

# Christopher Correnti

AGC Comments Addendum (Copies of Studies) -- Vol. 9

## **Committee for Risk Assessment (RAC)**

Opinion

on an Annex XV dossier proposing restrictions on

Per- and polyfluoroalkyl substances (PFAS)

ECHA/RAC/RES-O-0000007619-62-01/F

**Date: 2 March 2026**



**RAC**  
COMMITTEE FOR RISK  
ASSESSMENT

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON  
PER- AND POLYFLUOROALKYL SUBSTANCES (PFAS)

2 of March 2026

RES-O-0000007619-62-01/F

**Opinion of the Committee for Risk Assessment**

**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 Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 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 RAC and the Committee's justification for its opinion. The opinion of the Committee for Socio-economic Analysis (SEAC) on the proposed restriction and on its related socio-economic impact is referenced where relevant.

The Background Document, as a supportive document to both the RAC and SEAC opinions, 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 RAC 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**.

**Rapporteur, appointed by RAC:** Tiina SANTONEN

**Co-rapporteur, appointed by RAC:** Michal MARTÍNEK and Laure GEOFFROY

**Supporting the Rapporteurs:** Dania ESPOSITO, Manual FACCHIN, Zuzana KLÖSLOVÁ, Anja MENARD SRPČIČ, Ruth MÖLLER, Benjamin PIÑA, Nikolaos SPETSERIS, Christina TSITSIMPIKOU and Tereza ZLOCHOVÁ

The opinion of RAC as to whether the suggested restriction is appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **2 March 2026**.

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

The opinion of RAC was adopted **by consensus** of all members having the right to vote.

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON  
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## 1. OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

**Table 1: Proposed restriction**

| <b>Column 1</b><br><b>Designation of the substance, of the group of substances or of the mixture</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Column 2</b><br><b>Conditions of restriction</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Per- and polyfluoroalkyl substances (PFASs) defined as:<br/>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:<br/>CF<sub>3</sub>-X or X-CF<sub>2</sub>-X',<br/>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''';<br/>and where R/R'/R''/R''' is a hydrogen (-H), methyl (-CH<sub>3</sub>), methylene (-CH<sub>2</sub>-), an aromatic group or a carbonyl group (-C(O)-).</p> | <ol style="list-style-type: none"> <li>1. Shall not be manufactured, used or placed on the market as substances on their own;</li> <li>2. Shall not be placed on the market in: <ol style="list-style-type: none"> <li>a. another substance, as a constituent;</li> <li>b. a mixture,</li> <li>c. an article</li> </ol> <p>in a concentration of or above:</p> <ol style="list-style-type: none"> <li>i. 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification)</li> <li>ii. 250 ppb for the sum of PFASs measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors</li> <li>iii. 50 ppm for total PFASs (polymeric PFASs included).<br/>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</li> </ol> </li> </ol> |

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| <b>Column 1</b><br><b>Designation of the substance, of the group of substances or of the mixture</b> | <b>Column 2</b><br><b>Conditions of restriction</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
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|                                                                                                      | <p>specific spare parts exist until the end of service life of the complex object</p> <ul style="list-style-type: none"> <li>g. starting materials and intermediates in the manufacture of PFASs for a use listed under paragraphs 4, 5 or 6</li> <li>h. production of PFAS containing mixtures or articles in the upstream supply chain for a use listed under paragraphs 4, 5 or 6</li> <li>i. uses under product and process orientated research and development (PPORD; art. 67(1) of EU-REACH)</li> <li>j. paper and board articles containing recovered material, with the exception of food-contact material and packaging</li> <li>k. textile articles containing recovered material, with the exception of toys as defined in Directive 2009/48/EC, until 13.5 years after EiF</li> <li>l. plastic articles containing recovered material, with the exception of food-contact material and food-contact packaging and toys as defined in Directive 2009/48/EC, until 23.5 years after EiF</li> <li>m. production of PFAS with or without the use of fluorinated polymerisation aids in the production of polymeric PFAS under controlled conditions with average emission factors (= Annual emission of PFAS / total annual amount of PFAS manufactured on site) not exceeding <ul style="list-style-type: none"> <li>i. 0.0090% to air, 0.0010% to water and 0% to soil for emissions of non-polymeric PFAS residues from polymerization aid technology in fluoropolymer manufacturing until end of 2030;</li> <li>ii. 0.0030% to air, 0.0006% to water and 0% to soil for emissions of non-polymeric PFAS residues from polymerization aid technology in fluoropolymer manufacturing from end of 2030 onwards;</li> <li>iii. 0.01% to all compartments for all PFAS emissions not mentioned above from sites manufacturing polymeric and non-polymeric PFAS 6.5 years after EiF.</li> </ul> </li> </ul> <p>Manufacturers and importers of the active substances referred to in points a) – c) shall submit to the Agency every two years the following information:</p> <ul style="list-style-type: none"> <li>i. the derogation that the intended use belongs to;</li> <li>ii. the identity and quantity of the active substance placed on the market</li> </ul> <p>The Agency shall publish on its website a summary of the submitted information referred to in points i) – ii)</p> |

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| <b>Column 1</b><br><b>Designation of the substance, of the group of substances or of the mixture</b> | <b>Column 2</b><br><b>Conditions of restriction</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
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|                                                                                                      | <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 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> <ol style="list-style-type: none"> <li>a. personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, until 13.5 years after EiF;</li> <li>b. personal protective equipment (PPE) specifically designed for armed forces, the maintenance of law and order and other emergency response workers, until 13.5 years after EiF;</li> <li>c. impregnation agents for re-impregnation of articles referred to in paragraph 5a and 5b until 13.5 years after EiF;</li> <li>d. hard chrome plating until 6.5 years after EiF;</li> <li>e. refrigerants in low temperature refrigeration below -50 °C until 6.5 years after EiF;</li> <li>f. refrigerants in laboratory test and measurement equipment until 13.5 years after EiF;</li> <li>g. refrigerants in refrigerated centrifuges until 13.5 years after EiF;</li> <li>h. refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives;</li> </ol> |

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| <b>Column 1</b><br><b>Designation of the substance, of the group of substances or of the mixture</b> | <b>Column 2</b><br><b>Conditions of restriction</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
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|                                                                                                      | <ul style="list-style-type: none"> <li>i. foam blowing agents in thermal insulation foam until 13.5 years after EiF;</li> <li>j. propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required until 13.5 years after EiF. The derogation does not apply to products intended for entertainment and decorative purposes for the general public;</li> <li>k. fluorinated gases used as clean fire suppressing agents where current alternatives damage the assets to be protected or pose a risk to human health until 13.5 years after EiF;</li> <li>l. preservation of cultural paper-based materials until 13.5 years after EiF;</li> <li>m. insulating gases in high-voltage switchgear (above 145 kV) until 6.5 years after EiF</li> <li>n. refrigerants, clean fire-suppressing agents and insulation gases for maintenance and refilling of existing HVACR, fire-suppressing and switchgear equipment put on the market before 18 months (or placed on the market after 18 months after EiF 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 EiF].</li> <li>p. additives to hydraulic fluids in transport vehicles until 13.5 years after EiF;</li> <li>q. refrigerants in mobile air conditioning-systems and heat pump systems in i) light duty electrical vehicles until 6.5 years after EiF; ii) all other vehicles until 13.5 years after EiF</li> <li>r. refrigerants in transport refrigeration other than in marine applications until 6.5 years after EiF;</li> <li>s. coatings and films on displays and lenses of electronic complex objects for 6.5 years after EiF;</li> <li>t. printed circuit boards and antennas for 13.5 years after EiF</li> <li>u. photonics for 13.5 years after EiF;</li> <li>v. heat transfer fluids for 2-phase immersion cooling for 13.5 years after EiF;</li> <li>w. semiconductor manufacturing until 13.5 year after EiF;</li> <li>x. coatings and films of electronic components (excluding displays and lenses) for 13.5 years after EiF;</li> <li>y. binders and electrolytes in batteries until 13.5 years after EIF</li> <li>z. polymer additives used for fire safety purposes in construction products until 13.5 years after EiF;</li> </ul> |

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| <b>Column 1</b><br><b>Designation of the substance, of the group of substances or of the mixture</b> | <b>Column 2</b><br><b>Conditions of restriction</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
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|                                                                                                      | <ul style="list-style-type: none"> <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 performance requirement of &gt;20 cm hydrostatic head according to EN 13795 for 13.5 years;</li> <li>tt. impregnation agents for re-impregnation of articles referred to in paragraph 5ss until 13.5 years after EiF;</li> <li>uu. ionic liquids used in industrial uses until 6.5 years after EiF;</li> <li>vv. solvents used in industrial uses until 13.5 years after EiF;</li> <li>ww. catalysts and processing aids used in industrial uses until 13.5 years after EiF.</li> </ul> |

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| <b>Column 1</b><br><b>Designation of the substance, of the group of substances or of the mixture</b> | <b>Column 2</b><br><b>Conditions of restriction</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
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|                                                                                                      | <p>6. By way of derogation, paragraphs 1 and 2 shall not apply to fluoropolymers and perfluoropolyethers for the use in:</p> <ul style="list-style-type: none"> <li>a. polymer processing aids used in flexible plastic film extrusion (for food and non-food applications) until 6.5 years after EiF.</li> <li>b. non-stick coatings in industrial bakeware until 6.5 years after EiF;</li> <li>c. implantable medical devices (including medical implants and meshes) until 13.5 years after EiF;</li> <li>d. invasive medical devices (e.g. tubes and catheters) until 13.5 years after EiF;</li> <li>e. packaging for medical devices until 13.5 years after EiF;</li> <li>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.</li> <li>g. heat transfer fluids for industrial and professional use of vapor phase soldering for electronics for 13.5 years after EiF;</li> <li>h. wires and cables (incl. connectors) for 13.5 years after EiF</li> <li>i. insulation material of electronic components (excluding wires, cables and connectors) for 13.5 years after EiF;</li> </ul> |



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| <b>Column 1</b><br><b>Designation of the substance, of the group of substances or of the mixture</b> | <b>Column 2</b><br><b>Conditions of restriction</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                      | <ul style="list-style-type: none"> <li>j. anti-drip agent in plastics of electronic components for 13.5 years after EiF;</li> <li>k. fuel cells and electrolyzers until 13.5 years after EiF;</li> <li>l. separator coatings for batteries until 6.5 years after EIF</li> <li>m. PTFE nozzles in high voltage (&gt;145 kV) switchgears and circuit breakers until 6.5 years after EIF</li> <li>n. front- and backsheets in photovoltaic cells until 6.5 years after EIF</li> <li>o. bridge and building bearings until 13.5 years after EiF;</li> <li>p. sealing applications in industrial uses until 13.5 years after EiF</li> <li>q. machinery applications in industrial uses until 13.5 years after EIF</li> <li>r. coatings in release liners and backing film in transdermal patches until 13.5 years after EiF</li> <li>s. blisters for solid oral dose formulations until 6.5 years after EiF</li> <li>t. coated rubber stoppers in vials/flasks for injectable medicinal products until 13.5 years after EiF</li> <li>u. coated canisters in pressurized metered-dose inhalers (pMDIs) until 13.5 years after EiF;</li> <li>v. coated plungers in pre-filled syringes until 13.5 years after EiF</li> <li>w. pre-filled injection pens &amp; autoinjectors until 13.5 years after EiF</li> <li>x. explosives in military applications until 13.5 years after EiF</li> <li>y. industrial use of fluoropolymers in filtration and separation media for water treatment and purification for 6.5 years after EiF.</li> </ul> <p>7. Manufacturers, importers of PFASs or PFAS containing articles as well as downstream users formulating PFAS-containing mixtures making use of any of the derogations according to paragraphs 5 a)-c), e) – r), t) - jj), ll) - mm), oo) – qq), ss) – tt), vv)-ww), and 6c) – k), o) – r), t) – x), shall from (EiF + 18 months) provide by 31 May of each calendar year a report to the Agency containing:</p> <ul style="list-style-type: none"> <li>i. the derogation that the intended use belongs to;</li> <li>ii. the identity and quantity of the substances placed on the market in the previous year.</li> </ul> <p>The Agency shall make the information available to the Commission and Member States by 31st August every year;</p> |

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| <b>Column 1</b><br><b>Designation of the substance, of the group of substances or of the mixture</b> | <b>Column 2</b><br><b>Conditions of restriction</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                      | <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> |

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 DS proposal in red)**:

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON  
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**Table 2: Restriction proposed by RAC**

| <p><b>Column 1</b></p> <p>Designation of the substance, of the group of substances or of the mixture</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <p><b>Column 2</b></p> <p>Conditions of restriction</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Per- and polyfluoroalkyl substances (PFASs) defined as:<br/>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 proposes to exclude the following substances from the scope on the grounds that they are fully degradable:</i><br/>"A substance that only contains the following structural elements is excluded from the scope of the restriction:<br/>CF<sub>3</sub>-X or X-CF<sub>2</sub>-X',<br/>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''';<br/>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>RAC considers that the evidence provided is not sufficient to justify this exclusion (see section 3.1.1. of the RAC Opinion).</i></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> </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, <del>optionally</del> 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 to the enforcement authorities provide a proof for the fluorine measured (as content of either PFASs or non-PFASs).</li> </ol> <p>3. Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction.</p> <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> <p>7. Manufacturers, importers of PFAS or PFAS-containing <b>mixtures</b> or 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> <b>which continue to manufacture, place on the market or use PFAS for 13.5 years or longer after EiF or for fluorinated gases 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:</b></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 PFAS substances placed on the market in the previous year;</li> </ol> <p>The Agency shall make the information available to the European Commission and Member States by 31st August every year;</p> <p><b>8. a) Suppliers of PFAS or PFAS-containing mixtures or articles for an application with continued use of PFAS by</b></p> |

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| <b>Column 1</b><br>Designation of the substance, of the group of substances or of the mixture | <b>Column 2</b><br>Conditions of restriction                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                               | <p>way of a derogation from paragraph 1 and 2 shall provide from (EiF + 18 months):</p> <ul 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> </ul> <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 PFAS management plan which shall include:</p> <ul 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> </ul> <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 8 b 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</p> |

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| <b>Column 1</b>                                                            | <b>Column 2</b>                                                                                                                                                                                                                                                     |
|----------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Designation of the substance, of the group of substances or of the mixture | Conditions of restriction                                                                                                                                                                                                                                           |
|                                                                            | 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. |

## 1.2. THE OPINION OF SEAC

See SEAC Opinion

## 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:

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- 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 (vP) according to Annex XIII of the REACH Regulation (Regulation (EC) 1907/2006) 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 (L RTP), 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

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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 ( $\text{CF}_3$ -) or methylene ( $-\text{CF}_2$ -) carbon atom (without any H/Cl/Br/I attached to it). There are however a few exceptions (see paragraph below).

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 (Regulation (EU) 2019/1021)).

### 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

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<sup>1</sup> Any substance that contains at least one fully fluorinated methyl ( $\text{CF}_3$ -) or methylene ( $-\text{CF}_2$ -) carbon atom (without any H/Cl/Br/I attached to it).

## OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON PER- AND POLYFLUOROALKYL SUBSTANCES (PFAS)

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 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

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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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containing the evaluation of sector-/use-specific aspects from 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)
- **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.

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

RAC agrees with the Dossier Submitter on the approach focusing on the very persistent property of PFAS, supported by other hazards. Other properties of concern include (eco)toxicity, mobility, bioaccumulation, long-range transport and global warming potential. 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. RAC supports the use of the OECD definition for PFAS for the purpose of grouping the substances. The Dossier Submitter provided evidence to justify an exclusion from the scope of certain PFAS sub-groups on the grounds that they are fully degradable. However, RAC considers this evidence not sufficient to justify the exclusion of these sub-groups.

With regard to fluoropolymers particularly, RAC recognises that evidence of their mobility, bioaccumulative potential and (eco-)toxicological effects is limited. RAC notes, however, that the whole lifecycle of fluoropolymers needs to be considered and their production and waste stages result in emissions of non-polymeric PFAS. Use and waste stages of fluoropolymers may further result in the formation of micro- and nanosized polymer particles.

RAC further considers volatile PFAS (especially fluorinated gases) to be very persistent, very mobile and possessing global warming and long-range transport potential. RAC highlights that their atmospheric degradation contributes to increasing global trifluoroacetic acid (TFA) levels. RAC, however, recognises that fluorinated gases are generally of low toxicity to humans and to the environment and that some specific fluorinated gases (especially some HFOs) have lower global warming potential. RAC also recognises that there are quantitative differences between different fluorinated gases in their ability to degrade as TFA in the environment.

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 should therefore be minimised.

RAC generally supports the Dossier Submitter's assessment of emissions with a number of notable exceptions. Regarding fluoropolymers - and in contrast to the Dossier Submitter - RAC makes a distinction between emissions of

- a) e.g. fluorinated gases, polymerisation by-products and fluorosurfactants during manufacturing; non-polymeric residues, thermal decomposition products during processing; fluorinated gases and PFAAs when incinerated under suboptimal conditions; and
- b) fluoropolymer particles during processing and service life e.g. due to abrasion.

As a result, RAC has developed its own approach to calculate emissions mentioned under point a). While RAC acknowledges that particle emissions (point b) do occur, such emissions were not quantified by RAC.

RAC also deviates from the Dossier Submitter's approach to calculating emissions with respect to certain waste management options. Most notably in this respect, RAC assumes higher release factors for both hazardous and non-hazardous waste incineration as well as for wastewater treatment.

RAC estimates emissions from all PFAS uses evaluated in detail by RAC to be around 70 000 tonnes per year. Fluorinated gases are major contributors to these emissions (ca. 60 000 t/y), followed by the application of side-chain fluorinated polymers (considered as PFAA precursors) especially in textiles, upholstery, leather, apparel and carpets (TULAC). An

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additional approximately 5 000 tonnes per year of emissions were assumed by the Dossier Submitter regarding the eight new sectors mentioned above. These additional emissions could not be verified by RAC (see section 2.2).

RAC highlights the shortcomings of targeted analysis to provide a comprehensive picture of PFAS contamination at present. Nonetheless, environmental monitoring data shows cases of clearly increased environmental levels of specific non-regulated PFAS (substituting already regulated PFAS) next to the industrial sources. This supports the role of PFAS manufacturing and using industry as an important source of environmental contamination. RAC also shares the Dossier Submitter concern on the increasing TFA levels in the environment, which is in line with the significant emissions of fluorinated gases predicted by emissions estimates. Regarding human biomonitoring, RAC considers that data for non-restricted PFAS is currently limited and emphasises the importance of continued monitoring using both non-targeted and targeted approaches to cover all PFAS. Available monitoring data demonstrate that despite regulatory efforts, current risk management measures and operational conditions do not sufficiently address the risk of PFAS.

RAC concludes that PFAS releases present a risk and that the risk increases with continued use resulting in build-up of environmental stocks over time. RAC notes that this risk is relevant for whole Europe since PFAS are imported, manufactured and placed on the market in a variety of products in all EU Member States. In addition, many PFAS substances are highly mobile in the environment and have long-range transport potential. When combined with high persistence, this leads to global drift of PFAS over long distances from the point of release. These properties increase the concern in terms of containment and remediation of pollution. Based on the key principles of ensuring a high level of protection of human health and the environment across the Union, RAC supports the view that any necessary action to address risks associated with PFAS should be implemented on a Union-wide basis.

RAC agrees with the Dossier Submitter that a restriction on manufacturing, placing on the market and use of PFAS, and articles and mixtures containing PFAS is the most appropriate way to limit the risks to human health and the environment and to avoid regrettable substitution. RAC considers other EU legislation (Water Framework Directive (Directive 2000/60/EC), Industrial Emissions Directive (IED) (Directive 2010/75/EU), etc.) to be important in complementing the risk mitigation of the proposed restriction.

RAC notes that active substances, used as biocides, plant protection products and medicinal products and process chemicals and intermediates used to produce these active substances are excluded from the restriction since they are covered under sectorial legislation. RAC considers that current legislations on biocidal products (BPs) (Regulation (EU) 528/2012), plant protection products (PPPs) (Regulation (EC) 1107/2009) and medicinal products (MPs) (Regulation (EC) 726/2004, Regulation (EU) 2019/6 and Directive 2001/83/EC) do not fully address the concern associated with the emissions to the environment of persistent PFAS and considers it important that in case of a derogation, measures to minimise emissions from the use of PFAS as active substances in PPP, BP and MP are incorporated into respective sector-specific regulations.

RAC concludes that RO1, i.e. a full ban of PFAS, is an effective measure to minimise PFAS emissions. RAC calculates that a full ban as outlined by the Dossier Submitter could result in a 96% reduction of emissions over the assessment period compared to the baseline scenario. This corresponds to approximately 3.3 million tonnes of avoided emissions over the 30-year assessment period. RAC notes that this estimate does not take into account certain potential emissions from continued use in e.g. spare parts, second-hand articles, recycled materials nor from active substances. RAC notes that the Dossier Submitter has proposed several

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derogations for specific uses, which would reduce the effectiveness of the measure to 76% and result in additional emissions of approximately 700 000 tonnes over the assessment period compared to a full ban (RO1). RAC could only support one of the proposed derogations, namely for personal protective equipment and associated impregnating agents to prevent negative effects on the health and safety of workers. RAC expects emissions of an estimated 5 900 tonnes over the assessment period in addition to the RO1 emissions highlighted above.

RAC notes that any continued use of PFAS or PFAS-containing articles or mixtures eventually supported by the decision maker should come with additional risk management measures to ensure minimisation of associated emissions. RAC concludes that such measures should include:

1. Labelling, safe use and disposal instructions and effective supply chain communication by suppliers;
2. Site-specific PFAS management plans to be established by manufacturers and industrial users of PFAS and PFAS-containing mixtures, including information regarding the identity of PFAS used, a justification for their use and results of monitoring activities to assess potential emissions into the environment.

In addition, RAC supports the reporting requirements proposed by the Dossier Submitter and recommends to also require manufacturers and industrial users to report to ECHA emissions included in the site-specific PFAS management plans. RAC also recommends that reporting should apply to importers of PFAS-containing mixtures.

RAC further notes that the Dossier Submitter has developed a third restriction option (RO3) for several sectors to explore the impact of additional risk management measures and in some cases also time-unlimited derogations for certain uses. RAC notes that the effectiveness of RO3 is significantly lower than for RO1 in the sectors specifically evaluated by RAC.

RAC concludes that the proposed restriction is practical. RAC generally supports the proposed concentration limits but acknowledges that the 25 ppb limit may not be currently achievable for certain PFAS with the currently available analytical methods. Also taking into account Forum's advice, RAC highlights the strong need for a harmonised enforcement strategy including standardised analytical methods and methods for sample preparation.

RAC considers that labelling requirement for certain plastics proposed by the Dossier Submitter could be extended to cover all derogated uses of PFAS in various materials or products (with an exception of products manufactured from recovered/ recycled materials and articles which were already in end-use in the Union).

Regarding the certificate required to prove the recovered origin of paper and board, textiles and plastic in articles manufactured from recycled materials, RAC takes note of the potential challenges in enforcement which have been identified by the Forum. RAC acknowledges that a maximum concentration limit for PFAS in recycled material could be an effective risk mitigation measure. However, this was not identified in the Dossier Submitter's proposal and RAC could not establish such a limit.

Overall, RAC concludes that the restriction proposed is the most appropriate regulatory measure to address the risks from PFAS but considers that additional risk management measures, as described in section 1.1, are required to minimise emissions in case derogations for continued use (time limited or un-limited) are supported by the decision-maker.

RAC highlights a number of significant uncertainties that should be considered when interpreting RAC's conclusions. This includes several uncertainties related to the exposure assessment. RAC is nonetheless confident that its overall conclusions are robust.

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### 2.2.2. SEAC opinion summary

See SEAC Opinion

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

### 3.1. RISK ASSESSMENT

#### 3.1.1. Hazard(s)

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

The hazard assessment is summarised in section 1.1.4 of the Background Document. The detailed assessment is in sections B.3. to B.8. of Annex B of the Background Document.

##### RAC conclusion(s):

- RAC agrees with the Dossier Submitter on the approach focusing on the very persistent property of PFAS, supported by other hazards. Other properties of concern include mobility, (eco)toxicity, bioaccumulation, long-range transport and global warming potential. These properties vary between different PFAS.
- RAC acknowledges that, due to the very large number of PFAS covered by the assessment, the hazards are not homogeneous among the group of 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.
- Many PFAS substances are highly mobile in the environment and have long-range transport potential. When combined with high persistence, this leads to global drift of PFAS over long distances from the point of release. RAC is of the opinion that these properties increase the concern in terms of containment and remediation of pollution.
- The Dossier Submitter provided evidence to justify an exclusion from the scope of certain PFAS sub-groups on the grounds that they are fully degradable. RAC considers the evidence provided by the Dossier Submitter regarding the degradability of the groups of substances to be insufficient. Therefore, RAC does not consider that the exclusion of these sub-groups from the scope is justified, although it is recognised that there may be exceptions for the general very persistent property of PFAS.
- Fluoropolymers are persistent but generally not mobile nor bioaccumulative. The evidence of their (eco)toxicological effects *per se* is limited. However, their production, under current procedures, implies emissions of other PFAS - including fluorinated gases - into the environment, which have been shown by monitoring data. There are also concerns related to the waste stage of fluoropolymers since their disposal via incineration can produce volatile and non-volatile PFAS. In addition, micro- and nanosized polymer particles may be formed during use and disposal as waste. However, RAC notes that the data on the formation, bioavailability and (eco)toxicity of fluoropolymer micro- and nanoparticles is limited.
- Perfluoropolyethers are another group of polymeric PFAS which consists of a polymer chain made of perfluoroether monomers. They are typically liquids. Some of them have a low molecular weight (even below 1000 Da), which generally provide higher bioavailability because they can more easily cross biological membranes via passive diffusion and therefore be a concern for the environment and human health. RAC notes that there are

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limited data on the environmental fate or (eco)toxicological effects of various PFPE.

- Volatile PFAS (especially fluorinated gases) are very persistent, very mobile and have global warming and long-range transport potential. In addition, their atmospheric degradation contributes to the increasing global TFA levels. These characteristics represent grounds for concern. RAC however recognises that fluorinated gases are generally of low toxicity to humans and to the environment and that some specific fluorinated gases (especially some HFOs) have lower global warming potential.
- Although RAC recognises that there is variability in the environmental and human health hazards of different PFAS, their very persistent properties combined with difficult and costly remediation, have a potential to generate an irreversible stock of pollution, which may result in the exceedance of (eco)toxicologically critical concentrations and environmental or human health risks. Such risks have been demonstrated for some PFAS arrowhead compounds but remain largely uncharacterised for the whole group due to the large number of PFAS included.

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

The scope of the restriction proposal targets PFAS, which are defined as: Any substance that contains at least one fully fluorinated methyl ( $\text{CF}_3$ -) or methylene ( $-\text{CF}_2-$ ) carbon atom (without any H/Cl/Br/I attached to it).

This definition is aligned with the OECD definition of PFAS published in 2021 (OECD, 2021). It captures substances with a wide range of structures and properties, from discrete chemicals such as perfluorocarboxylic acids, perfluorosulfonic acids, and fluorotelomer alcohols, to side-chain fluorinated polymers and other polymers including high molecular weight fluoropolymers. Many of these are categorised as PFAAs (per- or polyfluoroalkyl acids) or their precursors. Important exceptions, which do not degrade as PFAAs are fluoropolymers and PFPEs and some perfluoroalkanes, which are categorised by OECD (2021) as "other PFAS". Some PFAS on the market also possess structural attributes other than perfluoroalkyl chains (for example, inclusion of ether linkages or chlorine atoms in the fluorinated hydrocarbon chains) (ECCC, HC, 2023).

Thus, PFAS covered by the restriction encompass a broad category of chemicals numbering in the thousands (at least around 10 000 chemicals substances according to the Dossier Submitter) which are used for many purposes across different sectors. According to the proposal, these substances shall not be manufactured, used or placed on the EU market as substances on their own or as a constituent of another substance, in a mixture or in an article, above the defined concentration limits unless for specific derogated uses.

According to the Dossier Submitter PFAS need to be considered as a group since they share a common concern: they or their breakdown products have very high persistence - exceeding by far the vP criteria according to Annex XIII criteria of REACH and of Annex I of CLP Regulation (Regulation (EC) 1272/2008). This persistence is the result of the perfluoroalkyl moieties they contain and the high stability of the C-F bond. All PFAS can therefore be considered either persistent themselves or able to transform into persistent PFAS degradation products or so-called arrowheads. In addition, many PFAS have shown other properties triggering additional concerns such as bioaccumulation, mobility, capability for long-range transport, and (eco)toxicity. Many volatile PFAS-compounds have high global warming potential. These properties are not, however, homogenous across all PFAS.

RAC agrees with the Dossier Submitter on the grouping based on structural similarity that triggers the same concern of the very persistent property for the whole group of PFAS. The grouping ensures that the restriction covers collectively the PFAS in their lifecycle, from stock

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and precursors to the terminal persistent breakdown products (referred to as 'arrowhead'). RAC also supports the need to consider the very persistent properties of PFAS together with other properties of concern (e.g.: mobility, eco-toxicity, bioaccumulation, long range transport and global warming potential, and human toxicity). These supporting properties, however, vary between the individual substances.

The chosen approach focusing on restricting the manufacturing, use and placing on the market of the whole group of PFAS aims to prevent the accumulation of permanent stocks of PFAS in the environment over time, which could potentially lead to adverse effects on ecosystems and human health. RAC agrees with the approach and highlights that also the technical challenges and high costs associated with removing PFAS from various environmental compartments underscore the necessity to regulate them. RAC has followed this same approach in the recent restriction of PFAS in fire-fighting foams (ECHA 2023a), which similarly to this restriction covers the whole group of PFAS as defined by OECD (2021) but limits its application to that specific use.

It is worth noting that the proposed grouping approach does not follow the so-called P-sufficient approach (Cousins et al., 2019) but those supporting properties triggering additional concerns in combination with being very persistent form the basis for the restriction proposal.

The hazards of PFAS are discussed further in the sections below when relevant. PFAS hazards have been also previously discussed in the recent RAC opinion on the restriction of PFAS in fire-fighting foams (ECHA, 2023a). However, polymeric PFAS and fluorinated gases were not addressed in detail in the RAC opinion on the restriction of PFAS in firefighting foams since they are not typically used for these applications. Hazards of fluoropolymers and fluorinated gases were also widely commented in the consultation on the Annex XV report. Therefore, special consideration is given to these compounds in the following sections.

It is important to differentiate between different types of perfluorinated polymers. The term "fluoropolymer" refers specifically to polymers with a perfluorinated carbon backbone. When only the term "fluoropolymer" is used in the opinion, then specifically fluoropolymers are meant. Side-chain polymeric PFAS do not have a perfluorinated carbon backbone but have perfluorinated side-chains and they are not included in the term "fluoropolymers". Side-chain fluorinated polymers are considered to degrade as arrowhead PFAS and, therefore, are considered as PFAA precursor substances (OECD, 2021). Perfluoropolyethers (PFPEs) constitute a subset of polymers made of perfluoroether monomers with a main use as lubricant, oil and water repellent. They differ from the fluoropolymers as they consist of a carbon-oxygen backbone with fluorine atoms directly attached to the carbon atoms (Plastics Europe, 2021) and many of them may have low molecular weight, even below 1000 Da. It is also important to differentiate perfluoroether non-polymers used as polymerisation aids in the manufacturing of polymers (like HFPO-DA<sup>3</sup> and 4,8-dioxa-3H-perfluorononanoic acid<sup>4</sup>) from these PFPE polymers. These are covered under non-polymeric PFAS.

### Persistence

According to the Dossier Submitter, the main concern in the case of PFAS and/or their degradation products is their very persistent (vP) property, exceeding by far the P and vP criteria according to Annex XIII criteria of REACH. Therefore, all PFAS in the scope of this restriction proposal are either very persistent themselves or degrade into very persistent PFAS in the environment. As depicted in Figure 1 of section 1.1.1. in the Background Document,

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<sup>3</sup> EC 236-236-8; also known as GenX

<sup>4</sup> EC 700-835-7; also known as ADONA

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numerous PFAS exhibit non-fluorinated moieties tethered to the perfluorinated moiety. Throughout degradation processes, these non-fluorinated moieties undergo transformation, with oxidative processes typically resulting in the gradual conversion of non-fluorinated carbon atoms into CO<sub>2</sub>, which is subsequently emitted into the atmosphere. Simultaneously, the structure of the degrading substance diminishes progressively. Ultimately, the majority of the non-fluorinated components are fully degraded, leaving the perfluoroalkyl portion intact, often bound to a functional group at its maximum oxidation state (e.g., carboxylic acid).

The very persistent property of PFAS is due to their carbon-fluorine bonds, which are the strongest carbon-halogen bonds in nature. The resistance to degradation of the perfluoroalkyl moiety is primarily due to the high electronegativity and low polarisability of fluorine, which results in the strongest covalent bond known to organic chemistry: the C-F bond (Kissa, 2001). Multiple C-F bonds on the same geminal carbon lead to additional strengthening of the C-F bond.

RAC notes that the very persistent property of PFAS has been clearly demonstrated either on the basis of their own very persistent properties or the very persistent properties of their terminal degradation product (arrowhead). In Section 4.1 of Annex B of the Background Document, the Dossier Submitter provides comprehensive evidence based on experimental studies and QSAR information on the persistence of PFAS with different chain lengths and chemical structures. This applies also to side-chain fluorinated polymers, where their backbone is degradable but the fluorinated side-chains are expected to form persistent arrowhead PFAS and polymers which have been proven to be very persistent under environmental conditions.

In line with this, RAC has previously made detailed evaluations of the persistence and degradation pathways of PFOA (ECHA, 2018a), C9-C14 PFCAs (ECHA, 2018b), PFHxS (ECHA 2020a), PFHxA (ECHA, 2021a) as part of the REACH restriction process. These were all found to fulfil the P and vP criteria according to REACH Annex XIII. The recent RAC opinion on PFAS in firefighting foams (ECHA, 2023a) concluded that the very persistent property is common to the whole PFAS group.

Fluoropolymers and Perfluoropolyethers are generally known to be very persistent under environmental conditions. For example, Henry et al., (2018) examined four fluoropolymers (PTFE, ETFE, FEP and PFA) and concluded that these are stable under hydrolytic, light, oxidative, biodegrading (aerobic and anaerobic) and thermal conditions.

Fluorinated gases are also considered very persistent substances but differ from other PFAS types in that the environmental compartment in which they normally reside and degrade is the atmosphere. In Section B.4.1.3.2 in Annex B of the Background Document the Dossier Submitter provides a comprehensive analysis of the different degradation pathways of fluorinated gases including Hydrofluorocarbons (HFCs) and hydrofluoroolefins (HFOs), Hydrofluoroethers (HFEs), Perfluoroalkyl ketones and Perfluoroalkyl nitrile compounds. The results of degradation differ among fluorinated gases (e.g. 100% TFA yield is assumed for HFO-1234yf, 2-30% for HFO-1234ze), but they all degrade into persistent degradation products. TFA later precipitates in rain and snow. Other persistent degradation products that might be formed include longer chain substances like PFBA which may be formed e.g. from the hydrofluoroether HFE-7100 (C<sub>4</sub>F<sub>9</sub>OCH<sub>3</sub>).

Lack of persistence of certain HFOs and HCFOs (e.g. HFO-1234yf, HFO-1234ze, HCFO-1233zd) and their degradation products has been suggested in several comments provided in the consultation on the Annex XV report (e.g. #4015, #4083, , #4234, #4288, #4488, #4624, #6195, #6316, #6321, #6324, #6360, #6640, #6735, #6771, #6772, #6860,



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#6917, #6994, , #7379, #7426, #7694, #8100, #8285, , #8947, #8948, #8950, #8967, #9004, #9062, #9080, #9101, #9188, #9203, #9268, #9355 and #9360). These comments argue that these compounds only transform to a very small extent to TFA.

RAC recognises that TFA yield of the above compounds varies between substances. Certain fluorinated gases (e.g. HFC-134a, HFC-125, HFO-1234yf) have been shown to form TFA as a significant degradation product and can be considered as major contributors to environmental emissions of TFA (MP/EEAP, 2023). TFA yields of some other fluorinated gases is lower (2-30% for HFO-1234ze and HCFO-1233zd, 4-60% HFO-1336mzz; see e.g., Madronich et al., 2023 and the sector-specific opinion on "Applications of fluorinated gases"). Further, a theoretical evaluation of the atmospheric degradation of 2-BTP ( $\text{CH}_2=\text{CBr}-\text{CF}_3$ ), submitted during the consultation of the Annex XV report (comment ID #8967), suggested that TFA might form in minor quantities, ranging from 0.27 to 0.32%. However, this theoretical assessment has not yet been confirmed through experimental studies. According to research by Patten et al. (2011), 2-BTP has an estimated atmospheric lifetime of about four days. Key oxidation products identified include TFA, bromine, formaldehyde,  $\text{CF}_3\text{C}(\text{O})\text{CH}_2\text{OH}$ , and  $\text{CF}_3\text{OH}$ . The distribution of these fluorinated species is influenced by the dynamics of wet deposition compared to the OH radical-mediated reactions of the intermediates. This interaction highlights the complexity of predicting environmental impacts based solely on theoretical data, underscoring the need for empirical validation to accurately assess the environmental fate of such compounds.

Nevertheless, RAC emphasises that the criteria for the identification of PBT/vPvB substances as described in the Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.11 (PBT/vPvB assessment. Version 4.0, December 2023) apply to all relevant constituents, impurities, additives and transformation/degradation products. There is no w/w threshold concentration below which a transformation/degradation product would not be considered a concern. In the same guidance it is stated that constituents, impurities and additives should normally be considered relevant for the PBT/vPvB assessment when they are present in concentration of  $\geq 0.1\%$  (w/w) (ECHA, 2023b). Therefore, even with a lower range yield of TFA of a 2%, such fluorinated gases would be considered very persistent. It is also worth mentioning that whatever the source of TFA in the atmosphere is, it will contribute to a continuous increase of TFA concentrations in the environment. RAC further notes that TFA is not the only degradation product of fluorinated gases.

RAC therefore agrees with the Dossier Submitter evaluation and concludes that PFAS are very persistent, either on the basis of their own persistent properties or the persistent properties of their terminal degradation product (arrowhead). However, there might be some exceptions to this general rule, which are discussed in the following chapter. The very persistent property of PFAS is concerning because the continued use and release of these substances results in sustained exposure and the accumulation of stocks within the environment. The prolonged presence of PFAS in the environment inevitably leads to their distribution from one environmental compartment to another. The persistent PFAS stocks will result in increasing likelihood that known and unknown effects occur, be it by a single chemical and/or in a mixture with other substances (e.g., Bil et al., 2021). Even if releases are minimised now, PFAS will remain in the environment for a very long time and their remediation is very costly and difficult.

PFAS that may be excluded from the scope as non-persistent

According to the Dossier Submitter, there are a few specific PFAS subgroups with certain structural elements that are fully degradable and cannot form persistent PFAS arrowheads. These substances contain the following structural elements:  $\text{CF}_3\text{-X}$  or  $\text{X-CF}_2\text{-X}'$ , where  $\text{X} = -$

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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'''; 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)-). The underlying hypothesis provided by the Dossier Submitter is that complex molecules containing a trifluoromethoxy, trifluoromethylamino, difluoromethanedioxy-group attached to a degradable moiety will degrade into the corresponding non-persistent trifluoromethanol, trifluoromethylamine and difluoromethanediol, respectively. As the above three key perfluorinated compounds are chemically unstable, all compounds that lead to these substances during degradation, and no other perfluorinated degradation products, will degrade under any relevant environmental conditions. This is explained to be different from the PFAS subgroups included in scope for which persistence is based on the stability of the C-F bond.

RAC has evaluated the Dossier Submitter's proposal for excluding specific PFAS subgroups, focusing on the degradation potential of trifluoromethanol, trifluoromethylamine, and difluoromethanediol, as well as the degradation of more complex molecules incorporating these groups. RAC's evaluation is based on the criteria for the identification of PBT/vPvB substances as described in Annex XIII of REACH and ECHA Guidance R11.

For the case of trifluoromethanol, some degradation rates found in literature indicate that CF<sub>3</sub>OH likely disappears fast in the atmosphere. Yet, some studies also suggest potential persistence since depending on the presence of a catalyst, the rate of degradation of CH<sub>3</sub>OH can be slow leading to high DT50s (see Parandaman et al., 2018 and Nguyen et al., 2009). It remains therefore uncertain how fast CF<sub>3</sub>OH would degrade under different environmental conditions, at low substance concentrations and without the presence of catalysts, also considering that the photolytic lifetime of trifluoromethanol below 40 km in the atmosphere is on the million-year scale (Buszek and Francisco 2009).

For the other two molecules, trifluoromethylamine and difluoromethanediol, RAC notes they are likely unstable, although the information provided by the Dossier Submitter to justify this is limited. RAC further notes that fast degradation in the atmosphere represents a degradation process which cannot be used on its own for persistence assessment but may be used as part of a Weight-of-Evidence approach. However, the Dossier Submitter did not provide any evidence on whether these substances could partition to other compartments: water, sediment or soil.

For the studies presented, concerns arise regarding their relevance to conclude on the group exemption. In particular, RAC highlights the insufficiency of a few examples to justify a group exemption, especially when some contradict the Dossier Submitter's hypothesis and only a subset of them (the soil simulation study, the inherent biodegradation study and the hydrolysis data) can be considered as relevant tests for persistency assessment in accordance with Annex XIII of REACH. RAC notes the rest of the studies were performed under conditions that either RAC cannot unequivocally relate to the standard methods used for persistency assessment (e.g.: see Peschka et al 2008 and the fixed bed bioreactors tests) or which are far from relevant conditions (Alexandrino et al 2020 and Bygd et al 2021).

Among the studies that contradict the Dossier Submitter's hypothesis, RAC notes that in the case of fludioxonil (a difluoromethanedioxy-derivative) its degradation rates in soil and sediment lead to the consideration of the substance as very persistent (see ECHA 2017, EFSA Journal 2007).

In another study (Fromel and Knepper 2015), 3-(trifluoromethoxy)-propan-1-ol (TFMP<sub>OH</sub>) only mineralised to the extent of 15% and transformed into a metabolite (3-trifluoromethoxy-propanoic acid) which did not show any further degradation under test conditions within a 47

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days period. This metabolite is a PFAS and could be potentially P/vP in the environment.

Similarly, in Peschka et al 2008, 10-(trifluoromethoxy) decane-1-sulfonate degraded to a PFAS metabolite (oxidized 10-(trifluoromethoxy)decane-1-sulfonate) which remained stable during the test duration. RAC notes that in this test a Fixed Bed Bioreactor was utilized in order to determine the biodegradability of the substance under aerobic conditions. This test set up may favor degradation in comparison to standard OECD 301 and 310 tests due to their operational advantages and the ability to optimize the microbial community. Yet, under these conditions a potentially P/vP metabolite was formed (see further analysis in the Annex to the opinion below).

At the same time some of the studies presented showed a potential for degradation (mineralisation) of certain PFAS substances. These studies, however, have uncertainties that prevent RAC from reaching a firm conclusion. For instance, Peschka et al 2008 also showed that 10-(trifluoromethoxy)decane-1-sulfonate was inherently biodegradable in a Zahn-Wellens test with a degradation > 75% in less than 28 days. As the degradation was not  $\leq 20\%$  the results do not suggest that degradation in the environment would be slow (ECHA Guidance Document R.11<sup>5</sup>). Unfortunately, based on the information provided it is not possible to conclusively determine whether the criteria outlined for not fulfilling the persistence (P/vP) criteria for an inherent test are met. Essential details such as the percentage of mineralisation within 7 days, the length of the log phase, and the percentage removal before degradation starts are not specified in the paper.

The soil degradation study performed according to OECD 307 with <sup>14</sup>C radiolabelled trifluoromethoxy derivative (confidential comment), shows rapid and extensive mineralisation of the CF<sub>3</sub>-labelled moiety. Thus, the parent substance can be considered not P/vP in soil based on the mineralisation half-lives calculated from 0-28 days. Also, DegT<sub>50</sub> values calculated from the decline of parent substance concentration are below the Annex XIII P/vP thresholds.

However, some uncertainties exist mainly due to the substantial NER (non-extractable residues) fraction that was formed and the fact that NERs were not further characterised into Type I, II or III; therefore, it cannot be excluded that total NER fraction includes Type I NER which might include parent and/or transformation product with a -CF<sub>3</sub> group. Further, when considering the total NERs as non-degradable parent substance, the Parent+NER modelling gives a DegT<sub>50</sub> above the P trigger in one soil.

Therefore, while the parent substance shows rapid degradation and can be considered not P/vP in soil based on the mineralisation half-lives calculated from 0-28 days, some uncertainty remains related to the nature and relevance of the NER fraction and the possibility that a second transformation route forms a very persistent transformation/degradation product in concentrations relevant for the P assessment (please see the Annex II to this Opinion for a more comprehensive analysis of this study).

Overall, RAC acknowledges that the weight of evidence presented by the Dossier Submitter suggests that some PFAS within the exemption group may not exhibit the very persistent properties typically associated with PFAS, which is the primary concern for the proposed restriction. Moreover, the evidence suggests that there are PFAS that may not be persistent (at least in one environmental compartment, e.g., soil). However, RAC disagrees with the Dossier Submitter that the available evidence leads to the conclusion that all PFAS from the

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<sup>5</sup> [https://echa.europa.eu/documents/10162/23047722/ir\\_csa\\_r11\\_msc\\_bpc\\_en.pdf/f43d277c-835e-a208-5c51-53c5826f0845](https://echa.europa.eu/documents/10162/23047722/ir_csa_r11_msc_bpc_en.pdf/f43d277c-835e-a208-5c51-53c5826f0845)

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subgroups described above are expected to fully mineralise in the environment and can therefore be excluded from the restriction.

RAC notes that for excluding the vP concern driven by the stability of the C-F bond, sufficient evidence, e.g. based on ready biodegradation data, inherent degradation data fulfilling certain conditions or data on degradation rates/half-lives should be available and representative for degradation in all environmental compartments (water, water-sediment and soil) for relevant conditions (see ECHA, 2023b). This evidence is not comprehensively provided by the Dossier Submitter. Neither sole hydrolysis data nor fast degradation or instability in one compartment (atmosphere) or degradation under very specific conditions (see for instance Bygd et al 2021, Alexandrino et al 2020 or Peschka et al 2008) are sufficient to render a substance automatically as non-persistent according to REACH Regulation Annex XIII (Regulation (EC) 1907/2006). In the absence of adequate data to exclude the P/vP concern, a substance can be generally considered “potentially P/vP” whereas a definitive conclusion P or vP is possible only when there is sufficient data to indicate that Annex XIII criteria are fulfilled.

Further, RAC notes that degradation data of a particular substance within a subgroup does not necessarily justify extrapolation of non-persistence to other substances in the group. A case needs to be built to demonstrate how degradation data of a particular substance and the conclusion that a PFAS is not very persistent can be extrapolated to other group members, taking into account how different chemical structures (e.g.: branching and alkyl chain length) would affect degradation rates and pathways and the stability of the C-F bond. No conclusive evidence is provided in this sense. On the contrary, evidence shows that some of the claimed fully degradable PFAS such as Fludioxonil exhibit very persistent properties with half-lives in soil of almost two years and half-lives in water sediment of 2.3 and 3.6 years. Additionally, some proposed PFAS degraded in the performed tests into PFAS metabolites (oxidized 10-(trifluoromethoxy)decane-1-sulfonate and 3-trifluoromethoxy-propanoic acid) that could be potentially very persistent themselves.

Following the above, RAC does not support the group exemption proposed by the Dossier Submitter.

RAC notes that, during the consultation on the Annex XV report, several comments have addressed the proposed exemption.

Some of the comments expressed concerns about the exemption for degradable PFAS. These comments reflected among others, that the exemption might be too wide, pointing also to the fact that the Dossier Submitter has not explained how different chemical structures (branching and alkyl chain length) would affect degradation rates and pathways of different substances.

One confidential comment provided supporting evidence to the proposed exemption including the finalised version of the soil degradation study performed with a PFAS substance. RAC has evaluated this study in detail in the Annex II to this Opinion.

### Mobility

The Dossier Submitter has summarised the available data concerning adsorption/desorption and mobility of PFAS in Section 1.1.4.4 and Annex B.4.2.1 of the Background Documents. Substances with a moderate to high solubility in water combined with a low adsorption potential can be considered to have a high mobility in the aqueous environment. In particular, short-chain PFAAs and many long-chain PFAAs can be considered mobile in water. Moreover, the degradation of precursor-PFAS in the environment to PFAAs also render the precursors mobile in water at some point of time. For instance, fluorinated olefins and alkenes, though not inherently mobile, undergo degradation into PFCAs, as outlined in Annex B.4.1.3 of the Background Document, becoming mobile. The same occurs, e.g. to side-chain fluorinated

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polymers.

In its analysis, the Dossier Submitter considered all PFCAs with carbon length up to 11 as mobile or very mobile since they have a  $\text{Log } K_{oc} \leq 4$  or  $\leq 3$ , respectively. PFSAAs up to 6 carbons and PFPAs are similar in mobility to PFCAs based on  $\text{Log } K_{oc}$  values. Overall, data for PFCAs, PFSAAs and perfluoroalkylphosphonic acids indicate that there is a trend of increasing  $\text{Log } K_{oc}$  values with increasing chain length (e.g. PFCAs  $\text{Log } K_{oc}$  0.437-3.3, PFSA 0.352-3.675). For perfluoroalkylamines, only 1,1,1-Trifluoro-N,N-bis(trifluoromethyl)methanamine (PFMAM) fulfils the M criterion based on the  $\text{Log } K_{oc}$  value. With the exception of  $\text{C}_4\text{F}_{10}\text{O}_2$  all perfluoroethers fulfil either the vM or M criterion based on their  $\text{Log } K_{oc}$  values.

RAC notes the above assessment is based on UBA (2019) criteria for mobility which establishes that a substance is mobile when it has a  $\text{Log } K_{oc} \leq 4$  and very mobile with a  $\text{Log } K_{oc} \leq 3$ . However, the recently adopted classification criteria for M/vM under CLP considers a substance as M when  $\text{Log } K_{oc}$  is  $< 3$  and very mobile when  $\text{Log } K_{oc}$  is  $< 2$ . Adsorption properties measured by the  $\text{log } K_{oc}$  reflect the potential of a substance to be adsorbed on the organic fraction of environmental matrices such as soil, sludge, sediment particles, and other organic matter. If the substance dissolves well in n-octanol (indicating hydrophobicity), then it generally has high  $\text{log } K_{oc}$ .  $\text{Log } K_{oc}$  is inversely related to a substance's potential of entering and be mobile in water bodies.

RAC observes that the carbon-fluorine bond in all PFAS compounds, whether precursor or arrowhead, is exceptionally robust, imparting physical traits such as high water and oil repellence. These characteristics render many PFAS substances highly mobile within the natural environment as well as persistent.

RAC agrees that short-chain PFAAs and many long-chain PFAAs can be considered mobile in water. Perfluoroalkanes with chain length of 4 carbons have boiling points below  $0^\circ\text{C}$ , hence it is more likely that these short-chain PFAS evaporate into the air when released to the environment.

Many PFAS belong to the precursors of PFAAs, which have been demonstrated to be either mobile or very mobile. Hence a large part of PFAS can be considered as mobile in water, either by themselves or as a result of their degradation into PFAAs. RAC also highlights that experimental data on mobility is mainly limited to the arrowhead substances (e.g. PFCAs, PFSAAs, PFPAs). Uncertainties remain regarding mobility of several other groups of PFAS in water. Fluoropolymers are not considered to be mobile.

Three PFAS have been accepted as being mobile so far under REACH:

- PFBS was identified as a substance of very high concern based on very high persistence, high mobility in water and soil, high potential for long-range transport, and difficulty of remediation and water purification as well as moderate bioaccumulation in humans (ECHA, 2019a)
- HFPO-DA has been identified as a substance of very high concern based on its equivalent level of concern due to its mobility and persistence (ECHA, 2019b);
- RAC has agreed that PFHxA, its salts and related substances possess properties, in particular very high persistence combined with mobility, that can be considered to constitute an intrinsic hazard (ECHA, 2021a).

PFAS mobility is also supported by monitoring data. Several PFAS have been found in fresh and ocean water as well as in groundwater and drinking water indicating their mobility. This is the case, for instance, of TFA, which has a  $\text{Log } k_{oc}=0.79$ , and for which recent reports have shown increasing TFA load in rainwater, surface water and spring water (Cahill et al 2022, UBA, 2021 and UBA, 2023), see restriction Dossier Annex B). In fact, available data indicate

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that TFA generally occurs in considerably higher concentrations than other PFAS in aquatic samples. Notably, research by Neuwald et al. (2022) and Sadia et al. (2023) identified concentrations in the order of 1 µg/L surpassing the limits given by the European Drinking Water Directive (Directive (EU) 2020/2184) (information received in the consultation on the Annex XV report, e.g., comment #9213). RAC notes that this Directive, implemented on 12 January 2021, sets a limit of 0.5 µg/L for the total concentration of all PFAS.

Although TFA present in sea water could be derived also from natural sources (Frank et al., 2002, Scott et al., 2005, Solomon et al., 2016) the evidence of this is questioned by some authors (Joudan et al., 2021). There seems to be less doubts on the anthropogenic origin of TFA present in freshwater as the only possible source (Frank et al., 2002, Fleet et al., 2017).

Also, other less studied PFAS such as 8:2 Cl-PFESA, 6:2 H-PFESA and 6:2 FTSA have been ubiquitously detected worldwide in surface waters (Wang et al., 2019). Besides the few routinely analysed PFAS, a large fraction of the total organofluorine in drinking water remains unidentified. This shows that drinking water may contain PFAS which cannot be currently identified and quantified.

Overall, RAC agrees with the Dossier Submitter that mobility of PFAS in the environment is another key concern since it contributes to the long-range transport potential of PFAS in water, their uptake in plants and crops and the potential to contaminate drinking water. For mobile substances there are no clear sinks for the pollution stock. Their only sink is fresh and salt water where concentrations can continuously increase posing a potential threat to wildlife and humans. RAC however notes that high-molecular weight fluoropolymers are not water-soluble and are not considered as mobile.

### Long range transport potential

Due to the intrinsic properties of PFAS, their contamination is not geographically limited. PFAS can be transported by air, water or by matrices and organisms to which they are adsorbed or absorbed, such as dust, sediments or migratory animals. The movement of their carriers leads to global drift of PFAS over long distances from the point of release. According to the Dossier Submitter, three main hypotheses are currently proposed for the global transport of PFAS:

- Non-charged, volatile precursor PFAS compounds could undergo long-range atmospheric transport and be degraded to persistent arrowhead PFAS being deposited via wet or dry atmospheric deposition in atmosphere and reaching remote areas (Ellis et al., 2004; Martin et al., 2006; Schenker et al., 2008; Wong et al., 2018).
- Ionic and water soluble PFAS could be transported directly by river waters into estuaries and coastal waters.
- Additionally, PFAS can be transported by particles to which they are adsorbed or absorbed, such as dust or sediments. Moreover, a long-range transport of PFAS may occur by biota e.g. migratory birds.

Because of the complex interaction between a substance and the different environmental compartments, the long-range transport potential will not be limited to one single compartment. Also, the long-range transport pathway may differ between the precursor and the arrowhead. For instance, volatile PFAS such as fluorinated gases are mainly transported via air although water becomes the main pathway when degrading into TFA. The long-range transport via water is the predominant pathway for anionic PFAS like PFCAs and PFSA. Likewise, plastic debris could be an important vector for adsorptive PFAS. RAC notes, however, that for many PFAS there is no data on transport pathways or point sources, adding a level of uncertainty on the magnitude of the global drift of PFAS.

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RAC concurs with the Dossier Submitter on the long-range transport potential of PFAS as evidenced by their widespread distribution around the globe and highlights the comprehensive evidence provided in sections from B.4.2.1 to B.4.2.8 of Annex B showing the presence and ubiquity of PFAS in diverse environmental compartments and biota, including very remote areas. For example, several studies have demonstrated the presence of a number of PFAS in ground and ocean waters, as well as in drinking water (Kabore et al 2018, Wang et al 2019, Pan et al 2018, Joeris et al., 2019, Liu et al., 2019, Bach et al., 2016a), Gyllenhammar et al., (2015), etc.). Similarly, measurable levels of several PFAS have been reported in soils, not only from sites near the point sources of emissions but also from remote areas further away from known sources (Ng et al. 2022, (Brendel et al., 2018), Strynar et al. (2012), Rankin et al. (2016), Hunter Anderson et al., 2019) and in biota (Spaan et al. (2020), Barrett et al. (2021). Calculated characteristic travel distances of for example FTOHs and PFCAs can reach thousands of kilometres in air and water. As shown by the data, in addition to long range transport potential another major concern is the migration potential from compartment to another; e.g. from soil to surface and groundwater, and the atmosphere resulting in human exposure via the soil-groundwater-drinking water path or the soil-groundwater-nutrition (plant or animal) path.

PFAS found in these studies, using targeted analytical methods, include not only those PFAS (PFOA, PFOS, PFHxS, PFHxA and C9-C14 PFCAs) already regulated under REACH or POPs Regulations (Regulation (EC) 1907/2006 and Regulation (EU) 2019/1021, respectively), but also a number of  $\geq$ C4 PFCAs and  $\geq$ C4 PFSA not covered by existing or other proposed restrictions. Less data is available on short (C1-C3) PFAAs, cyclic PFAAs, PFPA or PFAEs but also these data provide support for the mobility and potential for long-range transport of these compounds in the environment. Although many data on the environmental levels of PFAS come from targeted studies that can detect only a subset of PFAS, there are data from studies using total organic fluorine method and non-target/suspect screening methods, indicating contamination of environmental compartments with other (unidentified) PFAS not captured by targeted analyses.

Although, high-molecular weight fluoropolymers are not soluble in water and n-octanol, and not considered to fulfil the mobility criteria, fluoropolymer particles have a potential for long-range transport via waterways contributing to the transboundary pollution problem. Fluoropolymer microparticles have been found in the environment and biota in several ecosystems, including remote areas. For instance, Bergmann et al. (2017) investigated microplastics in sediment samples from the Arctic. Samples were collected at 2 340 – 5 570 m water depth and eighteen different polymer types were identified in total from all sediment samples. In the larger size fraction  $>500\mu\text{m}$ , all analysed particles were PTFE.

Capillo et al., (2020) analysed microplastics also in demersal fish from the Southern Tyrrhenian area (Central Mediterranean). Five polymers were identified, among them PTFE. The major contaminant that affected examined individuals was represented by polytetrafluoroethylene (PTFE, 75%) in *mullus barbatus* which is widely regarded as a bio-indicator species due to its benthic behaviour, habitat and feeding modalities and its reduced mobility.

Aves et al., 2022 collected snow samples from 19 sites across the Ross Island region of Antarctica and PTFE was among the microplastics found. To investigate sources, backward air mass trajectories were run from the time of sampling. These indicate potential long-range transportation of up to 6000 km. Local sources may include fragmentation of plastic equipment from research stations, clothing worn by base staff and researchers, and mismanaged waste.

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Finally, Park et al., 2022 studied the occurrence and characteristics of microplastics in fish of the Han River, South Korea. Most common polymer types found in 106 fish from 22 species were polypropylene (PP) ( $\geq 40\%$ ) and polyethylene (PE) ( $\geq 23\%$ ), followed by polytetrafluoroethylene (PTFE) ( $\geq 16\%$ ) at all sampling locations.

Overall, RAC agrees that the presented evidence supports the conclusion that many PFAS have potential for long-range transport mainly due to their high persistence, mobility in water and volatility. Also, high-molecular fluoropolymers can be transported long-distances via waterways. The long-range transport pathways will differ depending on the PFAS and may change when a precursor degrades to the corresponding arrowhead. The combination of the very high persistence of PFAS, their mobility and long-range transport potential will trigger specific challenges to decontamination.

### Bioaccumulation and accumulation in plants

Available data on the bioaccumulation potential of various PFAS have been summarised in Annex B.4.2.9, while monitoring data also provide information on bioaccumulation in the field as outlined in Annex B.4.2.6. and Annex B.4.2.7 of the Background Document. Accumulation in plants is discussed in Annex B.4.4. RAC previously discussed bioaccumulation of PFAS in the RAC opinion on the proposal to restrict PFAS in fire-fighting foams.

In general, the toxicokinetic behaviour of PFAS is governed by adsorption and distribution among protein-rich tissues (especially liver, serum, kidney) and thus, the toxicokinetic behaviour of PFAS differs considerably from the traditional hydrophobic chemicals. In this sense, the use of LogKow to predict bioaccumulation potential cannot be easily applied to many PFAS (e.g., PFAAs) due also to their surfactant-like properties.

Many well-studied PFAS are, for instance, transferred to the foetus via eggs and later via the placenta in mammals, and to the offspring via breast milk. Also, analyses of biota at different trophic levels of ecosystems clearly show that many of the currently well-studied PFAS bioaccumulate and biomagnify to high concentration levels in top predators (Simonnet-Laprade et al., 2019, De Silva et al., 2021, Chen et al. (2021), Müller et al., 2011; Zhao et al., 2013c). According to the Dossier Submitter, the characteristics related to the bioaccumulation and toxicokinetic behaviour of PFAS are related to protein binding and structure. However, the relationship between structure (e.g. chain length) and affinity to proteins is complex and thus still a matter of research.

The available data on PFAS bioaccumulation is based on a relatively small number of compounds. C11-C14 PFCAs and C6-PFSA, for example, have been shown to fulfil the vB-criterion and C8-C10-PFCA the B criterion of REACH Annex XIII. Recently, also PFHpA (C7-PFCA) has been added to the SVHC list based on - among others - PBT (art 57d) as well as vPvB (art 57e) properties while PFOA (C8-PFCA) has been formally concluded as POP under the POPs Regulation whose B criterion of 5000 L/kg equals the vB criterion under REACH. RAC notes that in the case of PFCAs and PFSAs, the carbon chain length affects the bioaccumulation ability with higher chain length compounds fulfilling B/vB criteria ( $>C6$  for PFSA and  $>C8$  for PFCA). Shorter carbon chain substances have not shown bioaccumulation in fish and seem also to have shorter elimination half-lives in air-breathing organism when compared to the long chain compounds.

However, there is wide variability between substances and between species. The available data on BCFs and BAFs in freshwater species from 22 taxonomic classes have been summarized by Burkhard (2021). Among the 43 PFAS compounds for which BCF and BAF studies are available in different aquatic species 62% (27 compounds) have a median  $\pm$  SD BCF and/or BAF values above the REACH threshold for B ( $\log BCF > 3.3$ ). BAFs seemed to be higher than BCFs in 60% of the cases probably due to multiple exposure routes in the field



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conditions. Air-breathing organisms are likely to show higher bioaccumulation potential when compared to gill-breathing organisms. High affinity to proteins seems to contribute to the bioaccumulation potential of PFAS whereas accumulation in lipids is not relevant. Significant species differences have been shown also between the different mammalian species; there is e.g. wide variation in the half-lives of various PFCAs or PFSAAs between mice, rats and humans.

Besides PFCAs and PFSAAs, RAC notes that the information on the bioconcentration potential of other main groups of PFAS is more limited, although some data exists e.g. on some PFPAs, fluorotelomers and PFESA/PFECAs (like HFPO-DA). PFPAs seem to have generally higher bioaccumulation potential than PFSAAs and PFCAs. Data on biomonitoring studies in different species and especially apex predators provide supporting evidence on the accumulation and biomagnification of specific PFAS, like PFOS, in the food chain. Novel analytical techniques also demonstrate the presence of emerging PFAS such as 7:3 FTCA or 6:2 Cl-PFESA in biota (e.g. George et al., 2023).

Similarly, there are testing data on the accumulation of PFAS in plants covering mainly PFCAs and PFSAAs, although some data exists also on other PFAS like some diPAP compounds, FTOH, fluorotelomer sulfonic acids, some PFAPs and PFAEs. Uptake of PFAS in plants has been observed in field studies in contaminated sites. In another study (UBA 2021b), growing concentrations of trifluoroacetate (TFA) were found in archived leaf samples of various tree species, with a two-to-five-fold increase between 1995 and 2018. As discussed in a review by Li et al (2022) and also in RAC opinion on PFAS in fire-fighting foams (2022), there is, however, a wide variability in the bioaccumulation of different PFAS in different plants.

Overall, RAC agrees with the Dossier Submitter that there is a justified concern that many PFAS are bioaccumulative. However, uncertainties remain due to a lack of data for a large proportion of PFAS. In addition, it is recognised that there is variability in the bioaccumulation potential of individual PFAS with some short carbon chain PFAS showing low bioaccumulation potential. RAC also notes that high molecular weight fluoropolymers and perfluoropolyethers are unlikely to bioaccumulate unless they break down into smaller oligomers or micro-/nanosized particles able to cross biological membranes.

### Persistence compensating low bioaccumulation potential

RAC considers that the high persistence of mobile PFAS can be a more critical aspect than any low bioaccumulation potential when evaluating the accumulation of a PFAS in the environment and in biota. This is also in line with a similar approach taken on its opinion on the microplastics restriction (ECHA, 2020b).

The main point is that accumulation in environmental media is a time-dependent process that depends on the rate of input (release, transport from other compartments, uptake in case of biota) and rate of removal (degradation, transport to other compartments and elimination in case of biota). Assuming a continuous release rate of a substance, the ultimate steady-state concentration reached in a given environmental compartment is a balance of these parameters. If the substance is mobile and has a high persistence, the levels of that substance gradually increase and may reach critical levels over time. To support this, modelling data by Crookes and Fisk (2018) and Cousins et al (2019) (see annex B, section B.4.3 of the Background Document) are presented. These modellings demonstrate the accumulation of substances with varying half-lives and BCFs/partition coefficients in the environment over time.

According to the modelling performed by Crookes and Fisk (2018) similar steady state levels in the biota can be reached in 5.5 years with a substance with BCF of 800 but with half-life of 1 year as with highly bioaccumulative (BCF 5000) but short half-life (60 d) substance. As the Dossier Submitter explains, this means that, for a given release rate, the longer the

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persistence of a substance is, the higher are the concentrations that could be reached in an exposure medium, and the lower the bioaccumulation potential would need to be to reach a given concentration in biota exposed to that medium. This model would be applicable to very persistent and mobile PFAS substances. Nevertheless, as the authors do not describe the applicability domain or uncertainties of the models, the results should be interpreted with caution.

Similar observations were made by Cousins et al (2019) by modelling the fate of substances with different properties: the higher the persistence of a chemical, the longer the time-to-steady state, the higher the steady-state concentrations, and the greater the long-lasting contamination tail after the end of the emissions. They also observed that the partition coefficients do not modify these general implications of high persistence. If the degradation half-lives are long in all media, the persistence related concerns are present irrespective of the values of the bioaccumulation properties of the substance.

RAC agrees with Dossier Submitter and considers that substances that are both persistent and mobile in the environment have the potential to be transported long distances from the point of emission and to be accumulated in biota and the environment irrespective of their physical-chemical properties.

### Ecotoxicity, effects on wildlife and environmental endocrine disrupting properties

The Dossier Submitter has reviewed available scientific literature on PFAS ecotoxicity and the PFASTox Database to get an overview of PFAS ecotoxicity and ecotoxicological threshold values reported in the scientific literature. These have been summarised in Table B.14 of the Annex B of the Background Document. RAC notes that most of the data on effects to aquatic species comes from PFCAs and PCSAs, for which toxicity has been studied mostly in freshwater invertebrates, which is generally the most sensitive trophic level and fish. In general, toxicity of the studied PFCAs and PFSA increases with the increasing carbon chain length (becoming more lipophilic), and perfluorosulfonates show higher toxicity compared to perfluorocarboxylates of the same chain-length (this pattern is also applicable to terrestrial invertebrates). 6:2 FTOH has been recently evaluated by RAC and warranted a classification of Aquatic Chronic 1 (ECHA, 2021b).

Data on terrestrial species (including birds) is limited and covers mainly PFOS, PFBS, PFHxS and PFOA. For the case of amphibians, Ankley et al 2021 indicate that effects of PFAS on growth and development in early life stages have been reported for several species. For reptiles, Ankley et al. (2021) compiled 5 studies that investigated the effects of PFAS (namely PFOS and PFHxS). Effects from those studies encompass decreased growth of juveniles and decreased egg viability. In the case of birds, the toxicity pattern observed is comparable to that of rodents: PFAS with C8 carbon chains are more toxic than short-chain PFAS, and sulfonates are more toxic than carboxylates with the same chain length. In addition, there seems to be variation between bird species in the toxicity of these PFAS. A recent study demonstrated significant ecotoxicological effects of PFOA and PFOS on earthworms (Delor et al., 2023).

Additionally, the Dossier Submitter has studied the effects of PFAS on wildlife via the evaluation of field-based effects studies (Ankley et al., 2021) although a clear link between PFAS measurements in the environment or PFAS body burdens and the effects found could rarely be established. Complementary laboratory studies for such a purpose would be needed but are in most cases not available. In the absence of data on PFAS toxicity in mammalian wildlife, studies on laboratory mammals inform on the toxicity in mammalian wildlife (see health section).

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The Dossier Submitter argues that conventional ecotoxicological tests may not be suitable to detect long term effects from exposure to PFAS. PFAS can remain in the environment for long time periods (decades-centuries or even longer) due to their high persistence, however ecotoxicological test systems usually cover only short time spans (few days or weeks). Thus, without reliable data that is suitable to detect also long-term effects of PFAS including inter-generational effects after inter-generational exposure, it is not possible to demonstrate safe use of PFAS with the conventional ecotoxicological tests. These challenges have been demonstrated by e.g. PCBs, which bioaccumulate in food webs and have resulted in later reproductive effects on e.g. seals and white-tailed eagles (Cousins et al 2019).

RAC acknowledges that the dose levels showing adverse effects vary between the studies, organisms and exact compounds and notes that the available studies cover only a limited subset of PFAS and limited number of species. However, it is recognised that there is active research in this field and the available data is constantly developing. RAC agrees with the Dossier Submitter that conventional ecotoxicological tests lasting a few days or weeks may not be able to detect long term effects from exposure to PFAS across several generations (intergenerational effects through intergenerational exposure).

The Dossier Submitter has also performed a review of the available literature of the endocrine disrupting properties of PFAS in the environment. These data are summarised in Table B.17 (and further in Appendix B.7.5) of the Annex B of the Background Document. As can be seen from the tables, there are some studies addressing endocrine disrupting properties in 32 different PFAS. Only in four cases (FTOH, PFBS, Cl-PFESA and mixture of PFOA, PFOS, PFBS, PFBA) such in vivo data exists which can be considered to result in population level effects. RAC agrees with the Dossier Submitter that there are indications of the endocrine disrupting effects in the environment for some individual PFAS but the data cover only a limited subset of PFAS and it is not possible to generalize these findings to the whole group of PFAS.

### *SFAs/PFAs*

Semi- and perfluorinated alkanes are a special group of PFAS used in ski waxes, petroleum and mining and in medical applications (in eye drops and ocular tamponades). Semi-fluorinated alkanes have been classified according to OECD (2021) as PFAA precursors. RAC, however, notes that there is limited information whether they degrade to PFAAs in the environment. Some SFAs are volatile, which according to RAC's view may explain why they have not been found in soil close to skiing areas. RAC agrees with the categorisation of SFAs as PFAA precursors in line with OECD (2021). Industry argued for the low ecotoxicity of SFAs 1-(Perfluorobutyl)pentane and 1-(Perfluorohexyl)octane in comments submitted in the consultation on the Annex XV report and provided some supporting ecotoxicity data (confidential comment)). These comments also emphasised that unlike PFAAs and their precursors, SFAs do not contain functional groups like carboxylic or sulphonic acids or alcohols, which make PFAS water-soluble. According to the industry, this limits their toxicity.

Per-fluorinated alkanes (e.g. perfluorodecalin, C<sub>10</sub>F<sub>18</sub>, perfluoro-octane C<sub>8</sub>F<sub>18</sub>, hexafluoroethane C<sub>2</sub>F<sub>6</sub>, octafluoropropane C<sub>3</sub>F<sub>8</sub>) are categorised as "other PFAS" by OECD (2021). They are fully saturated with fluorine, are extremely stable as such and do not degrade as PFAAs in normal conditions (temperatures).

### *Fluorinated gases*

RAC notes that in the consultation on the Annex XV report, several comments have requested a separate hazard and risk assessment for various fluorinated gases (e.g.: HFO-1234yf, HFO-1234ze, HCFO-1233zd and TFA) based on their low ecotoxicity, lack of persistent properties and bioaccumulation and the fact that for these substances a classical risk assessment based on PEC/PNEC comparison could be performed.

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RAC notes that TFA has a harmonised classification for aquatic Chronic 3. 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.

RAC notes the earlier evaluation by UBA (2023), which concludes that the official classification for aquatic toxicity is conservative because the lowest acute value >100 mg/L and the lowest chronic value EC10 is 5.6mg/L for algae. Nevertheless, Fleet et al (2017) observed a unique sensitivity of *Raphidocelis subcapitata* to TFA, with a NOEC of 0.12 mg/L, although further confirmation through repeat testing was recommended. Additionally, data from the REACH registry shows a NOEC of 0.12 mg/L, though the endpoint appears to be based on yield rather than growth inhibition, which is not a recommended response variable according to OECD 201. Conversely, based on growth rate, the study reports only a 6% inhibition at the highest concentration tested (nominal concentrations: 1.2, 0.36, 0.12, and 0.036 mg/L). On this basis the substance does not seem to be toxic to algae. The most recent algae test in the REACH registry shows EC10 of 5.6 mg/l for algae (see above).

The toxicity of TFA for terrestrial plants can also be assessed as low (UBA, 2021). For terrestrial toxicity, RAC found two key studies performed according to the OECD 208 testing guideline to measure the effect of sodium trifluoroacetate (NaTFA) in soil on seed germination and early plant growth of sunflower (*Helianthus annuus*), Mung bean (*Phaseolus aureus*) and wheat (*Triticum aestivum*). Results show statistically significant decreases in the proportion of seeds which had germinated and emerged after 14 days, EC50s = 208 – 1000 mg/TFA per kg (UBA, 2023).

However, due to the persistence of TFA, it remains a long time in the environment once released. For this reason, its long-term toxicity on the environment cannot be fully predicted by the standard tests. Its potential reproductive toxic properties (see above) further highlight the concern for the environment. Furthermore, as the Norwegian Environmental Agency points out, there is no information on toxicity to organisms und in salt lakes and playas. This is particularly important because salt lakes are the most likely site for accumulation of TFA in the natural environment (Fleet et al 2017).

### *Fluoropolymers, PFPEs and oligomeric PFAS*

Several comments have also been provided during the Annex XV consultation on the low ecotoxicity of high molecular weight fluoropolymers. Some ecotoxicity data or references to specific ecotoxicity data e.g. on PTFE have been submitted supporting the low bioavailability and toxicity of fluoropolymers *per se*. RAC acknowledges this information and agrees that in case of high molecular weight fluoropolymers, their molecular weight, neutrality, lack of reactive functional groups and resistance to degradation limit their bioavailability and ecotoxicity.

It has been proposed that micro- and nano-sized polymeric particles can be formed during the use or waste stage and may therefore become bioavailable and result in ecotoxicological effects (Lohmann et al., 2020). RAC, however, notes that there is limited information available on the formation of micro- and nanoparticles in the environment during the end-use and waste stages of the fluoropolymer life-cycle.

Additionally, PTFE micro-powders, used as additives in lubricants (see sector-specific evaluation of lubricant uses), are an intentionally manufactured form of micro-sized fluoropolymer particles with particle size and molecular weight varying from 1-20 µm and 30,000-200,000D, respectively. Also, dispersions with 0.1-0.2 µm PTFE or FEP (fluorinated ethylene propylene) particles are available in the market for use in various coatings.

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RAC did not find any specific information on the cellular uptake or ecotoxicological effects of nano- or submicron-sized fluoropolymers. As pointed out in comments received during the consultation on the Annex XV report, micro-sized PTFE (average size of approximately 5 µm and 10-50 µm) have shown low bioavailability and no toxicity (e.g. Lee et al., 2022a).

RAC, however, notes that, particles with a size of 0.1-0.2 µm may more easily enter the cells than larger polymer particles. For example, polystyrene particles of about 0.1 µm of size have been shown to enter the cells (Jiang et al., 2011). Gaspar et al (2018) showed that 0.05 µm polystyrene particles were accumulating in oyster tissues, especially hepatopancreatic tissues. However, RAC recognises that also other particle properties, i.e. other morphological properties, chemical composition and surface properties (hydrophobicity, hydrophilicity, functional groups and charge) can affect the cellular uptake (Augustine et al., 2020, cited in annex B of the Background Document; Lee et al., 2022b).

The available data related to environmental hazards of micro- and nanosized polymer particles (in general) have previously been summarised and discussed in the case of the microplastics restriction (ECHA, 2020b) and was used as a justification in the restriction of microplastics together with the persistence of these polymer particles. As noted in ECHA (2020b) and in the Annex B of the Background Document, there are multiple acute/short-term ecotoxicity studies on micro- and nano-plastics (using mostly polystyrene or PE/PP particles) available. They suggest adverse effects in various organisms. However, the data on long-term effects of various types of micro- and nano-plastics is still limited. Also, specific data on fluoropolymer particles is lacking. It is, however, noted that the ecotoxicity of micro- and nano-plastics is currently an area of active ongoing research.

RAC also notes the information submitted in the consultation on the Annex XV report concerning the toxicity of fluoropolymer fumes resulting from overheating of non-stick cook wares to domestic birds. These effects may be related either to toxic byproducts due to pyrolysis or fine particulates. Also, in humans, toxic lung reactions caused by fluoropolymer fumes have been observed (see Annex B of the Background document).

PFPEs are specific group of polymeric PFAS which differ from fluoropolymers. They are typically liquids and some of them may have relatively low molecular weight (<1000 Da, OECD, 2024). Low molecular weight makes those substances potentially bioavailable. Functionalisation of PFPEs with specific end-groups modifies the physico-chemical properties and may affect their (eco)toxicity. Limited information available and submitted during Annex XV report consultation suggests low (eco)toxicity of specific PFPEs within a with range of average molecular weight. An example of a low molecular weight oligomeric PFPE is CAS 161075-00-9 (Hexafluoropropene, oxidized, oligomers, reduced, fluorinated), which is registered under REACH as a multi-constituent substance. It is a low molecular weight substance, which tends to volatilise easily. According to short term studies conducted on fish, invertebrates and algae it is not acutely toxic to aquatic organisms. Since it is not readily biodegradable and has a Log K<sub>ow</sub> equal to 5.58 and poor solubility in water, it has been classified as Aquatic Chronic Category 4 (Registration Dossier, CAS 161075-00-9 (Hexafluoropropene, oxidized, oligomers, reduced, fluorinated)).

### *Overall conclusions on ecotoxicity, effects on wildlife and environmental endocrine disrupting properties*

Based on the above, RAC concludes that, overall, the data on the ecotoxicity and endocrine disrupting properties of PFAS in the environment is limited for all PFAS. However, there is evidence for a subset of PFAS that suggest adverse effects occur, as indicated by adverse effects observed in ecotoxicological tests with various environmentally relevant species, such as invertebrates, fish, amphibians, birds, reptiles, mammals, plants, or wildlife (see Annex

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B.7.1. and Annex B.7.2. of the Background Document). These adverse effects manifest at different levels, including molecular (e.g., genotoxic effects), organ-level (e.g., steatosis), and organism level (e.g., mortality or reproduction), with potential relevance at the population level.

The complexity of assessing ecotoxicity in PFAS arises from the large number of substances with heterogeneous properties, attributed to diverse functional groups within the PFAS group. Furthermore, conventional ecotoxicological tests may not adequately detect long-term effects across several generations of exposure to PFAS. Although the bioavailability and toxicity of high molecular weight fluoropolymers may be limited, there are potential concerns related to the bioavailability and ecotoxicological effects of micro- and nano-particles and especially nano-/sub-micron sized fluoropolymer particles formed in the environment or produced for different applications.

In light of these findings, RAC acknowledges the uncertainties surrounding the ecotoxicity and environmental endocrine disrupting properties of PFAS especially when considering the wide range of different PFAS falling under the current restriction proposal. Nevertheless, these uncertainties do not diminish the concern regarding the environmental effects of increasing PFAS levels.

### Human health effects

There are thousands of PFAS with potentially varying effects and potency. Although there is a large body of epidemiological and experimental data on the health effects of PFAS, this data is available for less than 50 different PFAS, with most research focused on PFOA and PFOS. These data on human health effects are reflected in the harmonised classification of individual PFAS, including PFOS, PFOA, PFNA (nonanoic), PFDA (decanoic) and their salts, as well as substance specific restrictions of these PFAS. Although the main body of available data is summarised by the Dossier Submitter in Annex B.5 of the Background Document, there is active ongoing research in this area, which means that the database on the effects of various PFAS is continuously increasing.

Considering toxicokinetics, Annex B.5 of the Background Document refers mostly to EFSA's (2020) evaluation, and the key findings are summarised below:

- Many of 27 PFAS<sup>6</sup> considered by EFSA are shown to be readily absorbed through the gastrointestinal tract in mammals, including humans. They distribute to the plasma and other parts of the body and depending on the specific PFAS tend to accumulate in the liver (EFSA, 2020).
- They are excreted in both urine and faeces. Neither PFCAs nor PFSA's are metabolised by animals or humans, whereas precursors such as fluorotelomer alcohols (FTOHs) and polyfluoroalkyl phosphate esters (PAPs) are biotransformed to several metabolites, including PFCAs.
- Routes and rates of elimination of PFAS vary according to the chemical end-group, the chain length and the species.
- In rodents, half-lives of the studied PFAS vary from few hours to several weeks and are in general much shorter than in humans. In humans, the estimated half-lives for short-chain PFAS (such as PFBA, PFBS and PFHxA) were found to range from a few days to approximately one month, whereas for compounds having a long perfluoroalkyl chain length (such as PFOA, PFNA, PFDA, PFHxS or PFOS), it can be several years.

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<sup>6</sup> The following PFAS are included: PFBA, PFPeA, PFHxA, PFHpA, PFOA, PFNA, PFDA, PFUnDA, PFDoDA, PFTTrDA, PFTeDA, PFPeDA, PFODA, PFBS, PFHxS, PFHpS, PFOS, PFDS, PFOSI, 8:2: FTOH, 8:2 monoPAP, 8:2 diPAP, FOSA, EtFOSA, EtFOSE, FC-807.

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- The long elimination half-lives of these PFAS mainly originate from their interactions with various transporters involved in the reabsorption processes occurring at the hepatic, intestinal and renal level (EFSA, 2020).

The good oral bioavailability of the above mentioned PFAS is supported by human biomonitoring data showing elevated levels in humans exposed via drinking water. RAC notes that while there is limited information on other routes of exposure, inhalation absorption can also be expected for substances absorbed well in the gastrointestinal tract, whereas the capacity for dermal absorption is likely to show variability between the substances.

The issue of variability in toxicokinetics was pointed out in some of the comments from the consultation on the Annex XV report. RAC fully recognises that, although some long-chain PFAS compounds have shown very long elimination half-lives and the ability to bioaccumulate in humans, already within the group of PFCAs and PFSAs, shorter chain compounds show shorter half-lives and higher urinary elimination when compared to longer chain compounds that are eliminated to a larger extent through bile. Among the group of PFAS, PFCAs and PFSAs are the best studied for their toxicokinetic behaviour, some data exists for fluorotelomers (FTOHs including ADONA), PFECAs and Gen-X (HFPO-DA), whereas other groups of PFAS have been less studied (or not at all).

Regarding human health effects, exposure to PFAS may affect multiple organs and systems. In addition to experimental animal studies, the links between exposure to specific PFAS (especially PFOS and PFOA) and adverse health effects have been studied also in epidemiological studies in humans. PFCAs and some PFSAs, especially PFOA and PFOS are the most studied PFAS compounds. The Dossier Submitter has provided in Table B.13. of Annex B of the Background Document a non-exhaustive list of PFAS for which human health data have been reported in one or more existing reviews, assessments, and studies evaluated by the Dossier Submitter.

Current peer-reviewed scientific studies have shown that exposure of humans to PFAS may lead to:

- Liver effects and increased serum levels of total cholesterol (TC) and LDL cholesterol (LDL-C). Association between PFAS (especially PFOA and PFOS but also with other long-chain PFCAs and PFSAs) and increased serum cholesterol levels have been shown in highly exposed groups, including workers.
- Developmental effects, especially effects on birth weight. Association observed in humans especially with PFOA and PFOS. Also, neurodevelopmental effects have shown rather consistent associations in epidemiological studies especially with PFOS and PFHxS.
- Effects on immune function, resulting in reduced antibody response after vaccination and reduced ability to fight against infections (especially respiratory tract infections). Reduced vaccination response was considered as a critical effect by EFSA (2020) who set a TWI based on these immune effects for a sum of four PFAS (PFOA + PFNA + PFHxS + PFOS).

Risk of cancer caused by PFAS exposure has been studied in epidemiological studies in humans but, overall, the epidemiological data is limited. IARC recently classified PFOA as carcinogenic to humans (Group 1) on the basis of sufficient evidence for cancer in experimental animals and strong mechanistic evidence for epigenetic alterations and immunosuppression in exposed humans. PFOS was classified as possibly carcinogenic to humans (Group 2B) on the basis of strong mechanistic evidence across test systems, including exposed humans (for epigenetic alterations and immunosuppression, as well as several other key characteristics of carcinogens). There was limited evidence for cancer in experimental

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animals and inadequate evidence regarding cancer in humans (Zahm et al., 2023).

RAC notes that also other effects have been observed in animal studies or in epidemiological studies, but the human evidence is lower than for the effects listed above. The majority of PFAS which have been studied for these other effects have been long-chain PFCAs or PFSAs but some data (e.g. on developmental and fertility effects in animals) exists also from TFA, 6:2 FTOH, some PFECAs (e.g., HFPO-DA), HFCs (see further details in Annex B of the Background Document). These effects include:

- Other reproductive effects such as effects on sex hormone levels, timing of puberty and decreased fertility, or developmental effects including neurodevelopmental effects.
- Endocrine disturbing effects, effects on thyroid function and metabolism with a risk of obesity.
- Increased high blood pressure and cardiovascular morbidity.
- Increased risk of allergies.

RAC concurs with the Dossier Submitters' concern associated with combined effects resulting from exposure to different PFAS. Many different PFAS co-occur in the environment, in drinking water, food and human blood and, for instance, human exposure to the combination of four PFAS (PFOA, PFNA, PFHxS, and PFOS) already exceeds the existing limit value established by EFSA. RAC however notes that even when considering PFCAs and PFSAs showing qualitatively similar toxicological effects, there are potency differences between the individual compounds (Bil et al., 2023).

One of the main uncertainties in the assessment of PFAS as a group is related to the lack of data from the majority of the individual PFAS. To accelerate PFAS hazard evaluation, new approach methodologies (NAMs) comprised of in vitro high-throughput toxicity screening, toxicokinetic data, and computational modeling are currently being employed in read-across strategies to evaluate the larger PFAS landscape. In 2018, a research program was initiated by the US Environmental Protection Agency (US EPA) and the US National Toxicology Program (NTP) to develop a risk-based approach for conducting PFAS toxicity testing to facilitate PFAS human health assessments (Patlewicz *et al.*, 2019). These new approach methods screen for potential liver, developmental neurotoxicity, developmental toxicity, immunotoxicity, and mitochondrial toxicity as well as help to better predict the disposition and excretion of PFAS from the body.

The preliminary US EPA's Tox21 data set shows that short- and long-chain PFCAs, PFSAs, and FTOHs can interact with around two dozen different nuclear receptors, with the number of receptors varying depending on the individual PFAS (Goodrum *et al.*, 2021).

Currently, US EPA and the US National Institutes of Health (NIH) are working together to use new chemical testing approach methods to test 150 PFAS chemicals. Results from the new approach methods testing will be used to prioritize (tier) PFAS for risk assessment, provide support for gap-filling approaches such as chemical read-across, and to inform further testing (Patlewicz *et al.*, 2019).

A number of comments received during the consultation on the Annex XV report make reference to various epidemiological studies on the association of PFAS exposure and health effects. RAC takes note of these but is not going to perform any quantitative risk assessment based on these epidemiological data. It needs to be noted that epidemiological studies showing associations between PFAS exposure and human health effects most often quantitate the magnitude of effects in relation to those legacy PFAS (like PFOA, PFOS) that are already restricted in the EU. This restriction, on the other hand, covers the whole array of PFAS, most of which are not evaluated for their health hazards and have not been measured in



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epidemiological studies. Considering that there are at least large quantitative differences in the human health hazards of different PFAS (as pointed out also in several consultation comments), RAC does not consider quantification of human health hazards possible or appropriate. This is in line with Dossier Submitter proposal; even though the Dossier Submitter acknowledges (see Annex E.3 of the Background Document) the existing epidemiological information and existing human health impact assessments, which are based mainly on data focusing on PFOS and PFOA (Goldenman et al., 2019), it is concluded that quantification of human health hazards is not possible. RAC concurs with this conclusion.

### *SFAs/PFAs*

Semi- and perfluorinated alkanes are a special group of PFAS used for instance in ski waxes and in medical applications (in eye drops and ocular tamponades). The low toxicity of SFAs 1-(Perfluorobutyl)pentane and 1-(Perfluorohexyl)octane used were claimed in the consultation on the Annex XV report (confidential comment). It was emphasised that unlike PFAAs and their precursors, SFAs do not contain functional groups like carboxylic or sulphonic acids or alcohols, which make PFAS water-soluble. Because of this, they have poor water-solubility affecting their bioavailability. The overview on the available toxicokinetics and toxicity data of 1-(Perfluorobutyl)pentane and 1-(Perfluorohexyl)octane provided by this comment suggests low absorption, no metabolism by liver microsomes, and low acute and repeated dose toxicity and lack of genotoxicity or local toxicity.

### *Fluorinated gases*

With regard to fluorinated gases, many comments in the consultation requested a separate hazard and risk assessment for trifluoroacetic acid (TFA), pointing out marked differences between TFA and longer chain PFCAs (such as PFOA) in terms of potency, bioaccumulation potential and risks. RAC acknowledges that the effect levels for TFA differ from e.g. those of PFOA; for example, effect levels for systemic and developmental toxicity of TFA are one to two orders of magnitude above those of PFOA (cf. ATSDR, 2021, cited in Annex B of the Background Document). However, both substances are persistent.

Similarly, comprehensive toxicology datasets were submitted in the consultation on the Annex XV report for certain HFOs. They demonstrate not only quantitative, but also qualitative differences from PFCAs with respect to health hazards. For example, the most consistent finding in animal studies with HFO-1234ze was cardiac toxicity. RAC notes that cardiac effects are common also with CFC compounds. Reproductive toxicity studies with e.g. HFO-1234ze did not show any effects on fertility or development.

### *Fluoropolymers, PFPEs and oligomeric PFAS*

Several comments have been made specifically on the lack of hazards of fluoropolymers. Some toxicity data or references to specific toxicity data on especially on PTFE, FFKM, PVDF has been submitted, all supporting the low bioavailability and toxicity of fluoropolymers *per se*. RAC acknowledges this information and agrees that in case of high molecular weight fluoropolymers, their molecular weight, neutrality, lack of reactive functional groups and resistance to degradation limit their bioavailability and toxicity to humans. These aspects have been discussed in reviews by Henry et al 2018; Korzeniowski et al 2023 frequently cited in the public comments to the Annex XV report.

However, these arguments cannot be generalised to all fluoropolymers or to perfluoropolyethers (PFPEs) since these polymer groups may contain a variety of differently sized compounds with differing properties. As discussed under ecotoxicity, RAC notes that some PFPEs have relatively low molecular weight (below 1000 Da) (OECD, 2024), which make them potentially bioavailable. There is little toxicological information publicly available on

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different molecular weight PFPEs or PFAS oligomers with only a few units (typically less than ten). In the Annex B of the Background Document, the Dossier Submitter refers to data on PCTFE oligomers (trimers and tetramers) showing that in animal studies they are absorbed after inhalation and oral administration, distributed to various organs, and able to cause liver or kidney effects. An example of a low molecular weight oligomeric PFPE is CAS 161075-00-9 (Hexafluoropropene, oxidized, oligomers, reduced, fluorinated), which is registered under REACH as a multi-constituent substance. Toxicity data provided in the registration dossier on the substance itself or related PFPE suggest low toxicity. Malinverno et al. (1996, see Annex B of restriction proposal) describes the results of the human toxicity testing of four PFPEs (Fomblin HC family) with MWs ranging from 650-6250 D. Dataset included also repeated dose testing, which was made with a MW 3200 D compound. The results showed limited toxicity. In repeated dose toxicity testing slight microscopic findings in kidney tubules of male rats were observed, which was considered insignificant by authors. No increase in fluoride levels in blood, urine or bile of exposed animals was seen.

The only known health effects described for fluoropolymers are the lung effects caused by fumes or aerosols of fluoropolymers (polymer fume fever and granulomatous lung disease). These effects have been described after exposure to fluoropolymer fumes formed by heating but also after exposure to sprayed PTFE. The mechanisms of these effects are unknown but may relate to the effects of fine/ultrafine fluoropolymer/oligomers particles although the role of degradation products cannot to be excluded. Also, granulomas after injection of FP suspensions have been reported in rare cases (see annex B of the Background Document) but RAC notes that such “foreign body granulomas” have been observed also after injection of various other fillers.

RAC notes that PTFE micropowders, used as additives in lubricants (see sector-specific evaluation of lubricant uses) are intentionally manufactured in the form of micro-sized fluoropolymer particles with particle size and molecular weight varying from 1-20 µm and 30 000-200 000 Da, respectively (Fluorochemie, 2024). Also, dispersions with 0.1-0.2 µm PTFE or FEP (fluorinated ethylene propylene) particles are available on the market (Teflon, 2024) for use in various coatings. As already discussed under ecotoxicity, micro-sized PTFE (average size of approximately 5 µm and 10-50 µm) have shown low bioavailability and no toxicity in animal studies (e.g. Lee et al., 2022a). RAC was, however, able to identify only limited information on the toxicokinetics or toxicological effects of nano- or submicron sized fluoropolymer particles. RAC notes, however, that in general particles especially with particle size of 0.1-0.2 µm may already enter the cells. For example, polystyrene particles of about 50-100 nm of size have been shown to enter the cells (Jiang et al., 2011, Gaspar et al 2018). However, it is noted that in addition to size, particles’ other morphological properties, chemical composition, surface properties (hydrophobicity, hydrophilicity, functional groups and charge) affect the cellular uptake (Augustine et al., 2020, cited in annex B of the Background Document; Lee et al., 2022b). A number of studies are available on the cellular effects of micro- and nanoplastics, the most commonly studied plastics being polystyrene, PE/PP. One recent in vitro study reported induction of oxidative stress and inflammation, but not cytotoxicity by PTFE microparticles in six different human cell lines (KC et al., 2023). One cross-sectional study limited in size suggested an association between blood PTFE microplastic occurrence and impaired sperm parameters (Zhang et al., 2024). Bioavailability of micro- and nanoplastics together with the persistence of the polymer particles was used in the case of the microplastics restriction (ECHA, 2020b) as a justification in the restriction of microplastics.

In addition to intentionally manufactured fluoropolymer micro-/nanoparticles, which are covered by the microplastics restriction (ECHA, 2020b), it has been suggested that fluoropolymers may form micro- and nanosized particles in the environment during use and

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at the end of their lifecycle (Lohmann et al., 2020). The information related to this is, however, limited (see further section 3.1.2 Emissions and exposure).

*Overall conclusion on human health hazards*

Overall, RAC agrees with the Dossier Submitter that generally PFAS are likely to be (or become) biologically available in humans. Bioavailability of high molecular weight fluoropolymers and perfluoropolyethers is more limited, but it is recognised that fluoropolymers are also available as small, nano-/sub-micron sized particles, which can be anticipated to be bioavailable. The toxicity of different PFAS varies and may be low for some substances, especially for high-molecular weight fluoropolymers.

As already concluded in the RAC opinion on the proposal to restrict PFAS in fire-fighting foams (ECHA, 2023a), considering the high number of PFAS in the scope of this restriction, it is not feasible to investigate each one individually. Similarly, RAC does not consider it appropriate to perform a quantitative human health risk assessment for the whole group of PFAS based on the available human health data on individual substances.

Global warming potential (GWP)

Fluorinated gases have replaced the use of CFC/HCFC compounds, which have been restricted via the Montreal Protocol due to their ozone depleting effects. Fluorinated gases replacing CFCs/HCFCs do not have ozone depleting properties. HFCs, which were initially replacing CFCs and HCFCs are, however, strong greenhouse gases and have been added to the Montreal Protocol via the Kigali Amendment. In fact, some of the strongest greenhouse gases known are PFAS. This is the case of fluorinated gases, e.g. hydrofluorocarbons (HFCs), and hydrofluoroethers (HFEs). Other fluorinated gases, such as hydrofluoro olefins (HFOs), have lower global warming potential. For comparison, HFC-134a has a global warming potential of 1430 whereas HFO1234yf has a GWP of 4 (see Sovacool et al 2021). Atmospheric lifetimes and global warming potential of fluorinated gases are provided by the Dossier Submitter and may be found in the IPPC Reports (see Table 3).

**Table 3: GWP-values (GWP-100)<sup>1</sup> collected from the IPCC fourth Assessment Report**

| Gas            | Chemical formula                                                                 | Atmospheric lifetime [y] | GWP    |
|----------------|----------------------------------------------------------------------------------|--------------------------|--------|
| Carbon dioxide | CO <sub>2</sub>                                                                  |                          | 1      |
| Methane        | CH <sub>4</sub>                                                                  | 12                       | 25     |
| Nitrous oxide  | N <sub>2</sub> O                                                                 | 114                      | 298    |
| HFC-23         | CHF <sub>3</sub>                                                                 | 270                      | 14 800 |
| HFC-32         | CH <sub>2</sub> F <sub>2</sub>                                                   | 4.90                     | 675    |
| HFC-152a       | CH <sub>3</sub> CHF <sub>2</sub>                                                 | 1.4                      | 124    |
| HFC-236fa      | CF <sub>3</sub> CH <sub>2</sub> CF <sub>3</sub>                                  | 240                      | 9 810  |
| PFC-14         | CF <sub>4</sub>                                                                  | 50 000                   | 7 390  |
| PFC-5-1-14     | CF <sub>3</sub> CF <sub>2</sub> CF <sub>2</sub> CF <sub>2</sub> CF <sub>3</sub>  | 3 200                    | 9 300  |
| HFE-125        | CHF <sub>2</sub> OCF <sub>3</sub>                                                | 136                      | 14 900 |
| HFE-143a       | CH <sub>3</sub> OCF <sub>3</sub>                                                 | 4.30                     | 756    |
| HFE-7100       | CF <sub>3</sub> CF <sub>2</sub> CF <sub>2</sub> CF <sub>2</sub> OCH <sub>3</sub> | 3.8                      | 297    |

<sup>1</sup> GWP is the heat-trapping ability of a gas measured against carbon dioxide. GWP100 looks at the GWP of the greenhouse gas over 100 years

Additional information related to the GWP of PFAS is provided by the fluorinated gases (F-gas) Regulation (Regulation (EU) 2024/573). Emitted gases will eventually degrade over a shorter or longer timeframe and the contribution to global warming will cease. They will

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however degrade, among other degradation products, into persistent PFAS degradation products such as TFA that will precipitate with rain.

In addition to PFAS covered by the F-gas Regulation, other PFAS can have a high global warming potential. One example is perfluorotributylamine ( $\text{N}(\text{C}_4\text{F}_9)_3$ ) which was studied by Tsai (2017) and was reported to have an atmospheric lifetime of 500 years and a GWP of 7 100.

RAC notes that, in the F-gas Regulation, more severe restrictions are applied to the substances with a GWP of 150 or above.

RAC further notes that waste management of PFAS may also contribute to Global Warming (see further section waste in 3.1.2 Emissions and exposure).

### **Applicability of the “polymers of low concern” concept and how it relates to fluoropolymers and perfluoropolyethers**

A significant number of comments were submitted in the consultation of the Annex XV report arguing that high molecular weight fluoropolymers should be considered as “polymers of low concern”. Numerous comments referred to the papers by Henry et al 2018 and Korzeniowski et al 2023, the first one focusing on PTFE, ETFE, FEP and PFA whereas the latter covered fluoroplastics (PVDF, ECTFE, PCTFE, FEVE, EFEP, CPT, THV), fluoroelastomers (FEP, FKM, FFKM) and amorphous fluoropolymers and fluorinated ionomers. All these PFAS compounds are neutral, high molecular weight compounds with low water solubility, high stability and are claimed by the authors to contain minimal or negligible monomer and oligomer content and no or minimal amount of low molecular weight leachable substances. Based on these properties, they were described as “polymers of low concern” by the authors. Generally, derogations or exemptions from the scope of the restriction were requested for these types of fluoropolymers. Similarly, a specific risk assessment of individual PFPEs and consideration of whether some of them can be considered as “polymers of low concern” were requested in various comments from the Annex XV report consultation.

RAC notes that there are currently no formal, adopted criteria for “polymers of low concern”. As discussed in the previous sections, fluoropolymers are generally known to be very persistent under environmental conditions. High-molecular weight fluoropolymers are not soluble in water and n-octanol, and not considered to fulfil the mobility criteria, which is fulfilled generally by shorter carbon chain PFAS. However, nano- and micro-sized particles potentially formed out of fluoropolymers may have a potential for environmental long-range transport via waterways. Available data on common fluoropolymers (e.g.: PTFE) suggest a low (eco)toxicological profile given their high molecular weight and physico-chemical properties, which result in limited bioavailability.

PFPEs, on the other hand, are specific group of polymeric PFAS which differ from fluoropolymers. They are typically liquids and some of them have relatively low molecular weight (<1000 Da) (OECD, 2024). The liquid state of PFPEs is due to flexible backbone chain, where perfluoro-alkyl groups are joined by ether groups. Functionalisation of PFPEs with specific end-groups modify the physico-chemical properties and may affect their (eco)toxicity. Lower molecular weight (<1000 Da) PFPEs are considered as potentially bioavailable. Limited information available and submitted during the Annex XV report consultation suggests low (eco)toxicity of PFPEs with average molecular weight ranging from <1000- >3000.

RAC notes that the groups of fluoropolymers and PFPEs are wide and may include a high number of compounds with varying properties, including varying molecular weight and particle sizes (in case of fluoropolymers) and monomer/oligomer residue profiles, which needs

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to be taken into account. Therefore, extrapolation of the findings from a few substances to the whole group of fluoropolymers or PFPEs cannot be made.

RAC also would like to point out that the proposed OECD policy criteria for “polymers of low concern” (which were often referred to in Annex XV report consultation comments, but which have not been adopted by OECD) only includes the end-use of polymers, making it an incomplete assessment which dismisses the following additional concerns:

- 1) The emissions of non-polymeric PFAS during the manufacturing of fluoropolymers.
- 2) The emissions of residual non-polymeric PFAS and thermal degradation products released from polymer-based end products especially during the manufacturing of these end-products in processes involving sintering, extrusion steps.
- 3) The emissions of non-polymeric PFAS during the waste stage.

They form the main concern for fluoropolymers and PFPEs.

RAC further elaborates on these issues under sections 3.1.2 Emissions and exposure and 3.1.3 Risk characterisation below.

### **3.1.2. Emissions and exposure**

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

The Dossier Submitter’s approach to the assessment of exposure and emissions is described in section B.9.1 of Annex B of the Background Document.

The Dossier Submitter’s approach to assessing waste stage emissions is described in Annex B of the Background Document (section B.9.18).

Second hand articles are assessed in Annex E of the Background Document, section E.3.2, spare parts in section E.3.3 and recycling in section E.3.4.

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

- General considerations:
  - Due to the wide scope and widespread use of PFAS, there are significant uncertainties related to the coverage of the uses assessed. This affects the emission estimates made by the Dossier Submitter.
  - Detailed conclusions on sector-specific emission estimates are described in the RAC sector-specific evaluations. Overarching conclusions relevant to all sectors are presented here.
  - Based on the available information, it has been estimated that a total of 270 000 t of PFAS were used in the EEA in 2020. Out of this, about 140 000 t were polymeric PFAS (mainly fluoropolymers), 100 000 t fluorinated gases<sup>7</sup> and 25 000 t other PFAAs and PFAA precursors<sup>8</sup> (including side-chain fluorinated polymers).
  - RAC estimates a total of 70 000 t/y of PFAS are emitted to the environment,

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<sup>7</sup> The Background Document presents the volumes in use of fluorinated gases (HFCs, HFOs, etc) independently from those of PFAAs and PFAA precursors. RAC has followed the same approach.

<sup>8</sup> While RAC agrees with the classification by the OECD (2021) of perfluoroalkanes (PFAs) as “other PFAS” since they do not degrade to PFAAs, RAC has accounted associated volumes and emissions of PFAs under the category of PFAAs and PFAA precursors for practical reasons (see sector-specific evaluations for “Ski wax” and “Petroleum and mining”). Estimated PFAs volumes in use are very low (in the range of less than 10t/y)

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Fluorinated gases are major contributors to these emissions (ca. 60 000 t/y), followed by the application of side-chain fluorinated polymers especially in the "TULAC" sector.

- The emissions estimated by RAC do not include the 8 new sectors added to the Background Document after the Annex XV report consultation<sup>9</sup>. PFAS emissions from these eight new sectors have been estimated by the Dossier Submitter at about 5 000 t/y, out of which ca. 4 000 are fluorinated gases (mainly from the "Other medical devices" sector).
- RAC notes the available environmental monitoring and human biomonitoring data, which shows the wide-spread environmental and human exposure to PFAS. This gives a strong support for the concern on the build-up of PFAS in the environment and human exposure to PFAS via different sources. There are also monitoring data on the occupational exposure to PFAS, although the data covers only a limited number of sectors and uses.
- However, the current environmental monitoring and human biomonitoring data is mainly focused on already regulated PFAS, and less data is available on the non-regulated PFAS covered by this restriction although the non-target approaches indicate their wide-spread environmental occurrence.
- Fluoropolymers:
  - The life cycle of fluoropolymers is associated with several types of emissions, including emissions of non-polymeric PFAS (such as fluorinated gases, polymerisation by-products and fluorosurfactants during manufacturing; non-polymeric residues, thermal decomposition products during processing; fluorinated gases and PFAAs when incinerated under suboptimal conditions) and fluoropolymer particles (during processing; service life e.g. due to abrasion; etc.) . RAC considers it important to distinguish between emissions of polymer particles and emissions of non-polymeric PFAS from fluoropolymers, because fluoropolymer particles are generally less bioavailable, less toxic than PFAAs and their precursors and their concern mostly relates to the general plastic pollution. The Dossier Submitter has not made a distinction between these two types of emissions in their estimates.
  - RAC notes that some of the default release factors in the ECHA IR&CSA Guidance R.16, which were applied by the Dossier Submitter to the whole fluoropolymer volume, were originally designed to be applied only to the amount of non-polymeric additive in a polymer. In RAC view, their automatic use for quantification of particle emissions without careful consideration of the particular scenario and the properties of the polymer in question may be inappropriate. Since adequate justification for such application of release factors was often missing in the dossier, and because a distinction between particles and non-polymeric PFAS was considered important by RAC, RAC developed its own approach to quantification of non-polymeric PFAS emissions from fluoropolymers.
  - RAC recognises that emissions of fluoropolymer particles are likely to occur in many uses. However, due to lack of data, RAC did not address these releases in a quantitative way.
- Waste stage:

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<sup>9</sup> See section 2.2. for further details related to the sectors of use specifically evaluated by RAC and the 8 new sectors incorporated to the Background Document by the Dossier Submitter after the end of the Annex XV report consultation.

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- RAC agrees with the Dossier Submitter's approach to assess emissions in the waste stage using specific data when available and otherwise default release factors for incineration, landfilling and wastewater treatment.
- RAC agrees that incineration in hazardous waste incinerators at  $\geq 1100$  °C is currently the most effective way of PFAS destruction, although even this treatment method may not achieve complete mineralisation.
- Combustion at low temperatures and/or insufficient oxygen supply leads to transformation of longer-chain PFAS (including fluoropolymers) to short-chain, more thermally stable PFAS. Therefore, it is considered critical that PFAS are incinerated under adequate conditions.
- For hazardous waste incineration RAC proposes to apply a release factor of 1% (RF:0.01), for non-hazardous waste incineration 2% (RF:0.02).
- RAC agrees with the Dossier Submitter that wastewater treatment is generally not effective in removing PFAS (with few exceptions) and proposes a release factor of 100% (RF:1) for PFAS in municipal and industrial wastewater treatment plants. Emissions of polymeric particles have not been quantified by RAC.
- Landfilling is considered as a relevant source of PFAS to the environment, particularly for PFAAs and PFAA precursors.
- For landfilling of PFAAs and PFAA precursors, the Dossier Submitter used a release factor of 3.36% (RF:0.0336). RAC agrees with the use of this release factor. As to PFPEs, RAC grouped them with PFAAs and PFAA precursors, given their liquid state and in some cases rather low molecular weight.
- For landfilling of polymeric PFAS the Dossier Submitter proposed a release factor of 0.16% (RF:0.0016). Following the RAC general approach to quantification of emissions from fluoropolymers, RAC instead quantified only emissions of non-polymeric residues within the fluoropolymer, using the release factor for PFAAs and PFAA precursors of 3.36% (RF:0.0336) (applied to the amount of the non-polymeric residue).
- RAC notes that PFAS may be present in different waste streams collected for recycling. This may result in environmental emissions and exposure of workers. However, compared to the disposal, additional emissions caused by recycling or reuse are likely to be minimal. The recycling of PFAS is currently limited and occurs mainly within the fluoropolymer manufacturing industry.
- Due to lack of information, no estimate on the emissions related to the production of spare parts were made.

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

Since PFAS share properties similar to PBT/vPvB substances, they are considered as non-threshold substances, and their emissions to the environment can serve as a proxy for risk (see section 3.1.3 below). Human exposure is acknowledged but not assessed in detail nor quantified in the dossier.

Emissions are quantified over the whole life cycle. ECHA guidance R.12 (ECHA Guidance on Information Requirements and Chemical Safety Assessment R.12) distinguishes five life cycle stages of a substance: manufacture, formulation/re-packing, end use (use at industrial sites, widespread use by professional workers, consumer use), service life and waste stage. The Dossier Submitter used a simplified approach dividing the life cycle into three stages: (1) manufacturing, (2) use of the substance, and (3) end of life (waste stage). The nature of the use stage varies according to the PFAS type and application, and often includes the production of articles and their service life. RAC considers either type of division appropriate as long as

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all emissions are described and assessed. RAC has in its assessment followed the Dossier Submitter's division but additionally also used ECHA Guidance R.12 to examine whether all relevant emissions across life cycle stages have been covered.

The release factors used in the Background Document are either based on sector-specific information, or they are default worst-case release factors corresponding to the Environmental Release Categories (ERCs; see ECHA guidance R.12 and R.16). The default factors are conservative and assume that no specific risk management measures (RMMs) are in place, thus ensuring that potential risks are not underestimated. This however means that the emissions would be overestimated if specific RMMs are present. In many cases a sufficiently detailed description of the processes was lacking, which made it difficult to determine whether all relevant emissions have been addressed and which release factors would be appropriate.

PFAS may be emitted to water, air or soil. For the purpose of this restriction proposal the Dossier Submitter assumed that the environment is one compartment. Compartment-specific release factors (for water, air and soil) have been summed up. RAC agrees with this approach.

Where possible, the Dossier Submitter disaggregated volumes into three PFAS types: (1) PFAAs and PFAA precursors, including side-chain fluorinated polymers; (2) fluorinated gases; and (3) polymeric PFAS, i.e. fluoropolymers and PFPEs. RAC follows the same approach.

For the quantification of PFAS emissions, the Dossier Submitter has considered emissions of PFAS and PFAA precursors, fluorinated gases, PFPEs, and non-polymeric PFAS and polymeric particles from fluoropolymers. Although RAC agrees that polymeric particles will be emitted from the manufacture and use of fluoropolymers, RAC has not made a quantitative emission estimation on those. In the following subsections RAC covers various horizontal elements of the emission assessment.

### **3.1.2.1. Summary of sector-specific volumes and emissions**

Table 4 below presents an overview of volume data mostly as presented by the Dossier Submitter, in several cases with adjustments by RAC. Volumes of the eight new sectors added by the Dossier Submitter after the Annex XV report consultation have not been assessed by RAC (see also section 2.2).

Various uncertainties have been identified during the assessment, possibly leading to underestimation or overestimation of volumes (details are described in the RAC sector-specific evaluations). Typical uncertainty of volume estimates is in the order of tens of percent.

Based on the available information, it has been estimated that a total of 266 000 tonnes of PFAS were used in the EEA in 2020. Out of this, about 143 000 tonnes were polymeric PFAS (mainly fluoropolymers), 100 000 tonnes fluorinated gases and 25 000 tonnes PFAAs and PFAA precursors (including side-chain fluorinated polymers).

Table 4 shows a difference between PFAS manufacturing and PFAS use volumes in the EEA. This difference may be caused e.g. by import/export and incomplete or inaccurate volume data.



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**Table 4: Annual PFAS volumes manufactured and volumes used across different sectors within the EU/EEA (in base year 2020)\***

| Manufacturing and use sectors                         | Volumes [t/y] (Mid values)  |                   |                    | Total PFAS     |
|-------------------------------------------------------|-----------------------------|-------------------|--------------------|----------------|
|                                                       | PFAAs and PFAA precursors** | Fluorinated gases | Polymeric PFAS *** |                |
| PFAS manufacturing                                    | 86 092                      | 7 911             | 63 380             | 157 383        |
| <i>Use sectors</i>                                    |                             |                   |                    |                |
| Textiles, upholstery, leather, apparel and carpet     | 17 911                      | 0                 | 45 805             | 63 716         |
| Food contact materials and packaging                  | 2 896                       | 0                 | 9 110              | 12 006         |
| Metal plating and manufacture of metal products       | 152                         | 0                 | 568                | 720            |
| Consumer mixtures and miscellaneous consumer articles | 20                          | 0                 | 62                 | 82             |
| Cosmetics                                             | 398                         | 0                 | 0                  | 398            |
| Ski wax                                               | 1.6                         | 0                 | 0                  | 1.6            |
| Applications of fluorinated gases                     | 0                           | 61 845            | 0                  | 61 845         |
| Medical devices                                       | 0                           | 0                 | 8 133              | 8 133          |
| Transport                                             | 13                          | 28 609            | 13 669             | 42 291         |
| Electronics and semiconductors                        | 204                         | 1 844             | 12 809             | 14 857         |
| Energy                                                | 131                         | 0                 | 5 367              | 5 498          |
| Construction products                                 | 2 411                       | 0                 | 10 435             | 12 846         |
| Lubricants                                            | 105                         | 13                | 6 288              | 6 406          |
| Petroleum and mining                                  | 7                           | 0                 | 0                  | 7              |
| <b>Total (14 sectors) #</b>                           | <b>24 250</b>               | <b>92 311</b>     | <b>112 246</b>     | <b>228 807</b> |
| Printing applications*                                | 63                          | 0                 | 114                | 177            |

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| Manufacturing and use sectors                           | Volumes [t/y] (Mid values)     |                   |                    | Total PFAS     |
|---------------------------------------------------------|--------------------------------|-------------------|--------------------|----------------|
|                                                         | PFAAs and PFAA<br>precursors** | Fluorinated gases | Polymeric PFAS *** |                |
| Sealing applications*                                   | 0                              | 0                 | 22 725             | 22 725         |
| Machinery applications*                                 | 0                              | 0                 | 594                | 594            |
| Other medical applications*                             | <1                             | 3 420             | 807                | 4 228          |
| Military applications*                                  | 0                              | 999               | 1 128              | 2 127          |
| Explosives*                                             | 0                              | 0                 | 326                | 326            |
| Technical Textiles*                                     | 727                            | 0                 | 4 605              | 5 332          |
| Broader industrial uses*                                | 200                            | 1 040             | 0                  | 1 240          |
| <b>Total (8 additional sectors)*</b>                    | <b>991</b>                     | <b>5 459</b>      | <b>30 299</b>      | <b>36 749</b>  |
| <b>Total volume (excluding PFAS manufacturing) ****</b> | <b>25 241</b>                  | <b>97 770</b>     | <b>142 545</b>     | <b>265 556</b> |

# The volumes for these sectors are based on Table 3 from the Background Document. Some corrections and adjustments were made by RAC in their sector-specific evaluations

\* The source for these volumes is Table 3 from the Background Document. These sectors were not evaluated in detail by RAC. The figures represent the volumes provided by the Dossier Submitter

\*\* Side-chain fluorinated polymers are included as part of per- and polyfluoroalkyl acids (PFAAs) and PFAA precursors due to their potential degradation into PFAAs. PFAS volumes were applicable (ski wax, petroleum and mining) are also considered here for practical reasons

\*\*\* Polymeric PFAS include both fluoropolymers (FPs) and perfluoropolyethers (PFPEs)

\*\*\*\* PFAS manufacturing volumes are excluded from the total to prevent double counting

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Table 5 shows emission estimates presented by the Dossier Submitter along with emission estimates calculated by RAC for the individual sectors. The differences between both estimates are largely due to the RAC approach to calculate fluoropolymer emissions, where RAC quantified only non-polymeric PFAS, and due to the use of different release factors for the waste stage. For more details see the sector-specific evaluations. RAC has not evaluated the emission estimates presented by the Dossier Submitter for the eight additional sectors added to the Background Document after the end of the six-month consultation on the Annex XV restriction report. Particle emissions have not been quantified by RAC (for justification see section 3.1.2.4 below).

The accuracy of the emission estimates is lower than that of volume estimates due to many additional uncertainties including those related to release factors and incomplete description of processes. Thus, the values in the table should be viewed as an indication of the order of magnitude of emissions, not as precise numbers.

Total emissions of PFAS from PFAS manufacturing and use in the EEA in 2020 have been estimated by RAC at about 70 000 t/y (excluding those sectors not evaluated specifically by RAC, see section 2.2). Out of this, ca. 60 000 t/y result from the uses of fluorinated gases in sectors “Applications of fluorinated gases” and “Transport”. A relatively high emission estimate has also been obtained for the “TULAC” sector; this sector uses high volumes of side-chain fluorinated polymers, which have a relatively high potential for release of non-polymeric PFAS.

Emissions from the eight new sectors (see section 2.2.) have been estimated by the Dossier Submitter at about 5 000 t/y. These sectors have not been evaluated in detail by RAC. Nevertheless, RAC takes note of the Dossier Submitter assumption that the majority of these emissions, 3 400 t/y, originate from the use of fluorinated gases as propellants in metered dose inhalers.

RAC also takes note that some of the new sectors (sealing applications in particular) use high volumes of fluoropolymers.

Regarding the uses of fluoropolymers, please refer to the RAC approach to calculation of fluoropolymer emissions in section 3.1.2.4. The RAC approach to calculate emissions for fluoropolymer uses results in generally lower total PFAS emissions when compared to the Dossier Submitter emissions estimates. This is exemplified in the “Medical devices” sector, where the RAC emission estimate is an order of magnitude lower when compared to the Dossier Submitter’s emission estimate. However, as discussed below under section 3.1.2.4., these estimates may represent some underestimation because of the limited consideration of the emissions during hot processing steps during the industrial use stage.

**Table 5: Annual PFAS emissions from PFAS manufacturing and across different sectors within the EU/EEA (in base year 2020)**

| Manufacturing and use sectors | Emissions                                                        |                                                  |
|-------------------------------|------------------------------------------------------------------|--------------------------------------------------|
|                               | Total PFAS emissions as presented by the Dossier Submitter [t/y] | Total PFAS emissions as calculated by RAC [t/y]* |
| PFAS manufacturing            | 755                                                              | 761                                              |
| Sectors of use                |                                                                  |                                                  |

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| Manufacturing and use sectors                         | Emissions                                                                 |                                                           |
|-------------------------------------------------------|---------------------------------------------------------------------------|-----------------------------------------------------------|
|                                                       | Total PFAS emissions<br>as presented by the<br>Dossier Submitter<br>[t/y] | Total PFAS<br>emissions as<br>calculated by<br>RAC [t/y]* |
| Textiles, upholstery, leather, apparel and carpet     | 11 207                                                                    | 6 526                                                     |
| Food contact materials and packaging                  | 696                                                                       | 582                                                       |
| Metal plating and manufacture of metal products       | 33                                                                        | 38                                                        |
| Consumer mixtures and miscellaneous consumer articles | 30                                                                        | 21                                                        |
| Cosmetics                                             | 36                                                                        | 40                                                        |
| Ski wax                                               | 1.1                                                                       | 1.1                                                       |
| Applications of fluorinated gases                     | 39 346**                                                                  | 39 346                                                    |
| Medical devices                                       | 4 293                                                                     | 127                                                       |
| Transport                                             | 19 446                                                                    | 19 106                                                    |
| Electronics and semiconductors                        | 639                                                                       | 440                                                       |
| Energy                                                | 230                                                                       | 84                                                        |
| Construction products                                 | 3 938                                                                     | 426                                                       |
| Lubricants                                            | 1 634                                                                     | 815                                                       |
| Petroleum and mining                                  | 1.6                                                                       | 1.6                                                       |
| <i>Total (14 sectors+ PFAS manufacturing)</i>         | <b>82 286</b>                                                             | <b>68 315</b>                                             |
| Printing applications***                              | 9                                                                         | n.a.                                                      |
| Sealing applications***                               | 502                                                                       | n.a.                                                      |
| Machinery applications***                             | 22                                                                        | n.a.                                                      |
| Other medical applications***                         | 3 427                                                                     | n.a.                                                      |
| Military applications***                              | 511                                                                       | n.a.                                                      |
| Explosives***                                         | 25                                                                        | n.a.                                                      |
| Technical Textiles***                                 | 607                                                                       | n.a.                                                      |
| Broader industrial uses***                            | 186                                                                       | n.a.                                                      |
| <b>Total (8 additional sectors)</b>                   | <b>5 289</b>                                                              | <b>n.a.</b>                                               |
| <b>Total emissions</b>                                | <b>87 575</b>                                                             | <b>68 315</b>                                             |

\* Emission values recalculated by RAC, polymeric particles not quantified; Emissions values are mid-point values for all sectors

\*\* 30 586 t/y is listed in Table B.59 of Annex B of the Background Document. However, this value represents only stock ( $\approx$  service life) emissions. When production and end of life emissions are added (Table B.58), the result is 39 346 t/y. The Dossier Submitter's emission estimate of ca. 39 346 t/y has been accepted as a basis for RAC assessment.

\*\*\* Sectors with grey shaded cells were not evaluated in detail by RAC.

### 3.1.2.2. Emissions from PFAS manufacturing

The Dossier Submitter estimated emissions from PFAS manufacturing in the EEA. A detailed assessment can be found in the RAC specific-sector evaluation on PFAS manufacturing. Still, RAC wants to highlight the relationship between sector-specific emission estimates and emissions from manufacturing as a general aspect relevant for the RAC Opinion.

RAC considers that the estimation of PFAS emissions for each sector of use would have been more representative if use-specific emission estimates covering the whole life cycle, from PFAS manufacturing through production and service life of products to the waste stage would

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have been calculated. However, the sector-specific emission estimates derived by the Dossier Submitter cover only the use stage (including production of articles) and the end of life. Emissions from PFAS manufacturing are quantified horizontally, without a direct link to individual sectors.

Allocation of PFAS manufacturing emissions to specific uses is complicated mainly due to import and export volumes. In particular, almost all fluorinated gases meeting the PFAS definition used in the EEA are imported. Emissions from manufacturing of imported PFAS occur outside the EEA and are not quantified in the Background Document. RAC did not attempt to allocate PFAS manufacturing emissions to specific uses.

Still, RAC acknowledges that emissions from PFAS manufacturing may represent a major part of the overall life cycle emissions in uses where use and waste stage emissions are low. This is particularly relevant for fluoropolymers. For such cases, RAC refers to the release factors used in the assessment of PFAS manufacturing. These release factors are generally in the order of 0.5% (RF: 0.005) (possibly an underestimation) (e.g. per 1000 t of manufactured PFAS, the associated PFAS emissions from its manufacturing can be estimated at  $\approx 5$  t).

### **3.1.2.3. Time frame of emissions**

In most of the sectors, use stage emissions have been calculated by the Dossier Submitter from the tonnage of PFAS placed on the EEA market for a particular use in a particular year (e.g. 2020). For example, the initial volume placed in the market in 2020 has been multiplied by a release factor for production or articles, yielding emissions from production. The remaining volume was then multiplied by a release factor for service life (a cumulative release factor covering the whole service life, e.g. 20 years), yielding service life emissions. The volume remaining at the end of life has been multiplied by a release factor for end of life (e.g. incineration, landfilling), yielding end of life emissions.

It is clear that in many cases the emissions from a substance placed on the market in a given year (e.g. 2020) would take place over multiple years or decades depending on the duration of service life and the method of disposal (e.g. incineration vs landfilling). Still, for the calculation of effectiveness these emissions have been attributed to a particular year, although in reality they may occur over extended periods of time.

A different approach to quantification of emissions has been chosen by the Dossier Submitter for several applications of fluorinated gases such as HVACR (heating, ventilation, air conditioning and refrigeration). The main source of information on volumes and emissions for HVACR, the Greenhouse Gas Inventory, provides yearly data for three volume-emission pairs:

- Volumes filled into new manufactured products – Emissions from manufacturing
- Volumes in operating systems (average annual stocks) – Emissions from stocks
- Volumes remaining in products at decommissioning – Emissions from disposal

Yearly emissions have been calculated as a sum of emissions from manufacturing, stocks and disposal. Stock emissions can be considered as a counterpart of service life emissions in the former approach.

The Dossier Submitter suggested (in Annex B of the Background Document, section B.28) that the two approaches to emission estimation are not comparable and that the latter approach, based on total stock, is more reliable. However, RAC is of the view that stock emissions are, under steady state conditions, comparable to service life emissions; see the following explanation.

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Service life emissions from new manufactured products are generally calculated as

- Yearly volume placed on the market (t/y) x service life release factor (%)

Service life RF can be split as follows:

- Service life release factor = yearly release factor (%/y) x service life (y)

Thus, service life emissions can be expressed as

- Yearly volume placed on the market (t/y) x yearly RF (%/y) x service life (y)

On the other hand, yearly emissions from stock can be calculated as

- Stock volume (t) x yearly release factor (%/y)

Under steady state conditions, the stock volume is approximately equal to the yearly volume placed on the market multiplied by service life (since at any given time the stock contains all articles that have not yet reached their end of life):

- Stock volume (t) = Yearly volume placed on the market (t/y) x service life (y)

Thus, stock emissions can be, under steady-state conditions, expressed as

- Yearly volume placed on the market (t/y) x service life (y) x yearly RF (%),

which is the same expression as for service life emissions from new manufactured products.

To illustrate this with a hypothetical example, if the new volume put on the market is 1 000 t per year, the service life of the article is 10 years and a steady state has been achieved, then the stock volume is approx. 10 000 tonnes. The stock at the end of each year consists of the new volume (1 000 t) and volumes from the previous 9 years (9 000 t) that have not yet reached their end of life. A service life release factor can be expressed either as e.g. 10% per the whole service life, or as 1% per year (10% / 10 years); both expressions are equivalent. Then the two types of emission estimates are calculated as follows:

- Service life emissions from new manufactured products:  
1 000 t per year x 10% per service life = 100 t
- Yearly emissions from the whole stock:  
10 000 t x 1% per year = 100 t

In conclusion, under the assumption of steady state conditions (i.e. the amount leaving the stock is equal to the amount entering the stock) and a constant release factor, both approaches should give similar results. Thus, the emission estimates derived for HVACR applications can in principle be directly compared to emissions from other sectors/uses. The volumes used in HVACR applications have to be calculated in a specific way, which is outlined in the RAC sector-specific evaluation on "Applications of fluorinated gases".

### **3.1.2.4. Emissions from fluoropolymers**

PFAS emissions from the life cycle of fluoropolymers can occur at multiple steps and in several forms:

- Emissions of fluorinated gases, polymerisation by-products, fluorosurfactants and particles during manufacturing (see the RAC sector-specific evaluation of PFAS manufacturing).
- Residues from polymerisation (e.g. oligomers, by-products, polymerisation aids). These residues are released mainly during processing at increased temperatures, to a lesser extent also during service life and landfilling.

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- Products of thermal decomposition. These are released mainly during processing at increased temperatures (e.g. sintering, extrusion).
- Emissions of fluoropolymer powders, granules and pellets during manufacture, formulation and processing.
- Fluoropolymer particles unintentionally formed from articles e.g. due to abrasion during service life.
- Products of incomplete combustion, e.g. short-chain perfluoroalkanes.

The Dossier Submitter did not differentiate between emissions of particles and emissions of non-polymeric PFAS. Their emission estimates are intended to cover PFAS in all forms.

In RAC's view, it is important to differentiate between particles and chemicals (low-molecular weight PFAS like PFAAs and oligomers) in emissions estimates to accurately understand their environmental impact. Although both forms are persistent, they have a different behaviour in the environment and different hazard profiles. As discussed in section 3.1.1, PFAS (micro)particles are generally less bioavailable and toxic than PFAAs and their precursors. Like in the case of other micro-/nanoplastics, their bioavailability and toxicity are affected by their particle properties (including size) and are not fully characterized yet (see 3.1.1 above).

Therefore, RAC used an alternative approach for estimating emissions from the use stage and landfilling of fluoropolymers. In that approach, the release factors proposed by the Dossier Submitter are applied only to the non-polymeric fraction, which has been, for the purpose of emission estimation, set by RAC at 0.1% (1000 ppm; see below for the reasoning underpinning this approach).

The principle behind this approach stems from the release factor (RF) corresponding to ERC 10A, which has been used by the Dossier Submitter for quantification of service life emissions in several sectors, and indirectly also for quantification of emissions from landfilling. The Dossier submitter applied the RF to the whole fluoropolymer volume. The data behind this RF are described in the OECD emission scenario document on plastic additives (OECD, 2009, p. 69), which specifies that this RF should be applied to the amount of additive present in the product (e.g. plasticiser in PVC). Translated to the situation of fluoropolymers, the RF should be applied to the amount of non-polymeric substances within the fluoropolymer matrix (i.e. not to the whole fluoropolymer volume).

RAC is of the opinion that the exposure assessment of the Dossier Submitter does not accurately quantify emissions of PFAS particles. Emissions of fluoropolymer particles are acknowledged by RAC and highlighted as an important uncertainty, but not quantified due to lack of appropriate RFs. RAC acknowledges that some ERC release factors can, in principle, be used to quantify also emissions of solid particles (e.g. ERC 12B). However, it should be carefully considered whether a particular RF is suitable for quantifying particle emissions in a particular scenario. For example, spillage of solid material during industrial production of articles is probably collected for disposal or further use. The generic assumption of no risk mitigation measures, implied in the ERC release factors, may be inappropriate and lead to excessive overestimation of emissions into the environment. A striking example of such overestimation is quantification of fluoropolymer emissions from production of medical devices, where the Dossier Submitter applied a release factor of 50% (ERC 5; see Annex B of the Background Document, B.9.10.2).

The 1000 ppm estimate of non-polymeric content is based on several sources and considerations. Lohmann et al. (2020) estimated the range of PFAA-leachables in PTFE between 15 and 1000 ppm. Henry et al. (2018) and Korzeniowski et al. (2023) presented data on a number of fluoropolymers. They reported generally negligible content of non-

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polymeric and oligomeric PFAS, but the detection limit for oligomers was often not reported and, in some cases, appears to be in the order of 1000 ppm. If only targeted analysis is used, it may miss a significant part of the residues. Further, the analysed materials may not be representative of all grades of fluoropolymer present on the market.

RAC recognises uncertainties of the 1000 ppm value and the adopted approach. The following paragraphs briefly describe the manufacturing and processing of PTFE (since most of the available data on non-polymeric residues are for PTFE) in order to clarify the issue. Manufacturing and processing of other fluoropolymers may differ in certain aspects.

The polymerization reaction occurs in a solvent, usually water. There are two main types of PTFE polymerisation processes: suspension polymerisation (using no or little surfactant), yielding granulate, and emulsion polymerisation (using a surfactant), yielding dispersions. Besides the high-MW polymeric chains, the polymerisation reaction yields unintended by-products such as non-polymeric and oligomeric PFAS. Surfactants, where used, also remain in the mixture and some of them may participate in the formation of by-products (for details see the specific opinion on "PFAS manufacturing").

The fluoropolymer particles are then separated and rinsed. Non-polymeric PFAS are partly rinsed out and end up in liquid waste from manufacturing. The remaining fraction of non-polymers remains within the polymer particles. Granulates are dried. Dispersions are either dried to fine powder, or concentrated and sold as aqueous dispersion products (e.g. for coating).

The content of non-polymeric residues in aqueous dispersions may reach hundreds to thousands of ppm. Fine powders produced by drying of dispersions contain units to tens of ppm because the increased temperature drives out the more volatile fraction (supplemental information in Wang et al., 2014; ECHA, 2018a; Meng et al., 2021; comment #6337). The content of non-polymeric residues in granular PTFE before drying is unknown, but is probably lower than in dispersions. Overall, 1000 ppm seems to be a reasonable estimate of non-polymeric PFAS concentration in raw fluoropolymers before drying and in aqueous dispersions, whereas the content of non-polymeric residues in dried powders and granules may be in the order of 50 ppm, and further decreases during subsequent high-temperature processing (sintering, extrusion, curing), probably to <1 to units of ppm (confidential comment). A certain fraction of PTFE, in the order of a few %, does not undergo hot processing (Wang et al., 2014, supplemental information p. 27).

Drying of the polymer sold as granulate or fine powder generally occurs at the manufacturing site and the associated emissions are covered by the release factor for manufacturing (this was confirmed by the Dossier Submitter during the discussion on "PFAS manufacturing" at RAC-74). Drying of polymers put on the market as aqueous dispersions occurs at the processing site and the associated emissions have to be covered in the sector-specific assessments. Fluoropolymers applied in the form of aqueous dispersions include PTFE, PVDF, FEP and PFA. The available information suggests that the share of PTFE sold as aqueous dispersion is around 17% (Norwegian Environment Agency, 2021; Prevedouros et al., 2006; a higher share was used in ECHA, 2018a).

The volatiles driven out during drying and processing may either be captured and incinerated, or released to the environment. There are indications that small processing facilities generally do not have efficient abatement systems for PFAS (e.g. ECHA, 2018a).

During hot processing (e.g. extrusion, sintering), fluoropolymers partly decompose. The main types of degradation products are fluoroalkenes (e.g. tetrafluoroethylene, hexafluoropropylene, perfluoroisobutylene), hydrogen fluoride, oxidation products (e.g. carbonyl fluoride) and ultrafine fluoropolymer particulates (Fluoropolymer Products Group pof



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Plastic Europe, 2025). Data on weight loss in % per hour for several fluoropolymers can be found in the guide by the Fluoropolymer Products Group of Plastic Europe (2025). These data are not easily translated into absolute values of % weight loss per operation as the duration and maximum temperature for a given polymer varies. One company estimated weight loss <0.2% during their extrusion process (Annex B of the Background Document, B.9.12.2.2). It is not clear how large a fraction of the decomposition products meet the PFAS definition, but the limited information in FPG (2025) suggests that the fraction of PFAS is rather minor at normal processing temperatures. For the purpose of sensitivity analysis, RAC will assume a release factor of 0.01% per a hot processing step, and no abatement.

As most of the fluoropolymer processing techniques significantly decrease the amount of non-polymeric residues, finished articles are likely to contain only low levels of non-polymeric PFAS (with some exceptions such as PTFE micropowders in lubricants). Given the high stability of fluoropolymers and the low content of residues, RAC assumes that service life emissions from fluoropolymer-containing articles are generally low.

The above analysis reveals two uncertainties in the “1000 ppm approach” adopted by RAC for quantification of fluoropolymer emissions:

- It does not take into account the fact that non-polymeric residues are to a large extent released as volatiles already during drying and hot processing (e.g. sintering, extrusion, curing), and only a small fraction remains at the beginning of service life. Only polymers not undergoing drying/hot processing and micropowders represent an exception.
- Processing at increased temperatures leads to thermal degradation of the polymer and release of decomposition products, a minor fraction of which may be PFAS.

To analyse the quantitative impact of these two identified issues on the emission estimates, RAC has conducted a sensitivity analysis using an illustrative example with an assumed total fluoropolymer volume of 1000 t, a processing release factor of 5% (applied in the “1000 ppm approach” only) and a service life release factor of 3% (applied in both the “1000 ppm approach” and the “sensitivity analysis”)<sup>10</sup>:

- Adopted (“1000 ppm”) approach<sup>11</sup>:
  - Processing: 0.05 t
  - Service life: 0.03 t
  - Total: 0.08 t
- Sensitivity analysis<sup>12</sup>:

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<sup>10</sup> Formulation of mixtures is another step, and this could be added in both approaches. Still, it is often followed by hot processing and therefore inclusion of formulation would not change the overall conclusion that the “1000 ppm” approach in many cases underestimates use stage emissions.

<sup>11</sup> Calculation of use stage emissions according to the adopted “1000 ppm” approach:

Amount of non-polymeric PFAS within the polymer:  $1000 \text{ t} \times 1000 \text{ ppm} (0.001) = 1 \text{ t}$

Emissions from processing:  $1 \text{ t} \times 5\% (0.05) = \mathbf{0.05 \text{ t}}$

Emissions from service life:  $\approx 1 \text{ t} \times 3\% (0.03) = \mathbf{0.03 \text{ t}}$

<sup>12</sup> Calculation of use stage emissions for sensitivity analysis:

Volume of dry products:  $1000 \text{ t} \times 83\% (0.83) = 830 \text{ t}$

Amount of non-polymeric PFAS within dry products:  $830 \text{ t} \times 50 \text{ ppm} (0.00005) = 0.042 \text{ t}$

Emissions from volatilization of residues (dry pr., 50 ppm → 5 ppm):  $0.042 \text{ t} \times 90\% (0.9) = 0.038 \text{ t}$

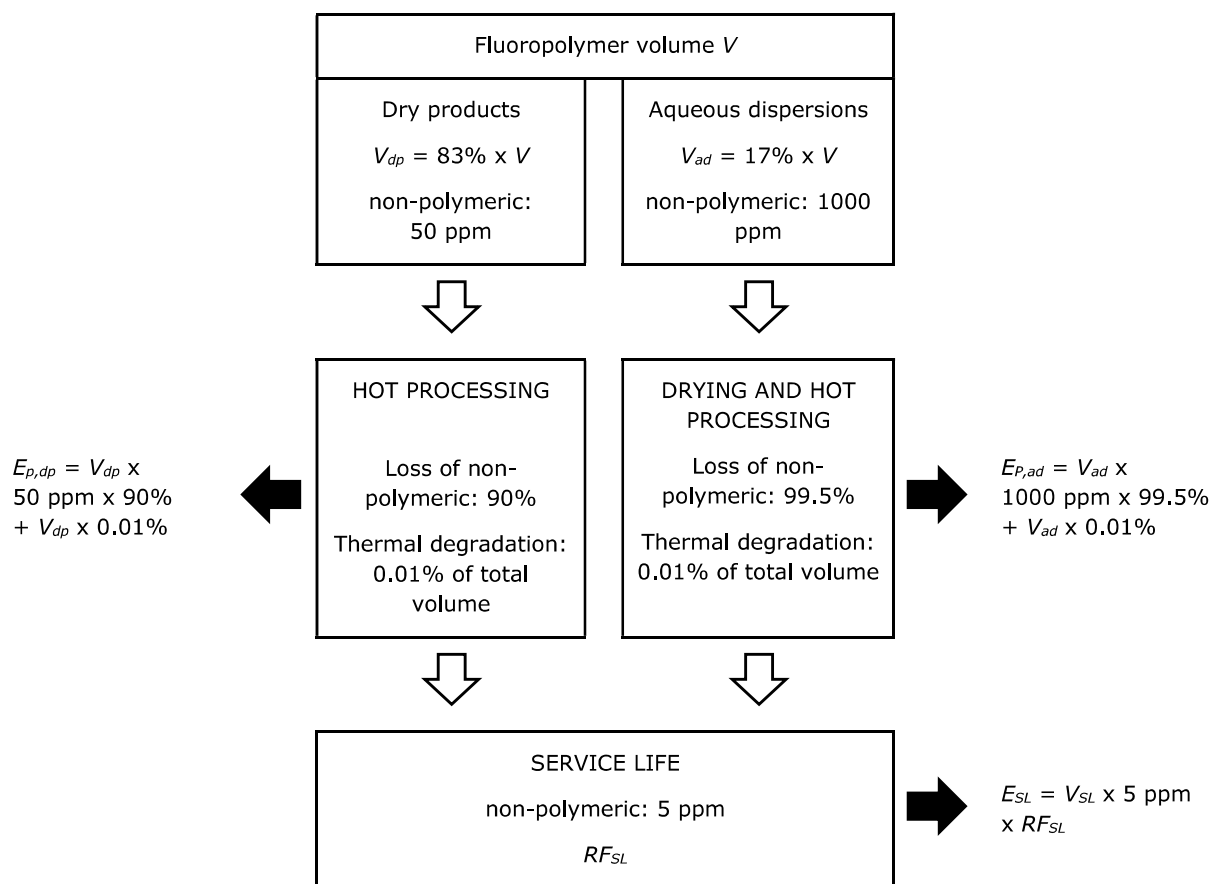
Volume of aqueous dispersions:  $1000 \text{ t} \times 17\% (0.17) = 170 \text{ t}$

Amount of non-polymeric PFAS within aqueous dispersions:  $170 \text{ t} \times 1000 \text{ ppm} (0.001) = 0.17 \text{ t}$

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- Processing – volatilization of residues: 0.21 t
- Processing – thermal degradation: 0.1 t
- Service life: 0.00015 t
- Total: ≈0.3 t

The calculation for sensitivity analysis is explained in a footnote and in the following figure:



According to the sensitivity analyses, there is not a major difference in terms of impact on the overall life cycle emissions of fluoropolymers, which are dominated by manufacturing and incineration.

However, RAC acknowledges that the sensitivity approach also has its uncertainties: it is based on the information for PTFE only, does not cover fluoropolymers not undergoing drying/hot processing and micropowders, and the release factor for thermal degradation is highly uncertain. Still, it indicates that the approach adopted by RAC may lead to some underestimation of use stage emissions in a number of cases. Overall, considering all the above elements, the “1000 ppm approach” is still considered by RAC as the preferred approach for both use stage and waste stage emissions.

Emissions from PFAS manufacturing are not included in the sector-specific emission

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Emissions from volatilization of resid. (aq. disp., 1000 ppm → 5 ppm): 0.17 t x 99.5% (0.995) ≈ 0.17 t  
 Emissions from volatilization of residues (dry products + aq. dispersions): 0.042 t + 0.17 t = **0.21 t**  
 Volume undergoing thermal decomposition: 1000 t  
 Emissions from thermal decomposition: 1000 t x 0.01% (0.0001) = **0.1 t**  
 Emissions from service life: ≈1000 t x 5 ppm (0.000005) x 3% (0.03) = **0.00015 t**

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estimates. Therefore, the sector-specific estimates do not show the full impact of individual uses in terms of PFAS emissions. This issue is particularly relevant for fluoropolymers, where the manufacturing step probably contributes the most to the overall life cycle emissions. To compensate for this, in the paragraph below RAC provides indicative order-of-magnitude estimates for individual life cycle steps. These estimates are associated with high uncertainty and may not correctly reflect certain uses but still may be useful for better insight into the life cycle emissions of fluoropolymers.

Per 1000 t of fluoropolymer:

- RAC assumes that roughly  $\approx 5$  t of non-polymeric PFAS (or more) are emitted during manufacturing (including manufacturing of monomers). For more information see the sector opinion on "PFAS manufacturing".
- Roughly  $\approx 0.3$  t of non-polymeric PFAS may be emitted during hot processing (if it occurs). For details see the sensitivity analysis above.
- Non-polymeric emissions from service life and landfilling are generally very low.
- Emissions from incineration of fluoropolymers (and PFAS in general) are highly uncertain, see the analysis below in section 3.1.2.6. Based on the available information, RAC estimates that non-polymeric PFAS emission from incineration of 1000 t of fluoropolymer in a hazardous waste incinerator are probably between 0.1 and 10 t (RF 1%, i.e. 10 t per 1 000 t, has been used in the RAC calculations). No relevant data are available for non-hazardous waste incineration, in the calculations RAC assumed 20 t emitted per 1000 t of fluoropolymer (RF 2%).

### PTFE micropowder

PTFE micropowder, used e.g. in lubricants and coatings, can be manufactured from virgin or recycled PTFE (e.g. scraps from production of articles). The material is degraded, e.g. by irradiation or thermal degradation, to reduce its molecular weight, and milled to the desired particle size. Alternatively, the micropowder may be produced through a controlled polymerisation process to create a lower molecular weight PTFE directly. PTFE micropowder has a few specifics with respect to emissions and bioavailability:

- Degradation, e.g. by irradiation or thermal degradation, creates low-MW by-products including PFAAs (e.g. Oshima et al., 2020). As a result, the content of non-polymeric PFAS in micropowders may be much higher than in other types of dry fluoropolymer.
- The intentional degradation may yield volatile decomposition by-products in higher amounts than normal hot processing.
- A certain fraction of the particles may be in submicron size and thus potentially bioavailable.

The uncertainty and possible underestimation of bioavailable emissions has been highlighted in the sector specific evaluations especially in the lubricants sector.

### **3.1.2.5. Emissions from other types of PFAS**

#### PFAAs and PFAA precursors (including side-chain fluorinated polymers)

This group of PFAS includes side-chain fluorinated polymers (SCFPs) and various non-polymeric PFAS (see also section 3.1.1). The potential for emissions during subsequent production of articles/mixtures and their service life greatly varies depending on the application, and this is addressed in the RAC sector-specific evaluations. In general, a

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significant fraction of the PFAAs/precursors is emitted in the use stage, but still a considerable amount often remains in the products at the end of life. RAC notes that many fluorinated gases are also PFAA precursors under the OECD classification (2021) (perfluoroalkanes being an exception) although they are evaluated separately due to their significantly higher emission potential (see sub-section below).

RAC agrees with the Dossier Submitter's approach to quantification of PFAAs and their precursors. SCFPs are discussed in more detail below.

The Dossier Submitter generally used the same release factors for non-polymeric PFAS and side-chain fluorinated polymers. In SCFPs, the fluorinated side chains (e.g. fluorotelomers) are attached to the non-fluorinated polymer backbone via ester bonds (e.g. in fluorotelomer acrylate or urethane SCFPs), ether bonds (e.g. oxethane SCFPs) or other types of bonds (OECD, 2022). The fluorinated side-chain may split off from the polymer backbone and eventually degrade to PFAAs.

Most of the available data on degradation of SCFPs are for fluorotelomer acrylates. The ester bond is prone to hydrolysis and the rate of hydrolysis can be measured. However, the results can be greatly influenced by residual monomers, the choice of extraction solvents or particle size of the test material. This makes degradation testing challenging. In the most reliable study (Washington et al. 2015), the degradation half-lives in soil ranged from 33 to 112 years. The degradation rates under biotic (soil) and abiotic (water) conditions were similar. The rate of abiotic hydrolysis increased at alkaline pH (Washington and Jenkins 2015). A set of confidential studies on degradation of a fluorotelomer-based acrylate in soil were submitted in the Annex XV report consultation however, the description of the methodology is not very detailed. Other types of bonds (e.g. ether bond) are assumed to be more stable, but there is little experimental data for these.

The study by Washington et al. (2015) has been analysed by RAC in the RAC opinion on the PFOA restriction, where "RAC assumed an overall environmental transformation of 1% per year of the fluorotelomer-based polymers into PFOA (recognising that this might be an over-estimate for some types)". The degradation factor of 1% per year was also used in the RAC opinion on the PFHxA restriction.

In the current restriction proposal, the Dossier Submitter did not apply a correction factor for incomplete degradation of SCFPs directly. Rather, they seem to have taken this into account indirectly in the selection of release factors. For example, the proposed service life release factors for PFAAs/precursors in textiles are in the order of units of % to tens of % depending on use. For landfilling of PFAAs/precursors the Dossier Submitter horizontally applied a release factor of ca. 3% (RF: 0.03). RAC agrees with the Dossier Submitter's general approach to calculation of SCFP emissions.

### PFPEs

PFPEs are polymers but, unlike fluoropolymers, they are liquids. The average molecular weight of PFPE products ranges from hundreds g/mol to tens of thousands g/mol. Short-chain products are volatile, long-chain products are not. Water solubility is generally low (<10 mg/l) with some exceptions (OECD, 2024). PFPEs might degrade to shorter-chain PFAS (OECD, 2024). The information on PFPEs and their emissions is still relatively limited, but the potential for emissions is generally higher compared to fluoropolymers.

The Dossier Submitter quantified PFPE volumes separately from fluoropolymers in four sectors: "Lubricants", "Electronics and semiconductors" (e.g. heat transfer fluids), "TULAC" (PFPEs probably used as fluorinated side-chains) and "Energy" (<1 t/y).

As some PFPE products have a rather low molecular weight and may be volatile, RAC

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concluded that PFPEs should not be grouped with fluoropolymers for the purpose of emission calculations in those sectors where PFPE volumes have been provided separately. In all cases RAC has applied the release factors (RFs) proposed by the Dossier Submitter to the whole PFPE volume without any corrections (e.g. RF 4.5% (0.045) for production of lubricants and heat transfer fluids; RF 7.1% (0.071) for treatment of textiles; RF 0.1% (0.001) or 6.5% (0.065) for service life of textiles; RF 10% (0.1) for service life of heat transfer fluids; RF 10% (0.1) or 50% (0.5) for service life of lubricants). RAC is of the view that specifically in the case of lubricants the application of RFs up to 50% (0.5) probably leads to significant overestimation of bioavailable emissions, given the polymeric nature and low solubility of PFPEs used in that sector. RAC acknowledged the overestimation in the sector-specific evaluation.

### Fluorinated gases

The emission potential of fluorinated gases is high mainly because of their gaseous state. Emissions occur at multiple points of the life cycle: during manufacture, handling of containers, filling into equipment/products, service life of products, end-of-life recovery, recycling, landfilling. Service life emissions of refrigerants in some applications are very high and the equipment requires regular refilling to compensate the losses. At the end of life, the remaining refrigerant is usually recovered from the equipment. Nevertheless, the recovery is often incomplete, and the remaining gas may be released later (e.g. in the landfill). Emissions from the use as foam-blowing agents are also high and difficult to control. Propellants are fully discharged during service life.

### **3.1.2.6. Emissions from the waste stage**

PFAS-containing waste generally arises from manufacturing of PFAS, from production of articles and from products reaching end of life. The waste is collected and destined for disposal or recycling. Emissions to the environment may occur during waste collection, transport, handling at waste transfer stations, recycling, incineration and landfilling.

The horizontal aspects of the waste stage of PFAS have been described in detail by the Dossier Submitter in the Background Document (section 1.1.5.5 of the main document, section B.26 of Annex B) and that information will not be repeated here. The RAC assessment in this section will focus on the waste stage release factors applied horizontally across sectors.

The Dossier Submitter has quantified in the sector-specific assessments emissions from landfilling and incineration as the two most important waste treatment methods. Emissions from recycling of PFAS-containing products have been assessed mostly qualitatively, in some cases also quantitatively (batteries, metal products). Recycling of PFAS as substances and recycling of PFAS-containing products is discussed in detail in section 3.1.2.7 below. Emissions related to treatment of waste from production of articles are covered by the release factors for production in the RAC sector-specific evaluations. Emissions from waste collection, transport, handling at waste transfer stations, and storage at incineration plants have not been quantified by the Dossier Submitter.

Quantification of waste stage emissions in the sector-specific assessments performed by the Dossier Submitter generally relies on three input values: (1) amount of PFAS in waste; (2) waste distribution among the different treatment methods (incineration, landfilling); (3) release factors for the treatment methods.

For the majority of applications, the Dossier Submitter used data on waste distribution between landfilling, non-hazardous waste incineration and hazardous waste incineration from the Eurostat database for the waste category correlating best with the type of waste expected

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from that use (see Annex B of the Background Document, Appendix B.9.26, Table B.179). For example, for plastic packaging, the Dossier Submitter used data for plastic waste; for consumer apparel, data for textile waste, etc. The distributions from Eurostat data were corrected for recycling since the Dossier Submitter assumed that the recycled material will finally also end up in either incineration or landfilling. For certain applications, the Dossier Submitter used sector-specific information on distribution from stakeholders or other sources. No waste stage emissions have been assumed for applications where almost the whole amount is likely to be released during the use stage (e.g. propellants, consumer mixtures).

Effectiveness of wastewater treatment for PFAS removal is also briefly discussed in this section. PFAS enter wastewater not only as a result of PFAS manufacturing, production of articles and their service life, but also at the end of life e.g. via landfill leachate, leachate from waste transfer stations or spent water from flue gas cleaning in incinerators.

The generic release factors proposed by the Dossier Submitter for landfilling, non-hazardous waste incineration, hazardous waste incineration and wastewater treatment can be found in Table B.120 of Annex B (section B.26) of the Background Document and are evaluated by RAC below. In some cases (e.g. "Electronics and semiconductors") the Dossier Submitter applied use-specific release factors. For several applications of fluorinated gases (e.g. HVACR) the Dossier Submitter directly used data on 'emissions from disposal' from the GHG inventory.

### Incineration

There are two basic types of waste incinerators that are commonly used for incineration of PFAS-containing waste: (1) moving grate incinerator, used for incineration of municipal solid waste (i.e. non-hazardous waste), and (2) rotary kiln, typically used for incineration of hazardous waste. Systems designed for thermal treatment of sewage sludge (pyrolysis, gasification, fluidised bed incinerators) are not taken into account in the current assessment.

According to the Industrial Emissions Directive, *"waste incineration plants shall be designed, equipped, built and operated in such a way that the gas resulting from the incineration of waste is raised, after the last injection of combustion air, in a controlled and homogeneous fashion and even under the most unfavourable conditions, to a temperature of at least 850 °C for at least two seconds"*. For hazardous waste containing >1% of halogenated substances the requirement is  $\geq 1100$  °C for at least 2 seconds. These conditions are achieved via afterburners, fuelled e.g. by natural gas. More details on incinerators and flue gas cleaning systems can be found e.g. in the BREF document for waste incineration (JRC, 2019).

Ideally, the incineration of PFAS should lead to their full conversion to inorganic compounds like CO<sub>2</sub> and HF, i.e. mineralisation. In practice, a given PFAS may be partly transformed to other fluorinated organic substances, called "products of incomplete combustion" (PICs). Therefore, a distinction has to be made between destruction efficiency, which is calculated as the output divided by the input of a particular substance (e.g. the mass of PFOA in the exhaust emissions and solid/liquid residues divided by the mass of PFOA in the waste feed), and mineralisation efficiency.

The chemistry of PFAS incineration is rather complex, but the current knowledge can be summarised as follows (based on US EPA, 2024; Wang et al., 2022; Tsang et al., 1998; Krug et al., 2022; Weber et al., 2023):

- Temperature has a critical impact on both the reaction kinetics and the chemical equilibrium. At the high temperatures and in the presence of oxygen and hydrogen in incinerators, the thermodynamics favours mineralization, but this may not be fully achieved due to kinetic (temperature) or transport (mixing) limitations.
- The most difficult fluorinated organic compound to decompose is CF<sub>4</sub>. The C–F bond is

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stronger than the C–C or C–H bond. Presence of C–C and C–H bonds provides a weak point in the structure and lowers temperatures needed for decomposition.

- Further, fluorinated organic compounds can be destroyed by free radical reactions in flames. When the C–C bonds are broken, the carbon-fluorine fragments may combine with one another, leading to formation of PICs. However, if the temperatures and concentrations of other radicals (particularly hydrogen atoms and hydroxyl radicals) are high, as occurs in flames, the carbon-fluorine species are likely to degrade further to CO<sub>2</sub> and HF.
- The most abundant PICs formed during incineration at suboptimal temperatures and/or oxygen supply are short-chain fluorocarbons or hydrofluorocarbons, e.g. C<sub>2</sub>F<sub>6</sub>, CF<sub>4</sub>, CHF<sub>3</sub>, C<sub>2</sub>HF<sub>5</sub>, C<sub>3</sub>HF<sub>7</sub> and C<sub>3</sub>F<sub>8</sub> (see Clarke et al., 1992; Shields et al., 2023).

Several studies also investigated thermal decomposition of PFAS in the presence of oxygen but without hydrocarbon flame. The main PICs identified in the studies by García et al. (2007) (decomposition of PTFE) and Weber et al. (2023, 2024) (decomposition of PFOS) were C<sub>2</sub>F<sub>6</sub>, CF<sub>4</sub> and tetrafluoroethylene. Mattila et al. (2024) investigated combustion products of several aqueous film-forming foams in an experimental combustor (US EPA Rainbow furnace), intentionally applying suboptimal conditions (foams injected post-flame at temperatures around 800 °C, dropped to ca. 600 °C within 2 s). Among the identified products were TFA and other short-chain PFCAs, trifluoroacetamide and several inorganic silicon-fluorine compounds (products of HF reaction with the refractory lining of the furnace).

There are numerous studies reporting presence of PFAS in flue gas, wastewater and solid residues from incineration (e.g. Björklund et al., 2023; Strandberg et al., 2021; comments #4024, #9274). Björklund et al. (2023) measured emissions of 18 PFAS (mainly ≥C<sub>4</sub> PFCAs and PFSA) from a moving grate incineration plant in Sweden combusting household and industrial waste. The authors sampled flue gas, bottom ash, treated process water and air pollution control residue. Eight individual PFAS were detected, C<sub>4</sub>-C<sub>7</sub> PFCAs were most prevalent. The total release of the measured PFAS was estimated to be between 7 and 20 g per year, or 0.07-0.1 µg per kg of incinerated waste. Addition of wastewater treatment sludge to the solid waste (5-8% of sludge in the mixture) lead to an increase in emissions (0.07-0.4 µg/kg waste). An overall emission factor cannot be calculated due to the unknown amount of PFAS in the waste and the limited number of PFAS measured; this also applies to several other studies.

For the purpose of release factor setting, there is a need for studies comprehensively quantifying both the PFAS input into the incinerator and the PFAS output from the incinerator. The three most relevant studies in this regard are summarised below.

Shields et al. (2023) performed experiments with an aqueous film forming foam containing PFOS and PFHxS in a pilot-scale combustor (US EPA Rainbow furnace). When the residence time was at least 2 s at >800 °C, destruction efficiencies for measured PFAS exceeded 99.95% and volatile substances were mostly non-detectable. The study had a relatively comprehensive analytical characterisation of gaseous emissions, including 30 non-polar fluorinated volatile organic substances ≥C<sub>1</sub> (e.g. CF<sub>4</sub>, C<sub>2</sub>F<sub>6</sub>), 49 polar PFAS ≥C<sub>4</sub> and non-target PFAS analysis. Ultra-short PFCAs (e.g. trifluoroacetic acid) were not among the target analytes. The LOQ for CF<sub>4</sub> was relatively high (ca. 200 µg/m<sup>3</sup>, corresponding to an RF in the order of 0.1-0.2%). In low-temperature runs the amounts of PICs increased with decreasing temperature, the highest concentrations were found for hydrofluorocarbons (e.g. CHF<sub>3</sub>, C<sub>2</sub>HF<sub>5</sub>, C<sub>3</sub>HF<sub>7</sub>) and perfluorocarbons (e.g. C<sub>3</sub>F<sub>8</sub>).

Gehrmann et al. (2024) investigated PFAS emissions from incineration of a mixture of fluoropolymers (PTFE, PVDF, PFA, FKM) in a pilot-scale rotary kiln (BRENDA facility in