proposed:

- Non-existence of technically and economically feasible alternatives on the market at the entry-into-force (EiF) date but where possible alternatives to the PFAS use have already been identified that are however still in the development phase, or
- Known alternatives are not available in sufficient quantities on the market at the EiF date or known alternatives cannot be implemented before the transition period ends.

When there is sufficiently strong evidence for either of the following, a 12-year derogation period on top of the standard 18 months is proposed:

- Non-existence of technically and economically feasible alternatives on the market at the EiF date, e.g. Research and Development efforts did not identify possible PFAS-free alternatives so that it is likely that they will not become available in the near future, or
- Certification or regulatory approval of PFAS-free alternatives cannot be achieved within a five-year derogation period.

While SEAC agrees with the criteria that were employed by the Dossier Submitter to decide on whether a shorter or longer derogation period is appropriate, the Committee does note that the specific time frames (5 and 12 years) have been chosen rather arbitrarily and have not been thoroughly justified. The Dossier Submitter indicates that in an ideal situation transition periods are chosen based on a socio-economic analysis where net social benefits are maximised. However, SEAC agrees with the Dossier Submitter on the chosen approach and acknowledges that the chosen default periods provide a more practical means to enforce the proposed restriction as a whole than bespoke transition periods for each derogation separately (for which there is a lack of information in any case).

Several comments<sup>87</sup> submitted by stakeholders during the consultation on the Annex XV report indicate a need for the inclusion of a **review clause/mechanism** for cases where no suitable alternatives are found during the proposed derogation periods. While SEAC supports close monitoring of the state of play on alternatives and effectiveness of the proposed restriction, the Committee notes that the Commission is able to review any restriction at any time based on new and scientifically relevant information.

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<sup>87</sup> E.g. #4442, #4453, #4577, #7211, #8394, #8518, #8661, #8666, #8808, #9388.

**3.4.3.2.5.8. Overview of SEAC's conclusions regarding derogations**

Table 9 below contains an overview of SEAC's conclusions regarding all derogations proposed by the Dossier Submitter as well as additional points for the decision maker's consideration. Furthermore, Table 10 contains an overview of additional derogations which could be or are likely justified based on the Committee's evaluation.

It is important to note that any derogation considered justified by SEAC should be regarded as necessary to ensure that a restriction is proportionate, but not as sufficient on their own. Additional derogations may be required for certain (sub-)uses in order for a restriction to be proportionate. However, uncertainties in the available information on the assessed (sub-)uses, as well as unknown or unidentified (sub-)uses, prevent SEAC from specifying such additional derogations.

SEAC further notes that RAC recommends the implementation of additional risk management measures to ensure PFAS emissions are minimised in case derogations are supported by the decision maker. SEAC discusses the proposed risk management measures in section 3.4.3.2.6 below.

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**Table 9: SEAC’s conclusions on the derogations proposed by the Dossier Submitter**

Derogation proposed by the Dossier Submitter		Relevant topic/sector	SEAC’s conclusion	Points for the decision maker to consider
<b>Derogations related to overarching issues</b>				
4a	Active substances in biocidal products within the scope of Regulation (EU) 528/2012	Section 3.4.1: Active substances	Not justified.	The Dossier Submitter has not analysed the impacts of a ban.  SEAC notes that current legislations on BP, PPP and MP do not fully address the concern associated with PFAS emissions to the environment. Therefore, while SEAC agrees that certain PFAS used as active substances in BP, PPP and MP can play a vital role in our society and banning them could lead to significant impacts, the Committee finds that excluding these applications from the ban on PFAS via a time-unlimited derogation is not justified and inconsistent with the rest of the restriction proposal (i.e. where derogations were proposed by the Dossier Submitter based on an analysis of alternatives and an assessment of socio-economic impacts of a ban was provided).
4b	Active substances in plant protection products within the scope of Regulation (EC) 1107/2009			
4c	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			
4d	Placing on the market of articles which were already in end-use in the Union	Section 3.4.2.2.4: Second-hand articles	Likely justified.	SEAC recommends a derogation for second-hand articles (i.e. articles already in end-use).
4e	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	Section 3.4.2.2.4: Spare parts	Partly justified.	SEAC recommends a derogation in cases where a continuing need exists (e.g. no alternatives available and/or significant redesign of object is necessary). Due to a lack of granular information, SEAC is unable to identify those uses where a continuing need exists.  A clear definition of “spare parts” that does not cover “consumables” needs to be elaborated.
4f	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		Justified from a general standpoint but SEAC is unable to conclude on the need for the proposed breadth of the derogation.	SEAC recommends the derogation as a pragmatic way forward that avoids impacting legal obligations in regard to spare parts.  A clear definition of “spare parts” that does not cover “consumables” needs to be elaborated.  Possible (partial) overlap may exist with derogation 6f(i).

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Derogation proposed by the Dossier Submitter		Relevant topic/sector	SEAC's conclusion	Points for the decision maker to consider
4g	Starting materials and intermediates in the manufacture of PFASs for a use listed under paragraphs 4, 5 or 6	Section 3.4.2.2.4: Upstream supply chain for derogated uses	Justified from a general standpoint (i.e. considering practicality) but SEAC is unable to conclude on socio-economic impacts.	SEAC recommends a derogation for the upstream supply chain of other derogated uses.  SEAC emphasizes that this derogation does not encompass the use of PFAS in, for example, equipment and instruments used to produce for the downstream derogated uses, or solvents and auxiliary chemicals, i.e. those that are not intentionally present in the end-product.
4h	Production of PFAS containing mixtures or articles in the upstream supply chain for a use listed under paragraphs 4, 5 or 6			
4i	Uses under product and process orientated research and development (PPORD; art. 67(1) of EU-REACH)	Section 3.4.2.2.4: PPORD	Partly justified, i.e. for PPORD activities linked to time-unlimited derogations.	SEAC only recommends a derogation for PPORD activities linked to time-unlimited derogations as unwanted circumstances might arise otherwise.
4j	Paper and board articles containing recovered material, with the exception of food-contact material and packaging  Suppliers of paper and board articles containing recovered paper and board shall submit to national enforcement authorities upon request documentary evidence to substantiate the claims on the recovered origin of paper and board in those articles. Claims made on the recovered origin of paper and board in imported articles shall be accompanied by a certificate that provides proof of traceability and recycled content, issued by an independent third party.	Section 3.4.2.2.4: Impacts on recycling and circular economy	Could be justified.	SEAC recommends derogations for the articles containing recovered material with the scope proposed by the Dossier Submitter, despite there being significant concerns associated with the assessment performed by the Dossier Submitter. In still recommending this derogation, SEAC considered potential impacts for recyclers as well as for downstream users of recycled materials, sustainability impacts and potential impacts on the compliance with other EU legislation.  SEAC recommends that these derogations are time-limited but cannot conclude on the exact length of the necessary derogation period.  SEAC also notes that the precise wording proposed by the Dossier Submitter could allow actors to circumvent the intention of the proposed derogation and lead to higher presence of PFAS than currently the case or circumventing the obligations for virgin material.  SEAC supports the proof of origin requirement proposed by the Dossier Submitter.  SEAC also supports the labelling requirement proposed by the Dossier Submitter for certain plastic articles or complex objects falling within the scope of the WEEE Directive and ELV Directive as well as for PVC articles listed in paragraph 18 (a to
4k	Textile articles containing recovered material, with the exception of toys as defined in Directive 2009/48/EC, until 13.5 years after EoF  Suppliers of textile articles containing recovered material shall submit to national enforcement authorities upon request documentary evidence to substantiate the claims on the recovered origin of textiles in those articles. Claims made on the recovered origin of textiles in imported articles shall be accompanied by a certificate that provides proof of traceability and recycled content,			

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Derogation proposed by the Dossier Submitter	Relevant topic/sector	SEAC's conclusion	Points for the decision maker to consider
	issued by an independent third party.		
4l	<p>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</p> <p>Suppliers of plastic articles containing recovered material shall submit to national enforcement authorities upon request documentary evidence to substantiate the claims on the recovered origin of plastic in those articles. Claims made on the recovered origin of 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> <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 PFAS 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 PFAS". 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>(*) Typographical error. Should read instead "Directive 2012/19/EU".</p>		f) of Commission Regulation (EU) 2023/923 on lead and its compounds in PVC.

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Derogation proposed by the Dossier Submitter	Relevant topic/sector	SEAC's conclusion	Points for the decision maker to consider	
<b>Sector/use-specific derogations – all PFAS</b>				
4m	<p>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</p> <p>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;</p> <p>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;</p> <p>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.</p>	<p>Sector-specific evaluation:</p> <p>PFAS manufacturing</p>	<p>Likely justified from a general standpoint but SEAC is unable to conclude on the specific proposal of the Dossier Submitter.</p>	<p>SEAC recommends a derogation with emission limits that are technically and economically feasible and implementable.</p> <p>SEAC cannot provide further points for the decision maker's consideration due to insufficient information on the technical and economic feasibility as well as uncertainties regarding the socio-economic impacts and the practicality of the emission limits proposed by the Dossier Submitter.</p>
5a	<p>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</p>	<p>Sector-specific evaluation:</p> <p>Textiles, upholstery, leather, apparel and carpets (TULAC)</p>	<p>Partly justified, i.e.:</p> <p>Justified for PPE intended to protect users against risks as specified in the PPE Regulation (Regulation (EU) 2016/425), Annex I, risk categories III(a) and III(c).</p> <p>Could be justified for risks as specified in the PPE Regulation, Annex I, risk categories III(b) and III(d-m).</p>	<p>SEAC recommends the 13.5-year derogation for PPE intended to protect users against risks as specified in the PPE Regulation, Annex I, risk categories III(a) and III (c).</p> <p>For PPE intended to protect users against risks as specified in the PPE Regulation, Annex I, risk categories III(b) and III(d-m), while SEAC finds that a derogation may be warranted, the existing uncertainties – mainly the lack of sufficiently granular cost information – prevent SEAC from reaching a definitive conclusion.</p>
5b	<p>Personal protective equipment (PPE) specifically designed for armed forces, the maintenance of law and order and other emergency response workers, until 13.5</p>	<p>Sector-specific evaluation:</p> <p>Textiles, upholstery,</p>	<p>Justified. SEAC is however unable to conclude whether the derogation period of 13.5 years is justified.</p>	<p>SEAC recommends a time-limited derogation.</p> <p>SEAC cannot determine a different, shorter than 13.5-year, derogation period due to insufficient</p>

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	years after Eif	leather, apparel and carpets (TULAC)		information regarding both the analysis of alternatives and socio-economic analysis.
5c	Impregnation agents for re-impregnation of articles referred to in paragraph 5a and 5b until 13.5 years after Eif	Sector-specific evaluation: Textiles, upholstery, leather, apparel and carpets (TULAC)	Justified.	SEAC recommends a time-limited derogation in alignment with its recommendations for derogations 5a and 5b.
5d	Hard chrome plating until 6.5 years after Eif	Sector-specific evaluation: Metal plating and manufacture of metal products	Justified.	SEAC recommends the 6.5-year derogation as proposed by the Dossier Submitter.
5e	Refrigerants in low temperature refrigeration below -50 °C until 6.5 years after Eif	Sector-specific evaluation: Applications of fluorinated gases	Not justified.	SEAC does not recommend a derogation as proposed by the Dossier Submitter because it would create a conflict with measures in the F-gas Regulation.  However, SEAC recommends a derogation whose only goal is to avoid interfering with current and future prohibitions in the F-gas Regulation. SEAC refers to the sector-specific evaluation for more details on alignment of the proposed restriction with the F-gas Regulation.  SEAC further recommends that the decision maker considers the addition of a time limit for otherwise time-unlimited exemptions from the F-gas Regulation, either in the REACH restriction or the F-gas Regulation itself. Further details are provided in the sector-specific evaluation.
5f	Refrigerants in laboratory test and measurement equipment until 13.5 years after Eif	Sector-specific evaluation: Applications of fluorinated gases	Not justified.	SEAC does not recommend a derogation as proposed by the Dossier Submitter because it would create a conflict with measures in the F-gas Regulation.  However, SEAC recommends a derogation whose only goal is to avoid interfering with current and future prohibitions in the F-gas Regulation. SEAC refers to the sector-specific evaluation for more

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Derogation proposed by the Dossier Submitter		Relevant topic/sector	SEAC's conclusion	Points for the decision maker to consider
				<p>details on alignment of the proposed restriction with the F-gas Regulation.</p> <p>SEAC further recommends that the decision maker considers the addition of a time limit for otherwise time-unlimited exemptions from the F-gas Regulation, either in the REACH restriction or the F-gas Regulation itself. Further details are provided in the sector-specific evaluation.</p>
5g	Refrigerants in refrigerated centrifuges until 13.5 years after EoF	<p>Sector-specific evaluation:</p> <p>Applications of fluorinated gases</p>	Not justified.	<p>SEAC does not recommend a derogation as proposed by the Dossier Submitter because it would create a conflict with measures in the F-gas Regulation.</p> <p>However, SEAC recommends a derogation whose only goal is to avoid interfering with current and future prohibitions in the F-gas Regulation. SEAC refers to the sector-specific evaluation for more details on alignment of the proposed restriction with the F-gas Regulation.</p> <p>SEAC further recommends that the decision maker considers the addition of a time limit for otherwise time-unlimited exemptions from the F-gas Regulation, either in the REACH restriction or the F-gas Regulation itself. Further details are provided in the sector-specific evaluation.</p>
5h	Refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives	<p>Sector-specific evaluation:</p> <p>Applications of fluorinated gases</p>	Not justified.	<p>SEAC does not recommend a derogation as proposed by the Dossier Submitter because it would create a conflict with measures in the F-gas Regulation.</p> <p>However, SEAC recommends a derogation whose only goal is to avoid interfering with current and future prohibitions in the F-gas Regulation. SEAC refers to sector-specific evaluation for more details on alignment of the proposed restriction with the F-gas Regulation.</p> <p>SEAC further recommends that the decision maker considers the addition of a time limit for otherwise time-unlimited exemptions from the F-gas</p>

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Derogation proposed by the Dossier Submitter		Relevant topic/sector	SEAC's conclusion	Points for the decision maker to consider
				Regulation, either in the REACH restriction or the F-gas Regulation itself. Further details are provided in the sector-specific evaluation.
5i	Foam blowing agents in thermal insulation foam until 13.5 years after EoF	Sector-specific evaluation:  Applications of fluorinated gases	Not justified.	<p>SEAC does not recommend a derogation as proposed by the Dossier Submitter because it would create a conflict with measures in the F-gas Regulation.</p> <p>However, SEAC recommends a derogation whose only goal is to avoid interfering with current and future prohibitions in the F-gas Regulation. SEAC refers to the sector-specific evaluation for more details on alignment of the proposed restriction with the F-gas Regulation.</p> <p>SEAC further recommends that the decision maker considers the addition of a time limit for otherwise time-unlimited exemptions from the F-gas Regulation, either in the REACH restriction or the F-gas Regulation itself. Further details are provided in the sector-specific evaluation.</p>
5j	Propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required until 13.5 years after EoF. The derogation does not apply to products intended for entertainment and decorative purposes for the general public.	Sector-specific evaluation:  Applications of fluorinated gases	Not justified.	<p>SEAC does not recommend a derogation as proposed by the Dossier Submitter because it would create a conflict with measures in the F-gas Regulation.</p> <p>However, SEAC recommends a derogation whose only goal is to avoid interfering with current and future prohibitions in the F-gas Regulation. SEAC refers to the sector-specific evaluation for more details on alignment of the proposed restriction with the F-gas Regulation.</p> <p>SEAC also recommends using the definition for "technical aerosols" that is included in the original F-gas Regulation (Regulation (EU) 517/2014).</p> <p>SEAC further recommends that the decision maker considers the addition of a time limit for otherwise time-unlimited exemptions from the F-gas Regulation, either in the REACH restriction or the F-gas Regulation itself. Further details are provided in</p>

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Derogation proposed by the Dossier Submitter	Relevant topic/sector	SEAC's conclusion	Points for the decision maker to consider
			the sector-specific evaluation.
5k	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 EiT	<p>Sector-specific evaluation:</p> <p>Applications of fluorinated gases</p> <p>Partly justified, i.e.:</p> <p>Not justified for substances already covered by the F-gas Regulation.</p> <p>Likely justified for the use of:</p> <ul style="list-style-type: none"> <li>• FK-5-1-12 (mixed with HF(C)O-1233zd(E)) to protect critical and culturally significant infrastructure;</li> <li>• 2-BTP in hand-held extinguishers on board aircraft.</li> </ul> <p>SEAC cannot conclude whether a derogation is justified for the use of 2-BTP in aviation cargo fire extinguisher systems since this use is still in the development phase and it is unclear if it will be approved.</p>	<p>SEAC recommends a 13.5-year derogation for the use of:</p> <ul style="list-style-type: none"> <li>• FK-5-1-12 (mixed with HF(C)O-1233zd(E)) to protect critical and culturally significant infrastructure;</li> <li>• 2-BTP in hand-held extinguishers on board aircraft.</li> </ul> <p>SEAC further recommends that the decision maker considers the addition of a time limit for otherwise time-unlimited exemptions from the F-gas Regulation, either in the REACH restriction or the F-gas Regulation itself. Further details are provided in the sector-specific evaluation.</p>
5l	Preservation of cultural paper-based materials until 13.5 years after EiT	<p>Sector-specific evaluation:</p> <p>Applications of fluorinated gases</p> <p>SEAC cannot conclude whether a derogation is justified.</p>	SEAC notes that both a full ban as well as a restriction with a derogation could be proportionate. Proportionality ultimately depends on the (monetary and non-monetary) value of the cultural materials to be preserved, for which the Committee has no information at hand.
5m	Insulating gases in high-voltage switchgear (above 145 kV) until 6.5 years after EiT	<p>Sector-specific evaluation:</p> <p>Applications of fluorinated gases</p> <p>Partly justified, i.e.:</p> <p>Not justified for substances already covered by the F-gas Regulation.</p> <p>Likely justified for the use of C5-FK and HFO-1234yf in electrical switchgear above 145 kV.</p>	<p>SEAC does not recommend a derogation as proposed by the Dossier Submitter.</p> <p>However, SEAC recommends a derogation whose only goal is to avoid interfering with current and future prohibitions in the F-gas Regulation. SEAC refers to the sector-specific evaluation for more details on alignment of the proposed restriction with the F-gas Regulation.</p> <p>Additionally, SEAC recommends a 6.5-year derogation for the use of C5-FK and HFO-1234yf in electrical switchgear above 145 kV.</p> <p>SEAC further recommends that the decision maker considers the addition of a time limit for otherwise time-unlimited exemptions from the F-gas</p>

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Derogation proposed by the Dossier Submitter		Relevant topic/sector	SEAC's conclusion	Points for the decision maker to consider
				Regulation, either in the REACH restriction or the F-gas Regulation itself. Further details are provided in the sector-specific evaluation.
5n	Refrigerants, clean fire-suppressing agents and insulation gases for maintenance and refilling of existing HVACR, fire-suppressing and switchgear equipment put on the market before 18 months (or placed on the market after 18 months after EoF based on an applicable derogation)	Sector-specific evaluation: Applications of fluorinated gases	Justified from a general standpoint (i.e. if aligned with already existing provisions under the F-gas Regulation).	SEAC recommends the proposed derogation for maintenance and refilling of existing HVACR, fire-suppressing and switchgear equipment to be aligned with the provisions from the F-gas Regulation. SEAC refers to the sector-specific evaluation for more details on alignment of the proposed restriction with the F-gas Regulation.
		Sectors-specific evaluation: Transport	Justified.	SEAC recommends the derogation as proposed by the Dossier Submitter for the maintenance and refilling of mobile air conditioning, heat pumps and transport refrigeration equipment.
5o	[Potential derogation for use of fluorinated gases at the CERN research installation unit until 13.5 years after EoF]	Sector-specific evaluation: Applications of fluorinated gases	Not justified.	SEAC does not recommend a derogation because it would create a conflict with measures in the F-gas Regulation.  The Background Document indicates that the CERN uses fluorinated gases in hundreds of chillers and heat pumps. SEAC notes that chillers and heat pumps are covered by the F-gas Regulation and several measures are in place to regulate the use of fluorinated gases in this equipment. This application is covered by SEAC's assessment for refrigerants further above in this table.
5p	Additives to hydraulic fluids in transport vehicles until 13.5 years after EoF	Sector-specific evaluation: Transport	Partly justified, i.e. likely justified for the use of PFAS in hydraulic fluids in aerospace applications. SEAC is however unable to conclude whether the derogation period of 13.5 years is justified.	SEAC recommends a derogation for the use of PFAS in hydraulic fluids in aerospace applications but cannot provide any details on the necessary length of the derogation period due to limited information for both the analysis of alternatives and the socio-economic analysis.
5q	Refrigerants in mobile air conditioning-systems and heat pump systems in i) light duty electrical vehicles until 6.5 years after EoF; ii) all other vehicles until 13.5 years after EoF	Sector-specific evaluation: Transport	SEAC cannot conclude whether a derogation is justified.	SEAC cannot provide further points for the decision maker's consideration.
5r	Refrigerants in transport refrigeration other	Sector-specific	SEAC cannot conclude whether a derogation is	SEAC cannot provide further points for the decision

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	than in marine applications until 6.5 years after Eif	evaluation: Transport	justified.	maker's consideration.
5s	Coatings and films on displays and lenses of electronic complex objects for 6.5 years after Eif	Sector-specific evaluation: Electronics and semiconductors	Likely justified.	SEAC recommends the 6.5-year derogation as proposed by the Dossier Submitter.
5t	Printed circuit boards and antennas for 13.5 years after Eif	Sector-specific evaluation: Electronics and semiconductors	Likely justified.	SEAC recommends the 13.5-year derogation as proposed by the Dossier Submitter.
5u	Photonics for 13.5 years after Eif	Sector-specific evaluation: Electronics and semiconductors	Likely justified.	SEAC recommends the 13.5-year derogation as proposed by the Dossier Submitter.
5v	Heat transfer fluids for 2-phase immersion cooling for 13.5 years after Eif	Sector-specific evaluation: Electronics and semiconductors	Likely justified.	SEAC recommends the 13.5-year derogation as proposed by the Dossier Submitter.
5w	Semiconductor manufacturing until 13.5 year after Eif	Sector-specific evaluation: Electronics and semiconductors	Likely justified.	SEAC recommends the 13.5-year derogation as proposed by the Dossier Submitter.
5x	Coatings and films of electronic components (excluding displays and lenses) for 13.5 years after Eif	Sector-specific evaluation: Electronics and semiconductors	Likely justified.	SEAC recommends the 13.5-year derogation as proposed by the Dossier Submitter.
5y	Binders and electrolytes in batteries until 13.5 years after Eif	Sector-specific evaluation: Energy	Likely justified. SEAC is however unable to conclude whether the derogation period of 13.5 years is justified.	SEAC recommends a derogation but cannot provide any details on the necessary length of the derogation period due to a lack of information.
5z	Polymer additives used for fire safety purposes in construction products until 13.5	Sector-specific evaluation:	SEAC cannot conclude whether a derogation is justified.	SEAC cannot provide further points for the decision maker's consideration due to an unclear scope and a lack of information preventing a meaningful

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	years after Eif	Construction products		technical assessment as well as a cost assessment.
5aa	Industrial and professional uses of lubricants or lubricant additives until 13.5 years after Eif	Sector-specific evaluation: Lubricants	Could be justified.	While there are indications that a derogation for industrial and professional uses where PFAS-based lubricants are currently used may be justified, SEAC is unable to reach a definitive conclusion due to uncertainties in the cost assessment and the significantly reduced benefits associated with the derogation.  In case a derogation is supported by the decision maker, SEAC considers it appropriate that it refers to industrial and professional uses generally, due to the impossibility of defining harsh conditions in an objective way.
5bb	Gas and oil tracers until 13.5 years after Eif	Sector-specific evaluation: Petroleum and mining	SEAC cannot conclude whether a derogation is justified.	SEAC notes that both a full ban as well as a restriction with a derogation for PFAS-based oil and gas tracers could be proportionate. Considering RAC's conclusion on the risk of alternatives, proportionality ultimately depends on which alternatives are implemented by industry and whether appropriate risk management measures for alternatives of comparable concern are in place to reduce the risk of their use.
5cc	Toners until 13.5 years after Eif	Printing applications	No detailed evaluation of the eight additional sectors that were assessed by the Dossier Submitter as a result of their analysis of the Annex XV report consultation comments: <ul style="list-style-type: none"> <li>• Printing applications</li> <li>• Sealing applications</li> <li>• Machinery applications</li> <li>• Other medical applications</li> </ul>	SEAC was unable to perform a thorough and robust evaluation for the uses/applications listed in paragraphs 5cc to 5ww within a reasonable timeframe <sup>88</sup> and without jeopardising the relevance and timelines of SEAC's evaluation for the uses/applications within the scope of the other sectors. As such, SEAC cannot conclude whether the derogations proposed for these uses/applications are justified to ensure proportionality of the restriction as a whole. Similarly, SEAC cannot
5dd	Latex printing inks until 13.5 years after Eif	Printing applications		
5ee	Electrophotographic press units until 13.5 years after Eif	Printing applications		
5ff	Kinetic printing components until 13.5 years after Eif	Printing applications		
5gg	Photosensitive materials until 13.5 years after Eif	Printing applications		

<sup>88</sup> The finalised assessments for these sector/uses/applications became available only at a later stage in the opinion development process.

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5hh	Toners for use in existing equipment put on the market until 13.5 years after EiF	Printing applications	<ul style="list-style-type: none"> <li>• Military applications</li> <li>• Explosives</li> <li>• Technical textiles</li> <li>• Broader industrial uses</li> </ul>	<p>conclude if additional derogations for other uses/applications assessed by the Dossier Submitter within these specific sectors would be justified.</p> <p>However, RAC concluded that, regardless of the sector of use, PFAS releases present a risk and that the risk increases with continued use due to the high persistence of PFAS and other properties of concern and the consequent build-up of environmental stocks over time. RAC concludes that there is no evidence that the release of PFAS from the manufacturing, use and disposal of PFAS, PFAS-containing mixtures and articles is adequately controlled and, therefore, it should be minimised.</p> <p>As such, SEAC recommends that an evaluation of all uses/applications assessed by the Dossier Submitter within these specific sectors is performed as soon as possible. In the interim, SEAC recommends a time-limited derogation for all uses/applications within the scope of these specific sectors. In this context "time-limited" means until the above-mentioned evaluation has been performed and an appropriate decision can be made on proportionality, not the derogation periods proposed by the Dossier Submitter.</p> <p>This would ensure that a decision on the need for derogations for uses/applications within the scope of these specific sectors is taken based on a detailed evaluation of the availability and technical and economic feasibility of alternatives, as well as socio-economic impacts.</p> <p>SEAC notes that RAC recommends the implementation of additional risk management measures to ensure PFAS emissions are minimised in case derogations are supported by the decision maker.</p>
5ii	Latex printing inks for use in existing equipment put on the market until 13.5 years after EiF	Printing applications		
5jj	Excipients in medicinal products for ophthalmic and dermatological therapies until 13.5 years after EiF	Other medical applications		
5kk	Propellants in pMDIs until 6.5 years after EiF	Other medical applications		
5ll	Military applications until 13.5 years after EiF	Military applications		
5mm	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 for 13.5 years after EiF, excluding general (HVAC) ventilation	Technical textiles		
5nn	Sound-permeable and vent filters for electrical and electronic equipment for 6.5 years after EiF	Technical textiles		
5oo	Oxygen-permeable membranes in zinc-air batteries and other types of alkaline metal-air batteries for 13.5 years after EiF	Technical textiles		
5pp	Industrial use as media in liquid-liquid separation for 13.5 years after EiF	Technical textiles		
5qq	Technical textiles in engine bays of transport vehicles for noise, vibration and harshness (NVH) insulation and ignition protection until 13.5 years after EiF	Technical textiles		
5rr	Technical textiles in transport vehicles for noise, vibration and harshness (NVH) insulation outside the engine bay until 6.5 years after EiF	Technical textiles		
5ss	Woven, knitted and nonwoven re-usable medical textiles as specified in Medical Device	Technical textiles		

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	Regulation (EU) 2017/745 of the European Parliament and of the Council with a minimum performance requirement of >20 cm hydrostatic head according to EN 13795 for 13.5 years			
5tt	Impregnation agents for re-impregnation of articles referred to in paragraph 5ss until 13.5 years after EiF	Technical textiles		
5uu	Ionic liquids used in industrial uses until 6.5 years after EiF	Broader industrial uses		
5vv	Solvents used in industrial uses until 13.5 years after EiF	Broader industrial uses		
5ww	Catalysts and processing aids used in industrial uses until 13.5 years after EiF	Broader industrial uses		
<b>Sector-/use-specific derogations – fluoropolymers and perfluoropolyethers</b>				
6a	Polymer processing aids used in flexible plastic film extrusion (for food and non-food applications) until 6.5 years after EiF	Sector-specific evaluation: Food contact materials and packaging	SEAC cannot conclude whether a derogation is justified.	SEAC cannot provide further points for the decision maker's consideration.
6b	Non-stick coatings in industrial bakeware until 6.5 years after EiF	Sector-specific evaluation: Food contact materials and packaging	SEAC cannot conclude whether a derogation is justified.	SEAC cannot provide further points for the decision maker's consideration.
6c	Implantable medical devices (including medical implants and meshes) until 13.5 years after EiF	Sector-specific evaluation: Medical devices	Justified.	SEAC recommends the 13.5-year derogation as proposed by the Dossier Submitter.
6d	Invasive medical devices (e.g. tubes and catheters) until 13.5 years after EiF	Sector-specific evaluation: Medical devices	Justified. Additionally, for the sub-use of vision applications, SEAC considers it justified to extend the substances within the scope of the derogation to also include PFAS other than fluoropolymers	SEAC recommends the 13.5-year derogation as proposed by the Dossier Submitter. SEAC additionally recommends extending the substances within the scope of the derogation to also include PFAS other than fluoropolymers and

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Derogation proposed by the Dossier Submitter		Relevant topic/sector	SEAC's conclusion	Points for the decision maker to consider
			and perfluoropolyethers.	perfluoropolyethers for the sub-use of vision applications.
6e	Packaging for medical devices until 13.5 years after EIF	Sector-specific evaluation: Medical devices	Partly justified, i.e. justified for PCTFE-based packaging for medical devices and the use of PPAs in flexible packaging of medical devices.	SEAC recommends the 13.5-year derogation for PCTFE-based packaging for medical devices and the use of PPAs in flexible packaging for medical devices.
6f(i)	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 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	Sector-specific evaluation: Transport	Justified.  Additionally, SEAC finds that the substances within the scope of the derogation should be extended to include PFAS other than fluoropolymers and perfluoropolyethers.	SEAC recommends the 13.5-year derogation as proposed by the Dossier Submitter.  SEAC additionally recommends extending the substances within the scope of the derogation to also include PFAS other than fluoropolymers and perfluoropolyethers.
6f(ii)	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	Sector-specific evaluation: Transport	Could be justified.	SEAC notes that there are general indications that polymeric PFAS might currently still be required to ensure safety and environmental performance even if these are not required by specific type approval standards or legislation (which especially seems to be the case in aerospace and defence).  SEAC does however note that the wording "strictly necessary for safety and environmental performance" has not been defined by the Dossier Submitter. This poses significant challenges related to the practicality of the proposed derogation since no direct link can be made to legal and technical requirements (e.g. type-approval legislation).  If implemented, SEAC cannot provide any details on the necessary scope (substance- and (sub-)use-related) as well as the length of the derogation

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Derogation proposed by the Dossier Submitter		Relevant topic/sector	SEAC's conclusion	Points for the decision maker to consider
				period.
6g	Heat transfer fluids for industrial and professional use of vapor phase soldering for electronics for 13.5 years after EiT	Sector-specific evaluation: Electronics and semiconductors	Likely justified.	SEAC recommends the 13.5-year derogation as proposed by the Dossier Submitter.
6h	Wires and cables (incl. connectors) for 13.5 years after EiT	Sector-specific evaluation: Electronics and semiconductors	Partly justified, i.e.:  Likely justified for wires and cables (other than low/mid-temperature applications of wire and cable insulation except extremely high frequency applications), including connectors.  But likely not justified for low/mid-temperature applications of wire and cable insulation (excluding extremely high frequency applications).	SEAC recommends that the 13.5-year derogation is at least partially implemented. As outlined in SEAC's sector-specific evaluation, the Committee acknowledges that it may be difficult to split up the proposed derogation according to temperature and frequency due to a lack of information (although some indications of the possible temperature and frequency ranges were given in the Annex XV report consultation).
6i	Insulation material of electronic components (excluding wires, cables and connectors) for 13.5 years after EiT	Sector-specific evaluation: Electronics and semiconductors	Partly justified, i.e.:  Likely justified for insulation material of electronic components (other than low/mid-temperature applications).  But likely not justified for low/mid-temperature applications of insulation material of electronic components.	SEAC recommends that the 13.5-year derogation is at least partially implemented. As outlined in SEAC's sector-specific evaluation, the Committee acknowledges that it may be difficult to split up the proposed derogation according to temperature, due to a lack of information (SEAC does not have information on what a "low/mid-temperature range" may be for this use).
6j	Anti-drip agent in plastics of electronic components for 13.5 years after EiT	Sector-specific evaluation: Electronics and semiconductors	Likely justified.	SEAC recommends the 13.5-year derogation as proposed by the Dossier Submitter.
6k	Fuel cells and electrolysers until 13.5 years after EiT	Sector-specific evaluation: Energy	Likely justified. SEAC is however unable to conclude whether the derogation period of 13.5-years is justified.  Additionally, SEAC notes that there are indications that a derogation is likely also justified for membranes in (redox) flow batteries due to the similarities with the membranes used in PEM fuel cells.	SEAC recommends a derogation but cannot provide any details on the necessary length of the derogation period due to a lack of information.  SEAC notes that this derogation could be amended to also include membranes in (redox) flow batteries.

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Derogation proposed by the Dossier Submitter		Relevant topic/sector	SEAC's conclusion	Points for the decision maker to consider
6l	Separator coatings for batteries until 6.5 years after Eif	Sector-specific evaluation: Energy	Likely justified.	SEAC recommends the 6.5-year derogation as proposed by the Dossier Submitter.
6m	PTFE nozzles in high voltage (>145 kV) switchgears and circuit breakers until 6.5 years after Eif	Sector-specific evaluation: Energy	SEAC cannot conclude whether a derogation is justified.	SEAC cannot provide further points for the decision maker's consideration.
6n	Front- and backsheets in photovoltaic cells until 6.5 years after Eif	Sector-specific evaluation: Energy	SEAC cannot conclude whether a derogation is justified.	SEAC cannot provide further points for the decision maker's consideration.
6o	Bridge and building bearings until 13.5 years after Eif	Sector-specific evaluation: Construction products	Partly justified, i.e. a derogation could be justified for bridge and building bearings where PTFE is currently necessary to reach a certain level of performance.	SEAC notes that different factors can influence the choice of bridge or building bearing and whether the bearing will include PTFE or not. In certain cases, these factors allow for the use of PFAS/PTFE-free bearings and in certain cases not. However, SEAC is unable to determine which combinations of factors influencing the choice of bridge or building bearing would allow for PFAS/PTFE-free bearings. This, together with a lack of sufficiently granular information on alternatives, costs and benefits, does not allow SEAC to determine the specific applications for which a derogation would be warranted, nor the appropriate duration.
6p	Sealing applications in industrial uses until 13.5 years after Eif	Sealing applications	<p>No detailed evaluation of the eight additional sectors that were assessed by the Dossier Submitter as a result of their analysis of the Annex XV report consultation comments:</p> <ul style="list-style-type: none"> <li>• Printing applications</li> <li>• Sealing applications</li> <li>• Machinery applications</li> </ul>	SEAC was unable to perform a thorough and robust evaluation for the uses/applications listed in paragraphs 6p to 6y within a reasonable timeframe <sup>89</sup> and without jeopardising the relevance and timelines of SEAC's evaluation for the uses/applications within the scope of the other sectors. As such, SEAC cannot conclude whether the derogations proposed for these uses/applications are justified to ensure proportionality of the restriction as a whole. Similarly, SEAC cannot
6q	Machinery applications in industrial uses until 13.5 years after Eif	Machinery applications		
6r	Coatings in release liners and backing film in transdermal patches until 13.5 years after Eif	Other medical applications		
6s	Blisters for solid oral dose formulations until 6.5 years after Eif	Other medical applications		

<sup>89</sup> The finalised assessments for these sector/uses/applications became available only at a later stage in the opinion development process.

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Derogation proposed by the Dossier Submitter		Relevant topic/sector	SEAC's conclusion	Points for the decision maker to consider
6t	Coated rubber stoppers in vials/flasks for injectable medicinal products until 13.5 years after EiF	Other medical applications	<ul style="list-style-type: none"> <li>• Other medical applications</li> <li>• Military applications</li> <li>• Explosives</li> <li>• Technical textiles</li> <li>• Broader industrial uses</li> </ul>	<p>conclude if additional derogations for other uses/applications assessed by the Dossier Submitter within these specific sectors would be justified.</p> <p>However, RAC concluded that, regardless of the sector of use, PFAS releases present a risk and that the risk increases with continued use due to the high persistence of PFAS and other properties of concern and the consequent build-up of environmental stocks over time. RAC concludes that there is no evidence that the release of PFAS from the manufacturing, use and disposal of PFAS, PFAS-containing mixtures and articles is adequately controlled and, therefore, it should be minimised.</p> <p>As such, SEAC recommends that an evaluation of all uses/applications assessed by the Dossier Submitter within these specific sectors is performed as soon as possible. In the interim, SEAC recommends a time-limited derogation for all uses/applications within the scope of these specific sectors. In this context "time-limited" means until the above-mentioned evaluation has been performed and an appropriate decision can be made on proportionality, not the derogation periods proposed by the Dossier Submitter.</p> <p>This would ensure that a decision on the need for derogations for uses/applications within the scope of these specific sectors is taken based on a detailed evaluation of the availability and technical and economic feasibility of alternatives, as well as socio-economic impacts.</p> <p>SEAC notes that RAC recommends the implementation of additional risk management measures to ensure PFAS emissions are minimised in case derogations are supported by the decision maker.</p>
6u	Coated canisters in pressurized metered-dose inhalers (pMDIs) until 13.5 years after EiF	Other medical applications		
6v	Coated plungers in pre-filled syringes until 13.5 years after EiF	Other medical applications		
6w	Pre-filled injection pens & autoinjectors until 13.5 years after EiF	Other medical applications		
6x	Explosives in military applications until 13.5 years after EiF	Explosives		
6y	Industrial use of fluoropolymers in filtration and separation media for water treatment and purification for 6.5 years after EiF	Technical textiles		

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**Table 10: Additional derogations considered by SEAC**

Additional derogations considered by SEAC	Relevant topic/sector	SEAC's conclusion	Points for the decision maker to consider
PVDF strings for musical instruments used by professional musicians until 13.5 years after EoF	Sector-specific evaluation:  Consumer mixtures and miscellaneous consumer articles	Could be justified.	SEAC considers that a decision on whether a time-limited derogation for this use is justified, depends on the socio-economic impacts related to the cultural value of using these strings. However, SEAC could not evaluate these costs due to a lack of data. As such, a decision must be taken based on policy priorities related to the cultural value of using these strings (which falls outside of SEAC's remit).
Use of PFAS in radiofrequency equipment, waveguides and capacitors until 13.5 years after EoF	Sector-specific evaluation:  Electronics and semiconductors	Likely justified.	SEAC recommends the 13.5-year derogation.

### **3.4.3.2.6. Conditions for continued use (paragraphs 4, 7 and 8)**

#### **3.4.3.2.6.1. Reporting requirements (paragraphs 4 and 7)**

The Dossier Submitter proposes **reporting requirements** for derogations with a derogation period of 12 years or time-unlimited, all applications of fluorinated gases and active substances in PPP, BP and MP. The information to be submitted by manufacturers and importers of PFAS and PFAS-containing articles as well as downstream users formulating PFAS-containing mixtures (i.e. formulators) relates to:

- the derogation that the intended use belongs to;
- the identity and quantity of the substances placed on the market in the previous year.

This reporting requirement was included by the Dossier Submitter to ensure that sufficient information on derogated uses is available to Member States for enforcement purposes and also allowing monitoring of the effectiveness of the restriction (via changes in tonnage used). The Dossier Submitter targeted the reporting requirement to actors within the supply chain that can be considered to perform the initial introduction of PFAS to the EU-market and are also already well-equipped to deal with this type of obligation. It is however likely that downstream users will have to report to these actors, leading to some additional administrative burden despite downstream users already being familiar with upstream supply chain communication as part of REACH.

SEAC agrees that a reporting requirement is, in general, an appropriate tool to monitor the continued use of PFAS and whether these uses are being substituted (or discontinued). The Committee also acknowledges that tonnages are related to possible emissions. It is however unclear how the reported tonnages would relate to the emissions considering the breadth of applications and types of PFAS covered. Extending the reporting requirement by also requesting information on the (potential) emissions of derogated PFAS uses could solve this issue. SEAC notes that an informed decision on the continued appropriateness of a derogation for a certain PFAS use can only be taken if the associated risk, for which emissions are a proxy, can be assessed. It would also make the reporting requirement more similar to the one that exists as part of the restriction of synthetic polymer microparticles. SEAC notes that RAC also suggests that an extension of the reporting requirement to include emission data could be appropriate in the context of the proposed restriction and may facilitate the implementation of PFAS monitoring requirements in the updated Urban Wastewater Treatment Directive (Directive (EU) 2024/3019) and the development of analytics for PFAS in wastewater. RAC additionally recommends the reporting requirement to also apply to importers of PFAS-containing mixtures.

SEAC has no information indicating whether the reporting requirement, as proposed by the Dossier Submitter, is a proportionate measure in terms of its costs and benefits. Additionally, it is unknown to SEAC whether a potential extension of the reporting requirement, as discussed above, would (significantly) affect the proportionality of this measure. SEAC agrees that the reporting requirement would only have limited added value for uses for which a 5-year derogation is proposed.

SEAC cannot conclude on the costs associated with the (extended) reporting requirement due to a lack of assessment by the Dossier Submitter as well as a general lack of data. Still, SEAC finds that costs associated with this requirement could be significant due to the broad scope of the restriction proposal and the potentially high number of companies being affected. SEAC notes that the lack of information adds to the already existing uncertainties related to the

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magnitude of costs on a sector level as well as the proposed restriction overall. Information on the benefits associated with this requirement are not available.

**3.4.3.2.6.2. Site-specific PFAS management plans (paragraph 8)**

The Dossier Submitter includes a legal obligation in paragraph 8 of the proposed restriction wording for manufacturers, importers and downstream users of fluoropolymers and perfluoropolyethers to establish a **site-specific PFAS management plan** if they make use of any of the proposed derogations. This plan should include the following:

- 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

SEAC cannot conclude on the costs associated with the establishment of site-specific PFAS management plans due to a lack of assessment by the Dossier Submitter as well as a general lack of data. Still, SEAC finds that costs associated with the requirement as proposed by the Dossier Submitter could be significant due to the broad scope of the restriction proposal and the potentially high number of companies being affected. SEAC notes that the lack of information adds to the already existing uncertainties related to the magnitude of costs on a sector level as well as the proposed restriction overall. SEAC also considers the requirement as proposed and worded by the Dossier Submitter to be difficult to enforce based on concerns raised by Forum and SEAC itself.

Based on all of these considerations, while SEAC finds that this type of measure can in principle contribute to ensuring the proper management of PFAS, the Committee does not find the requirement to establish a site-specific PFAS management plan as proposed and worded by the Dossier Submitter to be an appropriate and effective tool to *“support enforcement authorities during inspections”* and *“ensure users of fluoropolymers and perfluoropolyethers to adequately assess all life cycle stages of their PFAS-containing products during the transitional period and support the implementation of suitable risk management measures and operational conditions”*. However, the elaboration of appropriate guidance might mitigate concerns related to enforceability.

From its point of view, RAC considers that the site-specific PFAS management plan as proposed by the Dossier Submitter is not sufficient to achieve a significant reduction in risk. RAC therefore proposes the following in regard to site-specific PFAS management plans:

- Minimisation of emissions should be the main aim.
- The requirement should be extended to all types of PFAS and not just fluoropolymers and PFPE.
- The requirement should apply to industrial uses<sup>90</sup> and not professional/consumer

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<sup>90</sup> RAC indicates that this is intended to cover industrial uses of PFAS with high emission potential and in particular PFAS manufacturing and industrial downstream uses of PFAS and PFAS-containing mixtures (e.g. formulation of mixtures, production of articles).

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uses<sup>91</sup>.

- The site-specific PFAS management plan should be reviewed at least annually and be kept available for inspection by enforcement authorities on request.
- The following risk management measures should be included in the site-specific PFAS management plan:
  - Information on the identity of the PFAS substances and the products they are used in.
  - A justification for the use of PFAS. An assessment of the technical feasibility of alternatives should be part of this justification.
  - Details on the conditions of use and safe disposal of PFAS on site to minimise emissions to the environment and direct and indirect human exposure (including plans for the treatment and appropriate disposal of PFAS containing wastes arising in production, routine cleaning and maintenance of equipment, etc.).
  - A report of the results of monitoring activities<sup>92</sup> on PFAS presence on site to assess the potential emissions and concentrations into the environment (e.g. air emissions, waste, wastewater, soil).

SEAC notes that RAC's proposal for the site-specific PFAS management plan would entail even higher costs than the originally proposed provision by the Dossier Submitter due to the substantially larger scope of RAC's proposal.

While SEAC finds that this type of measure can in principle contribute to ensuring the proper management of PFAS, the Committee considers the requirement as proposed and worded by RAC to be difficult to enforce. SEAC notes that the elaboration of appropriate guidance might mitigate these concerns.

Based on practicality, cost and benefit considerations, SEAC cannot conclude whether the RAC proposal on site-specific PFAS management plans is a proportionate measure, as no data is available to the Committee to assess the related impacts.

### **3.4.3.2.6.3. Additional conditions considered by RAC**

Beyond the extension of the reporting requirement and the proposed changes to the site-specific PFAS management plans, RAC also recommends the following additional risk management measures in case derogations would be proposed by the decision maker:

- Supply chain communication:

RAC considers this essential to ensure minimisation of emissions in all relevant stages of the life cycle. RAC indicates that effective communication can be done through safety datasheets/technical datasheets, labels (see also below) or product passports. RAC indicates

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<sup>91</sup> SEAC notes that RAC does not specify what they consider to be industrial, professional and consumer uses in the context of this restriction. SEAC notes that the categorisation used by the Dossier Submitter in the Background Document (i.e. into sectors and/or uses) does generally not allow disentanglement of uses into industrial, professional or consumer uses.

<sup>92</sup> RAC notes that the results of monitoring activities should also be reported to the Agency.

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that it should be introduced for manufacturers and importers of PFAS and PFAS-containing mixtures and articles for all derogated industrial uses, with the exception of materials/articles produced from recycled/recovered plastics, textiles or paper and board, or articles which were already in end-use in the Union (reuse of articles).

RAC proposes the following communication requirements for suppliers of PFAS or PFAS-containing mixtures or articles derogated uses:

- i. The statement "This product contains PFAS";
- ii. Instructions for safe use and disposal explaining to industrial and professional users and the general public how to prevent releases of PFAS to the environment;
- iii. The identity of PFAS and quantity contained that enables manufacturers and industrial downstream users to comply with their obligations laid down in paragraph 7 and 8b (see restriction proposed by RAC in Table 2 above).

There is no information available to SEAC in order assess the impacts related to costs and benefits associated with RAC's proposal.

- Risk management measures for professional/consumer uses:

RAC does not consider site-specific PFAS management plans nor supply-chain communication as discussed above to be effective in reducing associated emissions for professional and consumer uses. RAC instead proposes a labelling requirement, similar to the microplastics restriction, to inform professionals and consumers on the presence of PFAS and recommend disposal practices to minimise emissions.

SEAC notes that RAC does not specify what they consider to be industrial, professional and consumer uses in the context of this restriction. SEAC notes that the categorisation used by the Dossier Submitter in the Background Document (i.e. into sectors and/or uses) does generally not allow disentanglement of uses into industrial, professional or consumer uses. There is no information available to SEAC in order assess the impacts related to costs and benefits associated with RAC's proposal.

- Labelling requirements:

Separate from labelling requirements as part of the additional measures discussed above, RAC recommends a general labelling obligation for all PFAS-containing products independently of whether PFAS are present as the result of impurities from the production process (e.g. use of polymerisation aids) or have been intentionally added. RAC considers this labelling requirement not to be practical for derogated recovered materials and articles containing recovered material, or for reuse of articles already in end-use in the Union.

There is no information available to SEAC in order assess the impacts associated with RAC's proposal. SEAC also notes that the Committee considered that a labelling requirement has added value for plastic articles or complex objects falling within the scope of the WEEE Directive and ELV Directive as well as for PVC articles listed in paragraph 18 (a to f) of Commission Regulation (EU) 2023/923 on lead and its compounds in PVC.

- SEAC's conclusion on additional measures for derogated uses:

SEAC notes and, in principle, supports RAC's recommendation to include additional measures (including reporting requirements or site-specific management plans) to ensure emissions are minimised for derogated uses. However, as discussed above, SEAC has concerns about the

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enforceability of some of the specific measures proposed by RAC (while noting that the elaboration of appropriate guidance might mitigate these concerns) and lacks the information to assess the impacts related to costs and benefits associated with these measures. This is also why SEAC cannot conclude whether the measures proposed by RAC are proportionate.

SEAC does however find that the general labelling requirement proposed by RAC may be implementable and would allow better knowledge throughout the supply chain and aid in raising awareness on uses of PFAS and the proposed restriction itself.

### **3.4.3.2.7. Interaction with other relevant legislation (paragraph 9)**

In **paragraph 9 of the proposed restriction wording** the Dossier Submitter indicates that the restriction proposal does not affect or overrule other REACH restrictions as well as the substances listed in the POPs Regulation in order to avoid overlapping or conflicting obligations. An exception to this are entries 28-30 of REACH Annex XVII since the Dossier Submitter considers these entries to be less strict.

The Dossier Submitter also indicates that other Union legislations addressing substances within the scope of the restriction proposal apply without prejudice to the current restriction proposal. While SEAC agrees with the goal of paragraph 9, it is unclear/doubtful whether the proposed wording is appropriate or effective in this regard.

## **3.5. SUMMARY OF UNCERTAINTIES**

### **3.5.1. Uncertainties evaluated by RAC**

#### **Relevant sections of the Background Document:**

See RAC Opinion.

#### **RAC conclusion(s):**

See RAC Opinion.

#### **Key elements underpinning the RAC conclusion(s):**

See RAC Opinion.

### **3.5.2. Uncertainties evaluated by SEAC**

#### **Relevant sections of the Background Document:**

Main report, section 3; Annex F.

#### **SEAC conclusion(s):**

SEAC agrees with the Dossier Submitter that the breadth and complexity of the proposed restriction induce a large number of uncertainties, which are additionally aggravated by the general lack of data the Dossier Submitter faced for the assessment. SEAC notes that for such a broad restriction proposal, both in terms of substances as well as sectors/uses covered, it is difficult to cover all specific substances and actual applications. This means that providing a comprehensive inventory of uses/applications as well as the related tonnages and emission estimates is difficult up to impossible. As a result, it also hampers any thorough assessment of the availability and technical and economic feasibility of alternative, costs, benefits and,

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consequently, the proportionality of a restriction.

SEAC stresses that a structured sensitivity analysis in order to account for these underlying uncertainties is necessary in order to still allow for a robust conclusion on the availability and feasibility of alternatives as well as the socio-economic impacts related to a restriction. The attempt of the Dossier Submitter to provide the Committee with a proper uncertainty assessment is acknowledged. However, SEAC notes that the uncertainty assessment rather points to the aforementioned general uncertainties and reemphasises the importance of a PFAS restriction instead of assessing the potential consequences of these general uncertainties for the outcome of the assessment of alternatives, costs, benefits and proportionality. This would, however, be important in order to robustly conclude on the most appropriate design of the restriction (e.g. in terms of the uses to be derogated and for which timeframe).

SEAC does not agree with all conclusions drawn by the Dossier Submitter in regard to the choice of specific uncertainty levels (negligible, low, moderate) for specific aspects of the restriction proposal, as provided in Table F.2 in Annex F of the Background Document. The respective issues are in detail pointed out in the relevant sections of the documents containing SEAC's evaluation of sector-/use-specific aspects. Furthermore, SEAC notes the Dossier Submitter's rating of the quality of evidence for conclusions on alternatives for the assessed uses in Table F.3 in Annex F of the Background Document. For these aspects, too, SEAC disagrees with the Dossier Submitter's assessment and conclusions for several (sub-)uses and points to the Committee's conclusions as summarised in tables within section S-3 in each of the documents containing SEAC's evaluation of sector-/use-specific aspects.

In summary, SEAC concludes that the **uncertainties for the restriction are overall substantial**. A structured uncertainty assessment and/or sensitivity analysis is, however, lacking.

Uncertainties related to the Dossier Submitter's sector-specific assessments are provided in the documents containing SEAC's evaluation of sector-/use-specific aspects of the proposed restriction. Additionally, overarching aspects in relation to uncertainties as well as relevant uncertainties that SEAC identified in its evaluation of the topics addressed in section 3.4.2.2.4 (other relevant impacts) are discussed in the key elements below.

### **Key elements underpinning the SEAC conclusion(s):**

#### **Overarching aspects**

##### Scope

The scope of the proposed restriction is broad, both in terms of substances and sectors/uses covered. SEAC notes that due to the broad scope, not all sectors and uses/applications where PFAS are used have been assessed specifically by the Dossier Submitter and/or evaluated by SEAC. Considering that the proposed restriction is nevertheless applicable to all sectors and uses, SEAC assumes large uncertainties with respect to the impact of each restriction option overall. In combination with a general lack of data, SEAC emphasizes that this broad scope induces uncertainties in regard to many aspects, such as the analysis of alternatives, the cost and benefits assessment and, consequently, the proportionality assessment.

##### Costs

SEAC identified several uncertainties regarding the cost assessment provided in the Background Document. These as well as SEAC's view are in detail explained in section

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3.4.2.2.2 on costs of this opinion. In summary, SEAC's main issues are:

- SEAC notes a general lack of cost-relevant data which induces uncertainty. Additionally, SEAC notes that for some sectors, the assumptions made for the cost assessment are unsubstantiated or the cost assessment isn't comprehensible. Also, the representativeness of data for several sectors is unclear. SEAC's detailed view on these aspects and their relevance for the uncertainties associated with the cost assessment is provided in the documents containing SEAC's evaluation of sector-/use-specific aspects.
- The main basis for the Dossier Submitter's cost assessment is the outcome of the analysis of alternatives. SEAC acknowledges that this is a relevant factor for assessing costs related to a restriction but is generally not sufficient on its own to assess and conclude on the magnitude of costs, which would require the establishment of robust non-use scenarios, most relevant cost impacts, etc.
- For the majority of sectors, only a qualitative cost assessment was possible for the Dossier Submitter. This, in general, induces uncertainties regarding the actual magnitude of costs.
- SEAC acknowledges the efforts of the Dossier Submitter to establish a qualitative cost categorisation scheme which should allow for a qualitative assessment of costs and, consequently, enable consistency and comparability of the results of the cost assessment across different sectors. The Committee however notes differences in the approach to and quality of the assessments provided for different sectors. Also, the cost categorisation scheme as well as the "strength of evidence"-approach have not been applied consistently across all sectors assessed, further hampering the comparability of the results and the achievement of a complete picture of costs for the restriction options assessed.
- For several overarching cost impacts, the information provided in the Background Document is scarce, such as costs associated with the proposed reporting requirements as well as the proposed site-specific PFAS management plans.

### Benefits

SEAC notes that a reduction of PFAS emissions will lead to a number of benefits that were described in section 3.4.2.2.3 of this opinion and further detailed in the RAC Opinion. Although clearly documented through ample supporting information, these benefits could not be quantified and/or monetized. The approximation of benefits through the quantification of the emission reduction potential of each restriction option is supported by SEAC but is in some cases associated with high uncertainties regarding the emission estimates provided by the Dossier Submitter and recalculated by RAC.

SEAC points out the very high uncertainties with respect to the overall emission reduction potential of the restriction options RO1, RO2 and RO3. The extent of uncertainties varies strongly between the sectors assessed and is further described in detail in the respective documents containing RAC's and SEAC's evaluation of sector-/use-specific aspects. SEAC generally bases its evaluation on the emission (reduction) estimates provided by RAC, which have corrected the Dossier Submitter's estimates (notably RAC has for fluoropolymers only taken the non-polymeric emissions into account and applied a different set of waste-state release factors compared to the Dossier Submitter). Nevertheless, SEAC notes that also the estimates provided by RAC are subject to uncertainties related to a lack of data as further

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detailed in the RAC Opinion.

As explained in detail in section 3.4.2.2.3 above, SEAC reiterates the underlying uncertainties of the Dossier Submitter's approach to evaluate the effectiveness of restriction options for each sector in relative terms (relative to the baseline of a particular sector). With this approach, the effectiveness is highly dependent on the delineation of a sector and could change, depending on any changes in the delineation.

In addition, the uncertainties related to emission estimates lead to uncertainties regarding the impact of each proposed derogation in terms of additional emissions resulting from them. These uncertainties are further described in the documents containing SEAC's evaluation of sector-/use-specific aspects.

### Proportionality

SEAC notes that the Dossier Submitter did not conclude on the overall costs associated with the restriction options RO1, RO2 and RO3 (discussed for specific sectors only) and, consequently, also not for the proposed restriction (which corresponds to RO2 for all sectors, except for PFAS manufacturing, for which RO3b is proposed). Altogether, a cost-benefit analysis of cost-effectiveness analysis was not possible on these grounds.

Furthermore, SEAC has articulated the concerns regarding the Dossier Submitter's approach to assess proportionality on a sector basis using cost qualifiers and sector-specific effectiveness figures. Details are provided in section 3.4.2.2.5 on proportionality in this opinion. The uncertainties discussed in that section prevent SEAC from concluding on the proportionality of RO2, RO3 and the proposed restriction option (which corresponds to RO2 for all sectors, except for PFAS manufacturing, for which RO3b is proposed).

Accordingly, SEAC has evaluated proportionality for each sector separately and provides its opinion in the documents containing SEAC's evaluation of sector-/use-specific aspects. For this purpose, SEAC has evaluated the necessity of each derogation to ensure proportionality of a restriction for the respective sector. SEAC points out a major uncertainty with respect to the issue whether any further derogations beyond those proposed by the Dossier Submitter and evaluated by SEAC would be justified or necessary to ensure proportionality of a restriction overall.

### **Uncertainties of other relevant impacts**

#### Second-hand articles

There is a lack of robust information to qualitatively or quantitatively assess the costs and benefits (in terms of emission reduction) of granting or not granting a derogation for the second-hand market.

#### Spare parts

A quantification of the related costs for the proposed restriction overall or on a sector basis is not available.

The available data lacks the granularity for the Dossier Submitter to determine the availability of alternatives and readiness of the respective complex objects to accommodate PFAS-free spare parts for all sectors and (sub-)uses.

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### Impacts on recycling and circular economy

- *Plastics:*
  - Analytical data on PFAS concentrations in a variety of recycled materials coming from different input streams is limited and its representativeness for the whole sector is uncertain.
  - No in-depth proportionality assessment based on the figures provided by stakeholders is available. The provided figures lack sufficient granularity and there are significant concerns regarding their representativeness as the reported data is not sufficiently substantiated.
  - The Dossier Submitter's conclusion that complying with the proposed concentration limits is not proportionate for recycled plastics is solely based on the consideration of economic impacts, while the relevant environmental impacts were not assessed.
  - Uncertainties on whether the wording of the proposed derogation would allow: i) the addition of PFAS to plastic articles outside of the PFAS already present in the recovered plastic material, ii) the introduction of PFAS-containing recovered plastic into articles where previously no PFAS were used or needed and/or iii) the use of higher amounts of PFAS-containing recovered material since the derogation does not contain concentration limits.
  - Uncertainties in regard to: i) the extent to which the proposed concentration limits can already be met by recyclers and for which plastic waste streams, ii) the actual magnitude of economic impacts in cases where the concentration limits cannot be met, as well as iii) the lack of information on additional emissions related to the proposed derogation for recycled plastics.
- *Paper and board:*
  - Data on PFAS in paper and board is scattered, the variability in reported concentrations is significant, and many PFAS are not analysed regularly and/or not detectable with commercially available equipment.
  - Limited information on the paper and board waste and recycling market was provided during the Annex XV report consultation, the Dossier Submitter's assessment is mainly based on information from one stakeholder (Confederation of European Paper Industries, CEPI), who represents the European pulp and paper industry.
  - The qualitative assessment and the related conclusions on impacts are not substantiated by supporting evidence.
  - The Dossier Submitter's conclusion that complying with the proposed concentration limits is not proportionate for recycled paper and board is solely based on the consideration of economic impacts, while the relevant environmental impacts were not assessed.
  - Uncertainties on whether the wording of the proposed derogation would allow: i) the addition of PFAS to paper and board articles outside of the PFAS already present in the recovered paper and board material, ii) the introduction of PFAS-containing recovered paper and board into articles where previously no PFAS

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were used or needed and/or iii) the use of higher amounts of PFAS-containing recovered material since the derogation does not contain concentration limits.

- Uncertainties in regard to: i) the extent to which the proposed concentration limits can already be met by recyclers and for which paper and board waste streams, ii) the actual magnitude of economic impacts in cases where the concentration limits cannot be met, as well as iii) the lack of information on additional emissions related to the proposed derogation for recycled paper and board.
- *Textiles:*
  - The data on PFAS in textile is limited and its representativeness for the whole sector is uncertain.
  - The qualitative assessment and the related conclusions on impacts are not substantiated by supporting evidence.
  - The Dossier Submitter's conclusion that complying with the proposed concentration limits is not proportionate for recycled textile is solely based on the consideration of economic impacts, while the relevant environmental impacts were not assessed.
  - Uncertainties on whether the wording of the proposed derogation would allow: i) the addition of PFAS to textile articles outside of the PFAS already present in the recovered textile material, ii) the introduction of PFAS-containing recovered textile into articles where previously no PFAS were used or needed and/or iii) the use of higher amounts of PFAS-containing recovered material since the derogation does not contain concentration limits.
  - Uncertainties in regard to: i) the extent to which the proposed concentration limits can already be met by recyclers and for which textile waste streams, ii) the actual magnitude of economic impacts in cases where the concentration limits cannot be met, as well as iii) the lack of information on additional emissions related to the proposed derogation for recycled textile.

### Cumulative impacts

No information is available on the proportion of companies that would be disproportionately affected by a ban compared to the proportion of "more resilient" companies in a sector and, therefore, also not on the overall magnitude of the related impacts.

### Overarching impacts on trade and competitiveness

No actual assessment is available and no conclusion is drawn on the potential magnitude of these impacts and/or their mitigation.

No assessment is available that would discuss and/or demonstrate these impacts for the sectors covered by the restriction proposal. Furthermore, the Dossier Submitter's sector-specific assessments are subject to large uncertainties in terms of the analysis of alternatives as well as the socio-economic impacts.

### Derogated uses lost due to low market volumes

There is a lack of substantiated arguments to assess the validity of derogated uses being lost and its possible impact.

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Upstream supply chain for derogated uses

There is no information available related to the impacts of (not) granting a derogation for upstream supply chain uses. In other words, any consequences in terms of cost and benefits are unknown.

SR&D and PPORD

It is unclear whether “*diagnostic laboratory testing*” (including in vitro diagnostic medical devices) and “*calibration of measurement instruments and as analytical reference materials*” are fully covered by the SR&D exemption.

It is unclear whether the use of fluoropolymers as materials in equipment and instruments in research-related activities will be covered under the SR&D exemption.

There is no information available to assess which exact use-specific PPORD derogations could be necessary in case of time-unlimited derogation.

## 4. REFERENCES

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Other references are included in the Background Document.

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## ANNEX I

### Descriptions for the sectors containing uses of PFAS as identified in the Background Document

Note that SEAC did not carry out detailed sector-specific evaluations for sectors 16 to 23, which are shown with their sector names in *italics*.

Sector	Description
<b>01. PFAS manufacturing</b>	<p>The assessment of the PFAS manufacturing sector covers all process steps in the manufacture of PFAS compounds at the manufacture site, including the processing of PFAS at the manufacturing site. This category also covers the use of PFAS as polymerisation aids in the manufacture of fluoropolymers.</p> <p>Note that processing PFAS into articles or mixtures offsite (e.g., foam moulding or fluoropolymer extrusion) is excluded and considered as part of other relevant sectors (e.g., Transport or Food contact materials and packaging).</p>
<b>02. Textiles, upholstery, leather, apparel and carpets (TULAC)</b>	<p>The assessment of the TULAC sector covers the uses of PFAS in home textiles, consumer apparel, professional apparel and personal protective equipment (PPE), leather and home fabric treatment sprays.</p> <p>PFAS uses related to TULAC but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• Packaging (considered as part of the Food contact materials and packaging sector)</li> <li>• Optical fibre weaving (considered as part of the Electronics and semiconductors sector)</li> <li>• Latex printing inks, including inks for printing on textile (considered as part of the Printing applications sector)</li> <li>• Components related to textile industry e.g., conveyor belts (considered as part of the Machinery applications sector)</li> <li>• Outdoor technical textiles, architectural membranes, other tensile fabrics and other construction applications, filtration and separation media, removable covers for industrial process equipment, medical applications, technical textiles in transport vehicles (considered as part of the Technical textiles sector)</li> <li>• Textiles in engine bays (considered as part of the Technical textiles sector)</li> </ul>
<b>03. Food contact materials (FCM) and packaging</b>	<p>The assessment of the Food contact materials and packaging sector covers the uses of PFAS in food and non-food packaging applications, non-stick coatings in consumer cookware and domestic appliances, and non-stick coatings in industrial bakeware.</p> <p>PFAS uses related to Food contact materials and packaging but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• Packaging of medical devices (considered as part of the Medical devices sector)</li> <li>• Immediate/primary packaging of medicinal and pharmaceutical products for human and veterinary uses (considered as part of the Other medical applications sector)</li> <li>• Inks, lacquers and waxes used in non-FCM applications (considered as part of the Printing applications sector)</li> <li>• Non-intentionally added substances in (recycled) packaging materials (considered and discussed in the Impacts on Recycling and Circular Economy section, please see e.g. section E.3.4. of Annex E)</li> </ul>

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	<ul style="list-style-type: none"> <li>• Advanced semiconductor packaging (considered as part of the Electronics and semiconductors sector)</li> <li>• Sealings, gaskets, piping and linings used in food and feed production (considered as part of the Sealing applications sector)</li> <li>• Conveyor belts, production/assembly line equipment, bearings and rollers used in food and feed production (considered as part of the Machinery applications sector)</li> <li>• Lubricants in industrial settings (considered as part of the Lubricants sector)</li> <li>• Membranes and filtration materials used in drinking water treatment (considered as part of the Technical textiles sector)</li> </ul>
<p><b>04. Metal plating and manufacture of metal products</b></p>	<p>The assessment of the Metal plating and manufacture of metal products sector covers the uses of PFAS in metal plating processes as well as in the manufacture of other metal products. Examples include wetting agents, mist/fume suppressing agents and processing aids in metal plating baths, coating of metal products and solvents in metal manufacturing.</p> <p>PFAS uses related to the manufacture of metal products but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• Production of parts for engines and other applications in technical components (considered as part of the Transport sector)</li> <li>• Production of parts in machinery, as well as other industrial applications, such as sealings (considered as part of the Sealing applications or Machinery applications sectors)</li> <li>• Production of parts for military equipment (considered as part of the Military Applications sector)</li> <li>• Coatings and paints for metal components specifically used in construction and machinery (considered as part of the Construction Products and Machinery applications sectors)</li> <li>• Cover gases for use in magnesium casting (considered as part of the Applications of fluorinated gases sector)</li> <li>• Precision cleaning fluids (considered as part of the Broader industrial uses sector)</li> </ul>
<p><b>05. Consumer mixtures and miscellaneous consumer articles</b></p>	<p>The assessment of the Consumer mixtures and miscellaneous consumer articles sector covers the uses of PFAS in various mixtures and articles intended specifically for consumer use. Examples include cleaners and cleaning products, waxes and polishes, automotive windscreen care products, anti-fogging agents for eyewear, fishing lines, synthetic turf as well as lubricants and string materials used in musical instruments.</p> <p>PFAS uses related to Consumer mixtures and miscellaneous consumer articles but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• Cosmetics (considered as part of the Cosmetics sector)</li> <li>• Ski waxes (considered as part of the Ski wax sector)</li> <li>• Home fabric treatments e.g. sprays used for stain repellence purposes (considered as part of the Textiles, upholstery, leather, apparel and carpets (TULAC) sector)</li> <li>• Consumer uses of lubricants, except for piano keys and strings of musical instruments (considered as part of the Lubricants sector)</li> <li>• Razor blade coatings (considered as part of the Metal plating and manufacture of metal products sector)</li> <li>• Electrical components for musical instruments (considered as part of the Electronics and semiconductors sector)</li> <li>• Spare parts are assessed as an overarching issue (please see Annex E, Section 3.3, of the Background Document)</li> </ul>

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<p><b>06. Cosmetics</b></p>	<p>The assessment of the Cosmetics sector covers the uses of PFAS in cosmetic products and the use of trifluoroacetic acid (TFA) in the synthesis of peptides as cosmetic ingredients.</p> <p>PFAS uses related to Cosmetics but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• Applications in manufacturing equipment used for the manufacture of cosmetics (depending on the application, these may be considered as part of e.g., the Sealing applications or Machinery applications sectors)</li> <li>• Packaging of cosmetics products (considered as part of the Food Contact Materials and Packaging sector)</li> <li>• Analytical instruments and equipment parts used in the cosmetics sector e.g., valves, tubing and connectors (considered as part of the Sealing applications sector. Analytical equipment in general is assessed as an overarching issue, please see the explanatory notes of the main report of the Background Document and in particular the sub-heading '<i>Scientific research and development</i>').</li> <li>• Uses of PFAS in excipients, immediate packaging and drug delivery devices (considered as part of Other Medical Applications)</li> <li>• Active substances in human and veterinary medicinal products are exempted from the restriction proposal (please see in particular Section 2.2.3 of the Background Document main report)</li> </ul>
<p><b>07. Ski wax</b></p>	<p>The assessment of the Ski wax sector covers the uses of PFAS in ski wax that can be applied to traditional skis, snowboards and skin skis across different kinds of snow sports. Examples include blocks of wax, liquid wax, paste wax, powder wax, spray wax or mixtures for cleaning and impregnation.</p> <p>PFAS uses related to Ski wax but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• Shoes and textiles for skiing (considered as part of the Textiles, upholstery, leather, apparel and carpets (TULAC) sector)</li> </ul>
<p><b>08. Applications of fluorinated gases</b></p>	<p>The assessment of the Applications of fluorinated gases sector covers uses of PFAS gases in various applications and uses. Examples include refrigeration, air conditioning and heat pumps, foam blowing agents, propellants, cover gases, clean fire suppressants, preservation of cultural paper-based materials and insulating gases.</p> <p>PFAS uses related to Applications of fluorinated gases but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• Mobile air conditioning (MAC) (considered as part of the Transport sector)</li> <li>• Transport refrigeration (considered as part of the Transport sector)</li> <li>• Heat transfer fluids (i.e. fluids that guide heat/cold away from an application but do not actively cool the application) for immersion cooling and indirect cooling of electronics and semiconductors (considered as part of the Electronics and semiconductors sector)</li> <li>• Semiconductor manufacture (considered as part of the Electronics and semiconductors sector)</li> <li>• Solvents for cleaning (considered as part of the Broader industrial uses, Electronics and semiconductors, or Metal plating and manufacture of metal products sectors)</li> <li>• Carrier solvents for lubricants (considered as part of the Lubricants sector)</li> <li>• Metered dose inhalers (MDI) (considered as part of the Other medical applications sector)</li> <li>• Use of fluoropolymers in equipment e.g. O-rings, gaskets, or similar components (considered as part of the Sealing applications and Machinery applications sectors)</li> </ul>

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	<ul style="list-style-type: none"> <li>• Use of fluorinated gases in various military both mobile and stationary applications (considered as part of the Military applications sector)</li> </ul>
<p><b>09. Medical devices</b></p>	<p>The assessment of the Medical devices sector covers uses of PFAS in various instruments, appliances and other articles intended for medical purposes in humans. Examples include implantable medical devices, invasive medical devices, non-implantable/non-invasive medical devices and packaging of medical devices.</p> <p>PFAS uses related to Medical devices but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• Electronic equipment for medical imaging, MRI, X-ray, etc. (considered as part of the Electronic and semiconductors sector)</li> <li>• Medical electronics (considered as part of the Electronic and semiconductors sector), except electronics in implantable and invasive medical devices (considered as part of the Medical devices sector)</li> <li>• Diagnostic laboratory testing (considered as an overarching issue, please see the explanatory notes of the Main report of the Background Document and in particular the sub-heading '<i>Scientific research and development</i>')</li> <li>• Excipients in pharmaceutical products (considered as part of the Other medical applications sector)</li> <li>• Drug delivery devices where the device is part of a drug-device combination product, e.g. pressurized metered-dose inhalers (pMDIs), pre-filled syringes, pre-filled injection pens, autoinjectors and pre-filled on-body delivery system, transdermal patches (considered as part of the Other medical applications sector)</li> <li>• Immediate packaging for medicines (considered as part of the Other medical applications sector)</li> <li>• Engineered fluids for diagnostic laboratory (considered as an overarching issue, please see the explanatory notes of the Main report of the Background Document and in particular the sub-heading '<i>Scientific research and development</i>')</li> <li>• Fluorinated gases used in industrial processes related to medical applications e.g. medical lasers (considered as part of the Broader industrial uses sector)</li> <li>• Medical textiles, including blood filtration filters, transducer membranes, membranes for venting, and virus and contaminant filters and membranes from water, air and other media (considered as part of the Technical textiles sector)</li> <li>• Personal protective equipment (PPE) e.g., clothing and drapes (considered as part of the TULAC sector)</li> <li>• Construction applications in hospitals (considered as part of the Construction products sector)</li> <li>• Parts of analytical and medical equipment e.g. valves, tubing, connectors (considered as part of the Sealing applications sector)</li> <li>• Packaging other than for medical devices and medicines (considered as part of the Food contact materials and packaging sector)</li> </ul>
<p><b>10. Transport</b></p>	<p>The assessment of the Transport sector covers the uses of PFAS in transport vehicles, mobile machinery, and associated infrastructure. Examples are automotive vehicles, aerospace vehicles, watercraft vehicles, rail vehicles, agricultural and forestry vehicles, construction and industrial vehicles, and transport-related infrastructure.</p> <p>PFAS uses related to Transport but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• Sealing applications e.g., gaskets, O-rings, pipe/tank linings (considered as part of the Sealing applications sector, except for hoses in combustion engines and hose linings in aerospace applications which are considered part of the Transport sector)</li> <li>• Machinery and equipment e.g., robotic arms, presses (considered as part of the Machinery applications sector)</li> </ul>

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	<ul style="list-style-type: none"> <li>• Lubricants e.g., lubricants in engines and self-lubricating parts (considered as part of the Lubricants and Machinery applications sectors)</li> <li>• Metal plating e.g., mist suppressants (considered as part of the Metal plating and manufacture of metal products sector)</li> <li>• Electrical and electronic equipment in transport vehicles, excluding cable linings and coatings in transport vehicles (considered as part of the Electronics and semiconductors sector)</li> <li>• Batteries and fuel cells (considered as part of the Energy sector)</li> <li>• Immersion cooling (considered as part of the Electronics and semiconductors sector)</li> <li>• Optical fibres (considered as part of the Electronics and semiconductors sector)</li> <li>• Membrane textiles for mould-injection (considered as part of the Technical textiles sector)</li> <li>• Textiles in engine bays (considered as part of the Technical textiles sector)</li> <li>• Textile cover sheets e.g., convertible tops, vehicle protection covers (considered as part of the Technical textiles sector)</li> <li>• Filters e.g., for air conditioning systems (considered as part of the Technical textiles sector)</li> <li>• Interior textile treatments e.g., seats, carpets, roof linings (considered as part of the TULAC sector)</li> <li>• Anti-drip additives/flame-retardant additives in plastics (considered as part of the Electronics and semiconductors sector)</li> <li>• Acrylic foam tape (considered as part of the Sealing applications sector)</li> <li>• Fire extinguishers for aircraft e.g., 2-BTP (considered as part of the Applications of fluorinated gases sector)</li> <li>• Propellants for spray biocides in aircraft (considered as part of the Applications of fluorinated gases sector)</li> </ul>
<p><b>11. Electronics and semiconductors (Electronics)</b></p>	<p>The assessment of electronics covers the uses of PFAS uses in electronic components and assemblies including wires and cables, circuit boards, connectors, sensors, insulation of electrical components, coatings of electrical components, photonics, etc. Plastic additives (e.g., flame retardancy and anti-drip performance), heat transfer fluids for immersion cooling, cold plate cooling and vapor phase soldering in relation to electronics are also in scope.</p> <p>PFAS uses related to electronics but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• Sealing applications e.g., gaskets, O-rings, pipe lining (considered as part of the Sealing applications sector)</li> <li>• Machinery applications e.g., conveyor systems, robotic arms (considered as part of the Machinery applications sector)</li> <li>• Technical textiles e.g., membranes, vents and filters (considered as part of the Technical textiles sector)</li> <li>• Lubricants e.g., for use in magnetic recording media (considered as part of the Lubricants sector)</li> <li>• Non-electronic industrial automation monitoring and control (IAMC) parts (considered as part of the Sealing applications or Machinery applications sectors)</li> <li>• All electrical parts (including wires) which are part of an implantable or invasive medical device (considered as part of the Medical devices sector)</li> <li>• Refrigerants (chillers) for cooling in electronics and semiconductor sector (considered as part of the Applications for fluorinated gases)</li> </ul>

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	<p>sector)</p> <ul style="list-style-type: none"> <li>• Electrical insulation gases (considered as part of the Applications for fluorinated gases sector)</li> <li>• Industrial precision cleaning other than specific uses related to chemical vapor deposition and etch cleaning in electronics and semiconductors (considered as part of the Broader industrial uses sector)</li> <li>• Non-electronic parts of sensors e.g. liners, filters, membranes and gaskets (considered as part of the Sealing applications, Machinery applications and Technical textiles sectors)</li> </ul>
<p><b>11. Electronics and semiconductors (Semiconductors)</b></p>	<p>The assessment of semiconductors covers the uses of PFAS in semiconductor manufacturing processes, including etching, chamber cleaning, wafer processing, photolithography and micro-electromechanical systems (MEMS). PFAS in semiconductor inspection equipment and semiconductor packaging are also in scope.</p> <p>PFAS uses related to semiconductors but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• Sealing applications e.g., gaskets, O-rings, pipe linings (considered as part of the Sealing applications sector)</li> <li>• Machinery applications e.g., conveyor systems, robotic arms (considered as part of the Machinery applications sector)</li> <li>• Technical textiles e.g., membranes, vents and filters (considered as part of the Technical textiles sector)</li> <li>• Lubricants e.g., for use in magnetic recording media (considered as part of the Lubricants sector)</li> <li>• Non-electronic industrial automation monitoring and control (IAMC) parts (considered as part of the Sealing applications or Machinery applications sectors)</li> <li>• All electrical parts (including wires) which are part of an implantable or invasive medical device (considered as part of the Medical devices sector)</li> <li>• Refrigerants (chillers) for cooling in electronics and semiconductor sector (considered as part of the Applications for fluorinated gases sector)</li> <li>• Electrical insulation gases (considered as part of the Applications for fluorinated gases sector)</li> <li>• Industrial precision cleaning other than specific uses related to chemical vapor deposition and etch cleaning in electronics and semiconductors (considered as part of the Broader industrial uses sector)</li> <li>• Non-electronic parts of sensors e.g. liners, filters, membranes and gaskets (considered as part of the Sealing applications, Machinery applications and Technical textiles sectors)</li> </ul>
<p><b>12. Energy</b></p>	<p>The assessment of the Energy sector covers the uses of PFAS in renewable energy generation, hydrogen technology, manufacturing of chemicals via electrolysis, batteries and electrical grids.</p> <p>PFAS uses related to Energy but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• Sealing applications e.g., pipe linings, tubing, tanks, O-rings, gaskets etc. (considered as part of the Sealing applications sector. Note that, in relation to sealing applications, PFAS used in the 'core' of membrane electrode assemblies (MEA) in fuel cells and electrolysers in energy applications are assessed in the Energy sector as part of hydrogen technology and manufacture of chemicals via electrolysis)</li> <li>• Machinery applications and equipment e.g., robotic arms, production and assembly line equipment (considered as part of the Machinery</li> </ul>

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	<p>applications sector)</p> <ul style="list-style-type: none"> <li>• Lubricants in relation to energy applications (considered as part of the Lubricants sector)</li> <li>• Hydropower applications (considered as part of the Sealing applications and Machinery applications sectors)</li> <li>• Anti-drip additives in polymers (considered as part of the Electronics and semiconductors sector)</li> <li>• Power plants, including fossil fuel power plants, nuclear power plants, waste-to-energy plants and engine power plants (considered cross-sectorally as part of sectors such as Sealing applications, Machinery applications, and Electronics and semiconductors)</li> <li>• Oil and gas applications (considered cross-sectorally as part of sectors such as the Sealing applications, Machinery applications, Electronics and semiconductors, and Lubricants sectors)</li> <li>• Membranes e.g., HEPA-filter, H2 and zinc-air battery membranes, excluding membranes for fuel cells and electrolyzers (considered as part of the Technical textiles sector)</li> <li>• Solid oxide electrolyser cell (SOEC) and Solid oxide fuel cell (SOFC) (considered as part of the Sealing applications sector)</li> <li>• Storage, refuelling and transport of hydrogen (considered as part of the Sealing applications and Machinery applications sectors)</li> <li>• Solvents for cleaning (considered as part of the Electronics and semiconductors, Broader industrial uses, or Metal plating and manufacture of metal products sectors)</li> <li>• Electrical grids, excluding PFAS uses in switchgear and circuit breakers, such as PTFE nozzles for arc quenching (considered as part of the Sealing applications, Machinery applications, Electronics and semiconductors, and Applications of fluorinated gases sectors)</li> <li>• Electronics e.g., wires and cables (considered as part of the Electronics and semiconductors sector)</li> <li>• Industrial automation monitoring and control (IAMC) (considered as part of the Sealing applications, Machinery applications and Electronics and semiconductors sectors)</li> <li>• Spare parts are assessed as an overarching issue (please see Annex E, Section 3.3)</li> </ul>
<b>13. Construction products</b>	<p>The assessment of the Construction products sector covers the uses of PFAS in building materials and construction products. Examples include roofing materials, paints and coatings, polymer additives for fire-safety purposes, impregnations, sealants, and adhesives.</p> <p>PFAS uses related to Construction products but NOT considered as part of the Construction products sector:</p> <ul style="list-style-type: none"> <li>• Architectural membranes and weatherproofing membranes, including vapour barriers, coated fabric and fiberglass coating (considered as part of the Technical textiles sector)</li> <li>• Sealings, PTFE thread sealing tape, valves and pipes (considered as part of the Sealing applications sector)</li> <li>• Flexible solar panels, renewable energy systems and film/coating of wind turbines/solar panels (considered as part of the Energy sector)</li> <li>• Foam blowing agents in roofing and fluorinated gases in foam insulation (considered as part of the Applications of fluorinated gases)</li> <li>• Wires and cables (incl. insulation) and electrochromic functionalities in e.g. glazing (considered as part of the Electronics and semiconductors sector)</li> <li>• Coil coating of metal products (considered as part of the Metal plating and manufacture of metal products sector)</li> </ul>

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	<ul style="list-style-type: none"> <li>• Lubricants in manufacturing PEX-pipes and compression sleeves for underfloor heating (considered as part of the Lubricants sector)</li> <li>• Plain bearings for non-building applications (e.g. energy systems, cranes, lifts or elevators) in machinery/equipment, pumps, valves, gas installations and coil coating in manufacturing process (considered as part of the Machinery applications sector)</li> <li>• Anti-drip agents and flame retardants for electronics (considered as part of the Electronics and Semiconductors sector)</li> <li>• Explosives used in the construction applications (considered as part of the Explosives sector)</li> </ul>
<p><b>14. Lubricants</b></p>	<p>The assessment of the Lubricants sector covers the uses of PFAS in liquid or semi-fluid lubricant mixtures designed to remain viscous throughout their lifecycle, as well as PFAS additives in coatings that provide low-friction properties once cured or solidified. Examples include low-viscosity lubricants (base oils, mineral or synthetic, sometimes with additives), greases (base oil combined with a thickening agent and additives), solid/dry films (lubricant mixed with alcohol, water, or other volatile solvents), release agents (such as dry films used in manufacturing thermoplastics and elastomers) and carrier solvents for lubricants.</p> <p>PFAS uses related to Lubricants but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• Lubricants for piano keys or the strings of musical instruments e.g., guitars, harps, ukuleles, violins, violas, lutes, and other old stringed instruments (considered as part of the Consumer mixtures and miscellaneous consumer articles sector)</li> <li>• Articles and complex objects e.g., bearings, bearing liners, pumps (considered as part of the Machinery applications sector)</li> <li>• Low friction sealings (considered as part of the Sealing applications sector)</li> <li>• Solvents e.g., for cleaning and dissolving purposes (considered as part of the Electronics and semiconductors and Metal plating and manufacture of metal products sectors)</li> <li>• General industrial precision cleaning fluids (considered as part of the Broader Industrial Uses sector)</li> <li>• EEE (electrical and electronic equipment) specialist equipment (considered as part of the Electronics and semiconductors sector)</li> <li>• Hydraulic oils (considered as part of the Transport or Broader industrial uses sectors)</li> </ul>
<p><b>15. Petroleum and mining</b></p>	<p>The assessment of the Petroleum and mining sector covers the uses of PFAS in petroleum extraction, mining operations, and downstream industries such as refineries, petrochemical plants, carbon capture and storage, and geothermal applications. Note that only non-polymeric PFAS are in the scope of this sector, while polymeric PFAS used in these industries are addressed cross-sectorial.</p> <p>PFAS uses related to Petroleum and mining, but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• Piping, tubing, tanks etc. used in the production and transportation of oil and gas (considered as part of the Sealing applications sector)</li> <li>• Sealing devices in petroleum and mining applications e.g., sealants in O-rings, V-rings, gaskets, fittings, and seals (considered as part of the Sealing applications sector)</li> <li>• Anti-corrosive coatings of equipment and infrastructure (considered as part of the Construction products sector and the Machinery applications sector)</li> <li>• Cables, specialised uses in petroleum and mining (considered as part of the Electronics and semiconductors sector)</li> <li>• Membranes, diaphragms, filters etc. in petroleum and mining applications (considered as part of the Technical textiles sector)</li> <li>• Machinery, valves, pumps etc. in petroleum and mining applications (considered as part of the Sealing applications and Machinery</li> </ul>

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	<p>applications sectors)</p> <ul style="list-style-type: none"> <li>• Bearings, skidways etc. in petroleum and mining applications (considered as part of the Machinery applications sector)</li> <li>• Lubrication of equipment (considered as part of the Lubricants sector)</li> <li>• Personal protective equipment (PPE) (considered as part of the TULAC sector)</li> <li>• Explosives in mining (considered as part of the Explosives sector)</li> </ul>
<p><b>16. Printing applications</b></p>	<p>The assessment of the Printing applications sector covers the uses of PFAS in various specific applications within printing, which are further organised in two use categories: consumables (e.g. toners, latex printing inks, PTFE wax, pigments and colourants, PTFE powders, photosensitive materials, surfactants used in printing equipment) and permanent parts (e.g. electrophotographic press units, kinetic printing components, printing plates (offset and letterpress printing), rollers). It should be noted that 'permanent parts' refer to components that are not consumed during use. However, while they are not used at the rate of consumables, they may still require replacement multiple times throughout the printer's lifespan - in some cases several times per year.</p> <p>PFAS uses related to Printing applications but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• PFAS in printing inks, lacquers and coatings that are used for food contact materials (considered as part of the Food contact materials and packaging sector)</li> <li>• Solvents for 3D-printing (considered as part of the Broader industrial uses sector)</li> <li>• Lubricants (considered as part of the Lubricants sector)</li> <li>• Printed circuit boards and sensors (considered as part of the Electronics and semiconductors sector)</li> <li>• Components that are used in printing machinery, but are not directly associated with the actual printing process (considered as part of other sectors, e.g. sealing applications are considered in the Sealing applications sector)</li> </ul>
<p><b>17. Sealing applications</b></p>	<p>The assessment of the Sealing applications sector covers the uses of fluoropolymers (FPs) and perfluoropolyethers (PFPEs) in applications designed to (i) prevent unintended substance migration, (ii) contain pressure, and (iii) avoid contamination. Sealing applications are used across multiple sectors and may entail the use of FPs and PFPEs as substances/mixtures, in the manufacturing of FP/PFPE-containing sealing articles and during their service life as components in complex objects. Examples of sealing applications include seals, gaskets, piping, linings, valve parts, and packing.</p> <p>PFAS uses related to Sealing applications but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• Hoses in combustion engines and hose linings in aerospace applications (considered as part of the Transport sector)</li> <li>• Cable linings (considered as part of the Electronics and semiconductors sector)</li> <li>• Vents for electronic components (considered as part of the Technical textiles sector)</li> <li>• PFAS used in the 'core' of fuel cells and electrolyzers i.e., membrane electrode assemblies (MEA) or similar assemblies (considered as part of the Energy sector)</li> <li>• Sealants and adhesive products for specific construction purposes (considered as part of the Construction Products sector)</li> <li>• Lubrication of dynamic seals related to use cases where PFAS-based lubricants are applied, not the seals themselves (considered as part of the Lubricants sector)</li> </ul>

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	<ul style="list-style-type: none"> <li>• Spare Parts (considered as an overarching issue in Annex E.3.3.)</li> </ul>
<p><b>18. Machinery applications</b></p>	<p>The assessment of the Machinery applications sector covers uses of fluoropolymers (FPs) and perfluoropolyethers (PFPEs) in industrial process equipment across various sectors, as well as in machinery applied for both professional and consumer uses, when such uses are not covered elsewhere in the Background Document. It includes the use of FPs and PFPEs as substances/mixtures, in the manufacture of FP/PFPE-containing machinery parts, and during their service life as components in complex objects. Examples include self-lubricating/low-friction elements, structural parts, machinery components and parts (e.g. bearings, belts, rollers, etc.) and protective/durable coatings in stationary and portable machinery not covered in the Transport sector.</p> <p>PFAS uses related to Machinery applications but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• FP/PFPE coatings e.g., on needles, surgical equipment, tubes (such as implantable probes and stents), endoscopes and medical devices (considered as part of the Medical devices sector)</li> <li>• Wind turbine-blade protection coatings and PTFE nozzles for the quenching of electrical arcs in switchgear (considered as part of the Energy sector)</li> <li>• FP/PFPE used in bridge and building bearings, coatings for metal components, skidways for specific construction purposes (considered as part of the Construction products sector)</li> <li>• PFAS-based lubricant mixtures used for specialised 'external' coatings of the contact surfaces of articles where the primary function is to provide low-friction (considered as part of the Lubricants sector)</li> <li>• FP/PFPE used in diaphragms and membranes (considered as part of the Technical textiles sector)</li> <li>• Spare Parts (considered as an overarching issue in Annex E.3.3.)</li> </ul>
<p><b>19. Other medical applications</b></p>	<p>The assessment of the Other medical applications sector covers the uses of PFAS in excipients, immediate packaging and drug delivery devices. Examples include propellants in pressurized metered dose inhalers (pMDIs), excipients in medicinal products for ophthalmic and dermatological therapies, coatings in release liners and backing films for transdermal patches, PFOB as a processing aid in the manufacture of porous particles (excipients in pMDIs), blisters for solid oral dose formulations, coated rubber stoppers for vials/flasks for injectable medicinal products, coated packaging for transdermal patches, fluorinated HDPE packaging (FHDPE) used for some veterinary medicinal products, coated canisters in pMDIs, coated plungers in prefilled syringes, and pre-filled injection pens, and autoinjectors.</p> <p>PFAS uses related to Other medical applications but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• Fluoropolymer-coated electronics in pre-filled on-body delivery systems (considered as part of the Electronic and semiconductors sector)</li> <li>• Lubricants in drug delivery devices (considered as part of the Lubricants sector)</li> <li>• Process chemicals (considered as part of the Broader industrial uses sector)</li> </ul>
<p><b>20. Military applications</b></p>	<p>The assessment of the Military applications sector covers the uses of PFAS (including fluoropolymers and fluorinated gases) in articles intended for military personnel. Examples include fluorinated gases used as refrigerants in military applications, fluorinated gases used in fire extinguishing systems for military vessels, vehicles, and aircraft, as well as other military uses.</p> <p>PFAS uses related to Military applications but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• Military electrical systems e.g. coatings and cabling of electronics (considered as part of the Electronic and semiconductors sector)</li> </ul>

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	<ul style="list-style-type: none"> <li>• Military applications of sealing materials (considered as part of the Sealing applications sector)</li> <li>• Military explosives e.g. munitions, flares and explosive charges (considered as part of the Explosives sector)</li> <li>• Military textiles e.g. tents, parachutes, filtration and separation media, medical textiles and textiles used in military vehicles (considered as part of the Technical textiles sector)</li> <li>• Military protective garments, uniforms and personal protective equipment (PPE) (considered as part of the TULAC sector)</li> </ul>
<b>21. Explosives</b>	<p>The assessment of the Explosives sector covers the uses of PFAS in products or compositions designed to provide a useful liberation of energy, typically causing a release of heat, light, gas/smoke or a combination of the above. Civil products with uses of explosives include professional/consumer uses (e.g. ammunition for hunting and sport shooting, fireworks, flares) and transport (e.g. safety pyro mechanisms). Additionally, explosives can be used independently in industrial processes such as mining and blasting or in military applications (e.g. large calibre ammunition).</p> <p>PFAS uses related to Explosives but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• Related uses of PFAS in petroleum and mining applications (considered as part of the Petroleum and mining sector)</li> <li>• Related uses of PFAS in military applications (considered as part of the Military applications sector)</li> <li>• Related uses of PFAS in transport applications (considered as part of the Transport sector)</li> </ul>
<b>22. Technical textiles</b>	<p>The assessment of the Technical textiles sector covers the uses of PFAS in textile materials (such as woven fabrics, knitted fabrics, non-wovens and felts) and textile manufactured products that are used primarily for their technical and functional properties and not for their aesthetic and decorative character. The assessment covers the uses of PFAS in outdoor technical textiles, architectural membranes, other tensile fabrics and other construction applications, filtration and separation media (e.g. virus and contaminant removal membranes and filters in water treatment and water, gas/air and other media filtration applications, purification applications), removable covers for industrial process equipment, technical textiles in medical applications (e.g., blood filtration textiles, transducer membranes, sterile ventilation membranes in medical devices, sound-permeable vent filters), and technical textiles for transport vehicles.</p> <p>PFAS uses related to Technical textiles but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• Home textiles, including comparable uses in vehicles (such as carpets and seat covers) and public settings, e.g. hospital settings and public transport (considered as part of the TULAC sector)</li> <li>• Consumer apparel (considered as part of the TULAC sector)</li> <li>• Professional apparel and personal protective equipment (PPE) (considered as part of the TULAC sector)</li> <li>• Leather (considered as part of the TULAC sector)</li> <li>• Home fabric treatments (considered as part of the TULAC sector)</li> <li>• Packaging (considered as part of the Food contact materials and packaging sector)</li> <li>• Optical fibre weaving solutions for lighting applications in health, costumes, automotive, safety, environment, communication, architecture and industrial applications (considered as part of the Electronics and semiconductors sector)</li> <li>• Latex printing inks, including applications for printing on textiles (considered as part of the Printing applications sector)</li> </ul>

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	<ul style="list-style-type: none"> <li>• Solvents for dry-cleaning of textiles (considered as part of the Applications of fluorinated gases sector)</li> <li>• Uses of PFAS in electrical components, sealing applications or machinery applications related to the manufacture of textiles or textile products (considered as part of the Electronics and semiconductors, Sealing applications and Machinery applications sectors respectively)</li> <li>• Conveyor belts (considered as part of the Machinery applications sector)</li> <li>• PTFE fibres/yarns used for the manufacture of braided packings for sealing applications (considered as part of the Sealing applications sector)</li> <li>• Use of PTFE in chemically inert fabrics used by the chemical and petrochemical industry for flange protection (considered as part of the Sealing applications sector)</li> <li>• Coating of fabric expansion joints (considered as part of the Sealing applications sector)</li> <li>• Uses of PFAS in relation to textiles used for self-lubricating /low-friction purposes (considered as part of the Machinery applications sector)</li> <li>• Uses of PFAS for textiles used for anti-adhesive/release purposes (considered as part of the Machinery applications sector)</li> <li>• Fuel-cell membranes and ion-exchange membranes for the manufacture of chemicals via electrolysis (considered as part of the Energy sector)</li> </ul>
<b>23. Broader industrial uses</b>	<p>The assessment of the Broader industrial uses sector covers the uses of PFAS in hydraulic fluids (if not covered under the Transport sector), solvents (solvents and reaction media for precision cleaning, extraction solvents and 3D printing), and catalysts and processing aids (catalytic reaction media and processing aids, including ionic liquids). These uses apply across different use sectors involving different actors (producers and users) along the supply/value chain.</p> <p>PFAS uses related to Broader industrial uses but NOT considered as part of this sector:</p> <ul style="list-style-type: none"> <li>• Precision cleaning in electronics and semiconductor manufacturing (considered as part of the Electronics and semiconductors sector)</li> <li>• Hydraulic fluids in transport (considered as part of the Transport sector, mainly for aviation)</li> <li>• Analytical and laboratory applications (considered as an overarching issue, please see the explanatory notes of the main report of the Background Document and in particular the sub-heading '<i>Scientific research and development</i>')</li> <li>• Engineered fluids: Fluids used for lubrication (considered as part of the Lubricants sector), cooling applications (considered as part of the Electronics and semiconductors sector), or precision cleaning agents (partly considered as part of the Broader industrial uses sector, partly considered as part of the Electronics and semiconductors sector)</li> <li>• Heat transfer fluids for immersion cooling and cold plate cooling (considered as part of the Electronics and semiconductors sector)</li> <li>• Engineered fluids for diagnostic laboratory applications (considered as an overarching issue, please see the explanatory notes of the main report of the Background Document and in particular the sub-heading '<i>Scientific research and development</i>')</li> <li>• Coatings for metals (considered as part of several different sectors, e.g. anti-acid coatings for metals are considered as part of the Metal plating and manufacture of metal products sector)</li> <li>• Solvents e.g., for cleaning and dissolving purposes (considered as part of the Electronics and semiconductors and Metal plating and manufacture of metal products sectors)</li> </ul>

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|  | <ul style="list-style-type: none"><li>• Solvents for dry-cleaning of textiles (considered as part of the Applications of fluorinated gases sector)</li><li>• Carrier solvents for lubricants (considered as part of the Lubricants sector)</li></ul> |
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