Committee for Risk Assessment (RAC)

Opinion

on an Annex XV dossier proposing restrictions on

Per- and polyfluoroalkyl substances (PFAS)

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

Date: 2 March 2026

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.

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1. OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Table 1: Proposed restriction

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Per- and polyfluoroalkyl substances (PFASs) defined as: Any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it). A substance that only contains the following structural elements is excluded from the scope of the restriction: CF_3-X or X-CF_2-X’, where X = -OR or -NRR’ and X’ = methyl (-CH_3), methylene (-CH_2-), an aromatic group, a carbonyl group (-C(O)-), -OR’’, -SR’’ or –NR’’R’’’; and where R/R’/R’’/R’’’ is a hydrogen (-H), methyl (-CH_3), methylene (-CH_2-), an aromatic group or a carbonyl group (-C(O)-).	1. Shall not be manufactured, used or placed on the market as substances on their own; 2. Shall not be placed on the market in: a. another substance, as a constituent; b. a mixture, c. an article in a concentration of or above: i. 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification) ii. 250 ppb for the sum of PFASs measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors iii. 50 ppm for total PFASs (polymeric PFASs included). If total fluorine exceeds 50 mg F/kg the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFASs or non-PFASs. 3. Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction. 4. By way of derogation, paragraphs 1 and 2 shall not apply to a. active substances in biocidal products within the scope of Regulation (EU) 528/2012 b. active substances in plant protection products within the scope of Regulation (EC) 1107/2009 c. active substances in human and veterinary medicinal products within the scope of Regulation (EC) No 726/2004, Regulation (EU) 2019/6 and Directive 2001/83/EC d. placing on the market of articles which were already in end-use in the Union 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 f. spare parts used in articles or complex objects for which legal obligations related to the use of

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	specific spare parts exist until the end of service life of the complex object g. starting materials and intermediates in the manufacture of PFASs for a use listed under paragraphs 4, 5 or 6 h. production of PFAS containing mixtures or articles in the upstream supply chain for a use listed under paragraphs 4, 5 or 6 i. uses under product and process orientated research and development (PPORD; art. 67(1) of EU-REACH) j. paper and board articles containing recovered material, with the exception of food-contact material and packaging k. textile articles containing recovered material, with the exception of toys as defined in Directive 2009/48/EC, until 13.5 years after EiF 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 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 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; 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; 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. Manufacturers and importers of the active substances referred to in points a) – c) shall submit to the Agency every two years the following information: i. the derogation that the intended use belongs to; ii. the identity and quantity of the active substance placed on the market The Agency shall publish on its website a summary of the submitted information referred to in points i) – ii)

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	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. Suppliers of plastic articles or complex objects falling under the scope of the WEEE Directive (Directive 2021/19/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. 5. By way of derogation, paragraphs 1 and 2 shall not apply to: 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; 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; c. impregnation agents for re-impregnation of articles referred to in paragraph 5a and 5b until 13.5 years after EiF; d. hard chrome plating until 6.5 years after EiF; e. refrigerants in low temperature refrigeration below -50 °C until 6.5 years after EiF; f. refrigerants in laboratory test and measurement equipment until 13.5 years after EiF; g. refrigerants in refrigerated centrifuges until 13.5 years after EiF; h. refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives;

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	i. foam blowing agents in thermal insulation foam until 13.5 years after EiF; 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; 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; l. preservation of cultural paper-based materials until 13.5 years after EiF; m. insulating gases in high-voltage switchgear (above 145 kV) until 6.5 years after EiF 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); o. [potential derogation for use of fluorinated gases at the CERN research installation unit until 13.5 years after EiF]. p. additives to hydraulic fluids in transport vehicles until 13.5 years after EiF; 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 r. refrigerants in transport refrigeration other than in marine applications until 6.5 years after EiF; s. coatings and films on displays and lenses of electronic complex objects for 6.5 years after EiF; t. printed circuit boards and antennas for 13.5 years after EiF u. photonics for 13.5 years after EiF; v. heat transfer fluids for 2-phase immersion cooling for 13.5 years after EiF; w. semiconductor manufacturing until 13.5 year after EiF; x. coatings and films of electronic components (excluding displays and lenses) for 13.5 years after EiF; y. binders and electrolytes in batteries until 13.5 years after EIF z. polymer additives used for fire safety purposes in construction products until 13.5 years after EiF;

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	aa. industrial and professional uses of lubricants or lubricant additives until 13.5 years after EIF; bb. gas and oil tracers until 13.5 years after EiF; cc. toners until 13.5 years after EiF; dd. latex printing inks until 13.5 years after EiF; ee. electrophotographic press units until 13.5 years after EiF; ff. kinetic printing components until 13.5 years after EiF; gg. photosensitive materials until 13.5 years after EiF hh. toners for use in existing equipment put on the market until 13.5 years after EiF; ii. latex printing inks for use in existing equipment put on the market until 13.5 years after EiF; jj. excipients in medicinal products for ophthalmic and dermatological therapies until 13.5 years after EiF kk. propellants in pMDIs until 6.5 years after EiF ll. military applications until 13.5 years after EiF 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; nn. sound-permeable and vent filters for electrical and electronic equipment for 6.5 years after EiF; oo. oxygen-permeable membranes in zinc-air batteries and other types of alkaline metal-air batteries for 13.5 years after EiF; pp. industrial use as media in liquid-liquid separation for 13.5 years after EiF; 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; rr. technical textiles in transport vehicles for noise, vibration and harshness (NVH) insulation outside the engine bay until 6.5 years after EiF; 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 >20 cm hydrostatic head according to EN 13795 for 13.5 years; tt. impregnation agents for re-impregnation of articles referred to in paragraph 5ss until 13.5 years after EiF; uu. ionic liquids used in industrial uses until 6.5 years after EiF; vv. solvents used in industrial uses until 13.5 years after EiF; ww. catalysts and processing aids used in industrial uses until 13.5 years after EiF.

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	6. By way of derogation, paragraphs 1 and 2 shall not apply to fluoropolymers and perfluoropolyethers for the use in: a. polymer processing aids used in flexible plastic film extrusion (for food and non-food applications) until 6.5 years after EiF. b. non-stick coatings in industrial bakeware until 6.5 years after EiF; c. implantable medical devices (including medical implants and meshes) until 13.5 years after EiF; d. invasive medical devices (e.g. tubes and catheters) until 13.5 years after EiF; e. packaging for medical devices until 13.5 years after EIF; 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. g. heat transfer fluids for industrial and professional use of vapor phase soldering for electronics for 13.5 years after EiF; h. wires and cables (incl. connectors) for 13.5 years after EiF i. insulation material of electronic components (excluding wires, cables and connectors) for 13.5 years after EiF;

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	j. anti-drip agent in plastics of electronic components for 13.5 years after EiF; k. fuel cells and electrolysers until 13.5 years after EiF; l. separator coatings for batteries until 6.5 years after EIF m. PTFE nozzles in high voltage (>145 kV) switchgears and circuit breakers until 6.5 years after EIF n. front- and backsheets in photovoltaic cells until 6.5 years after EIF o. bridge and building bearings until 13.5 years after EiF; p. sealing applications in industrial uses until 13.5 years after EiF q. machinery applications in industrial uses until 13.5 years after EIF r. coatings in release liners and backing film in transdermal patches until 13.5 years after EiF s. blisters for solid oral dose formulations until 6.5 years after EiF t. coated rubber stoppers in vials/flasks for injectable medicinal products until 13.5 years after EiF u. coated canisters in pressurized metered-dose inhalers (pMDIs) until 13.5 years after EiF; v. coated plungers in pre-filled syringes until 13.5 years after EiF w. pre-filled injection pens & autoinjectors until 13.5 years after EiF x. explosives in military applications until 13.5 years after EiF y. industrial use of fluoropolymers in filtration and separation media for water treatment and purification for 6.5 years after EiF. 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: i. the derogation that the intended use belongs to; ii. the identity and quantity of the substances placed on the market in the previous year. The Agency shall make the information available to the Commission and Member States by 31st August every year;

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	8. Without prejudice to paragraph 7, manufacturers, importers and downstream users of fluoropolymers and perfluoropolyethers making use of any of the derogations in paragraphs 5 or 6 shall establish a site-specific management plan which shall include: i. information on the identity of the substances and the products they are used in ii. a justification for the use; iii. details on the conditions of use and safe disposal. The management plan shall be reviewed annually and kept available for inspection by enforcement authorities upon request. 9. 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.

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)**:

Table 2: Restriction proposed by RAC

Column 1 Designation of the substance, of the group of substances or of the mixture	**Column 2** Conditions of restriction
Per- and polyfluoroalkyl substances (PFASs) defined as: Any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it). *The Dossier Submitter proposes to exclude the following substances from the scope on the grounds that they are fully degradable:* “A substance that only contains the following structural elements is excluded from the scope of the restriction: CF_3-X or X-CF_2-X’, where X = -OR or -NRR’ and X’ = methyl (-CH_3), methylene (-CH_2-), an aromatic group, a carbonyl group (-C(O)-), -OR’’, -SR’’ or –NR’’R’’’; and where R/R’/R’’/R’’’ is a hydrogen (-H), methyl (-CH_3), methylene (-CH_2-), an aromatic group or a carbonyl group (-C(O)-).” *RAC considers that the evidence provided is not sufficient to justify this exclusion (see section 3.1.1. of the RAC Opinion).*	1. Shall not be manufactured, used or placed on the market as substances on their own; 2. Shall not be placed on the market in: a. another substance, as a constituent; b. a mixture, c. an article in a concentration of or above: i. 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification) ii. 250 ppb for the sum of PFASs measured as sum of targeted PFAS analysis~~, optionally~~ with prior degradation of precursors 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). 3. Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction. 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) 7. Manufacturers, importers of PFAS or PFAS-containing mixtures or articles as well as industrial 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)~~, 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: i. the derogation that the intended use belongs to; ii. the identity and quantity of the PFAS substances placed on the market in the previous year; The Agency shall make the information available to the European Commission and Member States by 31st August every year; 8. a) Suppliers of PFAS or PFAS-containing mixtures or articles for an application with continued use of PFAS by

Column 1 Designation of the substance, of the group of substances or of the mixture	**Column 2** Conditions of restriction
	way of a derogation from paragraph 1 and 2 shall provide from (EiF + 18 months): i. the statement "This product contains PFAS" ii. instructions for safe use and disposal explaining to industrial and professional users and the general public how to prevent releases of PFAS to the environment. iii. the identity of PFAS and quantity contained that enables manufacturers and industrial downstream users to comply with their obligations laid down in paragraph 7 and 8b; 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. 8. b) Without prejudice to paragraph 8a, manufacturers~~,~~ ~~importers~~ and industrial downstream users of ~~fluoropolymers and perfluoropolyethers,~~ PFAS or PFAS-containing mixtures ~~making use of any of the derogations in paragraphs 5 or 6~~ 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: i. information on the identity of the PFAS substances and the products they are used in; ii. a justification for the use of PFAS (including an assessment of the technical feasibility of alternatives); 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.); 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). The management plan shall be reviewed annually and kept available for inspection by enforcement authorities upon request. 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. 9. This restriction does not affect existing entries of REACH

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	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:

- 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 (LRTP), accumulation in plants, global warming potential and (eco)toxicological effects. PFAS enter the environment via emissions during manufacture, the use phase, and the waste stage.

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

Regulatory risk management options

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

Scope

The chemical scope of the restriction proposal is defined as: Any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-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[1] 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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[1] Any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it).

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[2]. 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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[2] 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

containing the evaluation of sector-/use-specific aspects form the Committees' opinion on the proposed restriction.

The sector-specific evaluations include:

- **Sector 1:** PFAS manufacturing
- **Sector 2:** Textiles, upholstery, leather, apparel and carpets (TULAC)
- **Sector 3:** Food contact materials and packaging
- **Sector 4:** Metal plating and manufacture of metal products
- **Sector 5:** Consumer mixtures and miscellaneous consumer articles
- **Sector 6:** Cosmetics
- **Sector 7:** Ski wax
- **Sector 8:** Applications of fluorinated gases
- **Sector 9:** Medical devices
- **Sector 10:** Transport
- **Sector 11:** Electronics and semiconductors
- **Sector 12:** Energy
- **Sector 13:** Construction products
- **Sector 14:** Lubricants
- **Sector 15:** Petroleum and mining

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

These eight additional sectors are as follows:

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

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

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

2.2.1. RAC opinion summary

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 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 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 managements 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.

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

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 (CF_3-) or methylene (-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 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[3] and 4,8-dioxa-3H-perfluorononanoic acid[4]) 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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[3] EC 236-236-8; also known as GenX

[4] EC 700-835-7; also known as ADONA

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_2, 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 ($C_4F_9OCH_3$).

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,

#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 (CH2=CBr-CF3), 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, CF3C(O)CH2OH, and CF3OH. 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 ≥ 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.

<u>PFAS that may be excluded from the scope as non-persistent</u>

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: CF3-X or X-CF2-X', where X = -

OR or -NRR′ and X′ = methyl (-CH3), methylene (-CH2-), an aromatic group, a carbonyl group (-C(O)-), -OR′′, -SR′′ or –NR′′R′′′; and where R/R′/R′′/R′′′ is a hydrogen (-H), methyl (-CH3), methylene (-CH2-), 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_3OH 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_3OH can be slow leading to high DT50s (see Parandaman et al., 2018 and Nguyen et al., 2009). It remains therefore uncertain how fast CF_3OH 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 (TFMPrOH) 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 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 ≤20% the results do not suggest that degradation in the environment would be slow (ECHA Guidance Document R.11[5]). 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 ^{14}C radiolabelled trifluoromethoxy derivative (confidential comment), shows rapid and extensive mineralisation of the CF3-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, DegT50 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 -CF3 group. Further, when considering the total NERs as non-degradable parent substance, the Parent+NER modelling gives a $DegT_{50}$ 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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[5] https://echa.europa.eu/documents/10162/23047722/ir_csa_r11_msc_bpc_en.pdf/f43d277c-835e-a208-5c51-53c5826f0845

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 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 Log K_{oc} ≤4 or ≤3, respectively. PFSAs up to 6 carbons and PFPAs are similar in mobility to PFCAs based on Log K_{oc} values. Overall, data for PFCAs, PFSAs and perfluoroalkylphosphonic acids indicate that there is a trend of increasing Log K_{OC} values with increasing chain length (e.g. PFCAs 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 Log K_{oc} value. With the exception of $C4F_{10}O_2$ all perfluoroethers fulfil either the vM or M criterion based on their 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 Log K_{oc} ≤4 and very mobile with a Log K_{oc} ≤3. However, the recently adopted classification criteria for M/vM under CLP considers a substance as M when Log K_{oc} is < 3 and very mobile when Log K_{oc} is < 2. Adsorption properties measured by the log Koc 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 log K_{oc}. 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°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, PFSAs, 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 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 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 PFSAs. 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.

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 208, Joerss 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 ≥C4 PFCAs and ≥C4 PFSAs not covered by existing or other proposed restrictions. Less data is available on short (C1-C3) PFAAs, cyclic PFAAs, PFPAs 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 >500μm, 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.

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) (≥40%) and polyethylene (PE) (≥23%), followed by polytetrafluoroethylene (PTFE) (≥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 ± 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 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 PFSAs between mice, rats and humans.

Besides PFCAs and PFSAs, 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 PFSAs 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 PFSAs, 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 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 PFSAs increases with the increasing carbon chain length (becoming more lipophilic), and perfluorosulfonates show higher toxicity compared to perfluorocarbonates 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 live 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).

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, C10F18, perfluoro-octane C8F18, hexafluoroethane C2F6, octafluoropropane C3F8) 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.

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.

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_{ow} 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

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

- 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 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 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 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 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)[1] collected from the IPCC fourth Assessment Report

Gas	Chemical formula	Atmospheric lifetime [y]	GWP
Carbon dioxide	CO_2		1
Methane	CH_4	12	25
Nitrous oxide	N_2O	114	298
HFC-23	CHF_3	270	14 800
HFC-32	CH_2F_2	4.90	675
HFC-152a	CH_3CHF_2	1.4	124
HFC-236fa	$CF_3CH_2CF_3$	240	9 810
PFC-14	CF_4	50 000	7 390
PFC-5-1-14	$CF_3CF_2CF_2CF_2CF_2CF_3$	3 200	9 300
HFE-125	CHF_2OCF_3	136	14 900
HFE-143a	CH_3OCF_3	4.30	756
HFE-7100	$CF_3CF_2CF_2CF_2OCH_3$	3.8	297

[1] 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 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 ($N(C_4F_9)_3$) 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 (FEPM, 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 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[7] and 25 000 t other PFAAs and PFAA precursors[8] (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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[7] 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.

[8] 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)

  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[9]. 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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[9] 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.

  - 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 ≥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 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.

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)**			
	PFAAs and PFAA precursors**	**Fluorinated gases**	**Polymeric PFAS *****	**Total PFAS**
PFAS manufacturing	86 092	7 911	63 380	157 383
Use sectors				
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
Total (14 sectors) #	***24 250***	***92 311***	***112 246***	***228 807***
Printing applications*	63	0	114	177

Manufacturing and use sectors	**Volumes [t/y] (Mid values)**			
	PFAAs and PFAA precursors**	**Fluorinated gases**	**Polymeric PFAS** ***	**Total 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
Total (8 additional sectors)*	***991***	***5 459***	***30 299***	***36 749***
Total volume (excluding PFAS manufacturing)******	**25 241**	**97 770**	**142 545**	**265 556**

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

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 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		

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]***
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
Total (14 sectors+ PFAS manufacturing)	***82 286***	***68 315***
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.
Total (8 additional sectors)	***5 289***	***n.a.***
Total emissions	**87 575**	**68 315**

* 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 (≈ 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 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 ≈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.

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 live 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.

- 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 of 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-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

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")[10]:

- Adopted ("1000 ppm") approach[11]:
    - Processing: 0.05 t
    - Service life: 0.03 t
    - Total: 0.08 t
- Sensitivity analysis[12]:

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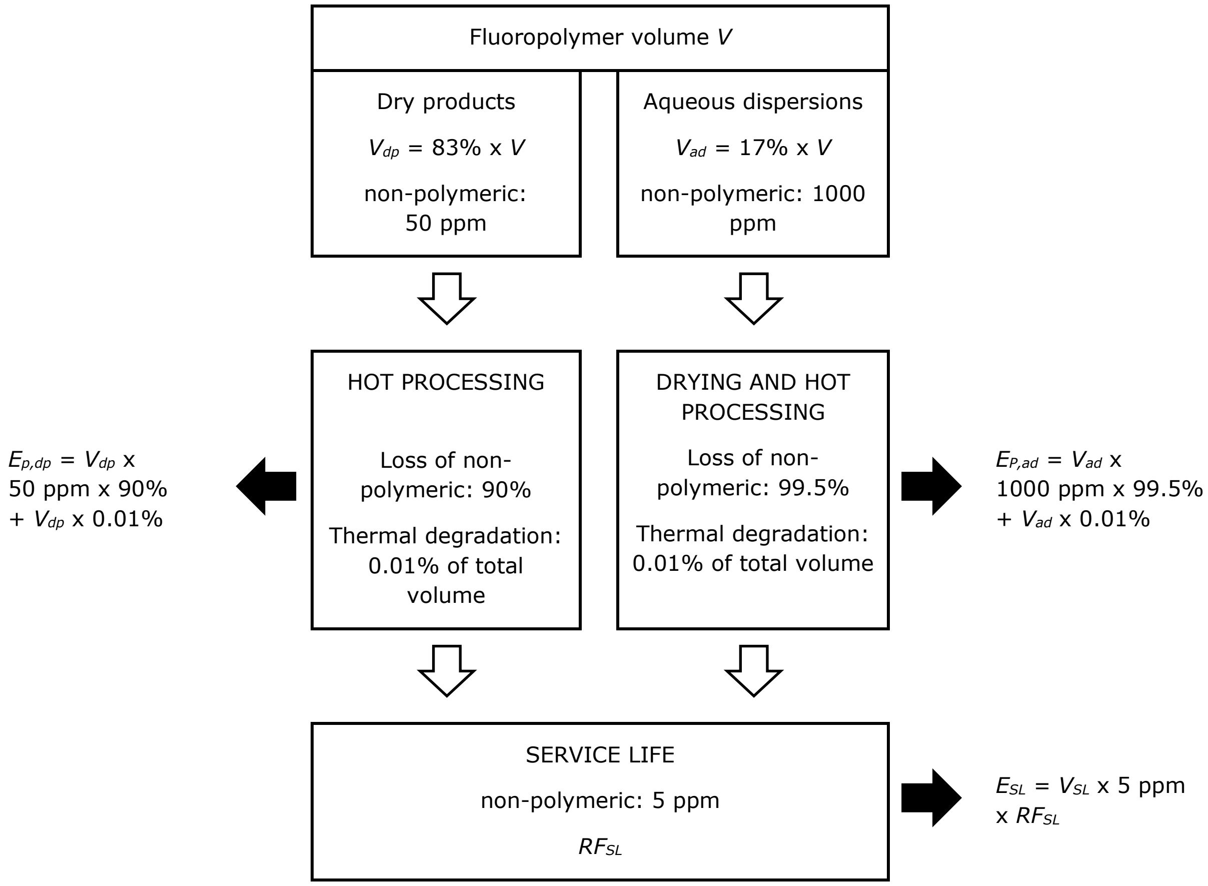
[10] Formulation of mixtures is another step, and this could be added in both approaches. Still, it is often followed by hot processing and therefore inclusion of formulation would not change the overall conclusion that the "1000 ppm" approach in many cases underestimates use stage emissions.

[11] Calculation of use stage emissions according to the adopted "1000 ppm" approach:
Amount of non-polymeric PFAS within the polymer: 1000 t x 1000 ppm (0.001) = 1 t
Emissions from processing: 1 t x 5% (0.05) = **0.05 t**
Emissions from service life: ≈1 t x 3% (0.03) = **0.03 t**

[12] Calculation of use stage emissions for sensitivity analysis:
Volume of dry products: 1000 t x 83% (0.83) = 830 t
Amount of non-polymeric PFAS within dry products: 830 t x 50 ppm (0.00005) = 0.042 t
Emissions from volatilization of residues (dry pr., 50 ppm → 5 ppm): 0.042 t x 90% (0.9) = 0.038 t
Volume of aqueous dispersions: 1000 t x 17% (0.17) = 170 t
Amount of non-polymeric PFAS within aqueous dispersions: 170 t x 1000 ppm (0.001) = 0.17 t

- 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**

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 ≈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 ≈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 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 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 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 ≥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_2 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_4. The C–F bond is

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_2 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_2F_6, CF_4, CHF_3, C_2HF_5, C_3HF_7 and C_3F_8 (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_2F_6, CF_4 and tetrafluorethylene. 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, trifluoracetamide 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 ≥C4 PFCAs and PFSAs) 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, C4-C7 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 ≥C1 (e.g. CF_4, C_2F_6), 49 polar PFAS ≥C4 and non-target PFAS analysis. Ultra-short PFCAs (e.g. trifluoroacetic acid) were not among the target analytes. The LOQ for CF_4 was relatively high (ca. 200 $\mu g/m^3$, 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_3, C_2HF_5, C_3HF_7) and perfluorocarbons (e.g. C_3F_8).

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

Karlsruhe Institute of Technology, Germany). Residence time in the post-combustion chamber was 2 s at temperatures 860 or 1100 °C. Flue gas was analysed for ca. 50 PFAS including C1-C3 compounds (e.g. trifluoroacetic acid, CF_4, CHF_3, C_2F_6) and for inorganic fluorine. The LOQs for C1-C3 fluorocarbons in gaseous samples were up to 40 $\mu g/m^3$ (corresponding to an RF in the order of 0.05%), for trifluoroacetic acid 30-90 ng/m^3 and for the rest mostly in the low ng/m^3 range. Additionally, the gas scrubber water, water from the wet deslagger and the solid residues from the filter and boiler were analysed for longer-chain PFAS. Reliable >LOQ values were found for PFOA (0.2 ng/m^3 in flue gas), PFBS (in solid residue) and PFOS (in wastewater). Fluorine recovery (based on HF measurement by tunable diode laser) was ≈80% in the 860 °C run and ≈70% in the 1100 °C run. The authors attributed the incomplete recovery to the reactivity of fluorine with the material of the walls of the furnace (predominantly Al_2O_3 and SiO_2).

US EPA (2025) investigated PFAS destruction in a full-scale hazardous waste incinerator (Clean Harbors Aragonite incineration facility in Utah, USA) under normal operating conditions. The exit gas temperatures of the rotary kiln and the afterburner ranged between approx. 1 100 and 1 200 °C. The experiment consisted of (1) three background runs with normal waste feed material, (2) three runs with normal waste spiked with C_2F_6, and (3) three runs with a mixture of normal waste, an aqueous fire-fighting foam and a spike of nine PFAS (C4-C10 PFCAs, C4-C8 K-PFSAs, HFPO-DA). Liquid input waste streams were analysed for PFAS content in order to obtain a mass balance, solid input was not analysed due to its heterogeneity (this may lead to underestimation of PFAS destruction efficiency). The analysis of liquid input material showed that almost all PFAS input originated from the fire-fighting foam and spikes. Exhaust gas was sampled and analysed by target analysis for ca. 80 fluorinated substances (incl. ≥C4 PFAAs and ≥C1 fluorocarbons). In addition, it was continuously analysed for CF_4 and C_2F_6 by FTIR. Other process streams (e.g. process water, slag/ash) were analysed for ca. 50 polar PFAS. Destruction efficiencies for each of the spiked PFAS were >99.96% (except HFPO-DA, which had 99.94% in one of the runs; however, this was attributed to external contamination). Since mineralization efficiency may be lower than destruction efficiency, it is important to examine concentrations of thermostable PICs such as CF_4. CF_4, measured with reporting limits in the order of units of $\mu g/m^3$, was detected at highest levels in the runs with fire-fighting foam and nine spiked PFAS, up to 16 $\mu g/m^3$ by FTIR or 6 $\mu g/m^3$ by GC-MS. It can be estimated (based on data in Appendix A, tables A-1-2 and A-2-6) that these CF_4 concentrations correspond a release factor in the order of 0.01% to 0.02%. C_2F_6 was detected by FTIR in one C_2F_6-spiking run at 7 $\mu g/m^3$. Other substances in the exhaust gas were mostly below the reporting limits or below 1 $\mu g/m^3$.

The **Dossier Submitter** has used the following release factors (RF):

- **0.01% (0.0001) for hazardous waste incineration**. This RF is based on the ECHA guidance R.18 and several publications indicating high PFAS destruction efficiencies in hazardous waste incinerators. The Dossier Submitter acknowledged that this RF may underestimate emissions of the short-chain PFAS, which are most thermostable.
- **1% (0.01) for non-hazardous waste incineration**. This RF was previously proposed in the Annex XV report for the restriction on PFAS in firefighting foams. RAC notes that in the fire-fighting foam restriction proposal, this RF was used for hazardous waste incineration.

RAC agreed to use different release factors than proposed by the Dossier Submitter:

- **1% (0.01) for hazardous waste incineration**. The starting point for setting of this RF was the restriction on PFAS in fire-fighting foams. For that restriction RAC concluded that 1% (0.01) may be overly optimistic for incineration of fire-fighting foams in hazardous waste incinerators. When assessing the current restriction proposal, RAC did not find sufficient grounds to use a RF lower than 1% due to the uncertainties such as incomplete fluorine mass balance in the Gehrmann et al. study, incomplete analytical characterisation of emissions and variability of incineration conditions (including the possibility of transiently suboptimal temperature or mixing of waste).

- **2% (0.02) for non-hazardous waste incineration**. The rationale behind this RF is that non-hazardous waste incineration is likely to produce more PFAS emissions because of the lower temperature (850 °C vs 1100 °C). The factor of 2 (i.e. RF for non-hazardous waste incineration 2-fold higher than the RF for hazardous waste incineration) is arbitrary as there are no studies to derive an RF for moving grate incinerators.

Both sets of emission factors have their pros and cons. The Dossier Submitter's release factor for hazardous waste incineration (0.01%) is in the same order of magnitude as the destruction efficiencies found in studies Shields et al. (2023) and US EPA (2025). With respect to mineralisation efficiency, the study by US EPA (2025) with its relatively comprehensive analytical characterisation and relatively low LOQs does not question the Dossier Submitter's RF. Since the Dossier Submitter's RF is based on actually measured emissions, it can be compared with other release factors obtained in this way, such as the RF for landfilling or the RFs for PFAS manufacturing. The main disadvantage of the RF of 0.01% is that it does not sufficiently reflect the remaining uncertainties highlighted above by RAC and therefore may underestimate emissions.

The RAC RF for hazardous waste incineration (1% (0.01)) probably does not underestimate the emissions. Although 20-30% of fluorine was missing in the fluorine mass balance (measured as HF and target analytes) in the Gehrmann et al. study, it is not plausible that all this fluorine was in the form of PFAS. At the conditions of the study (temperature, oxygen, gas burner), the main PICs to be expected are short-chain fluorocarbons. These were measured but not detected. Since HF is known to react with refractory materials (e.g. with Al_2O_3 to form solid AlF_3; with SiO_2 to form various volatile silicon-fluorine species such as SiF_4; see Che et al., 2004; Mattila et al., 2024; Weber et al., 2024), 100% fluorine mass balance is unlikely to be achieved. Silicon-fluorine species (non-PFAS) were not measured in the Gehrmann et al. study. When applying this release factor, it has to be acknowledged that it is not based on real measured emissions but rather reflects uncertainties. Therefore, it cannot be compared with RFs which are based on measured emissions. For example, it cannot be concluded that emissions from incineration of fluoropolymers (RAC RF 1% (0.01) or 2% (0.02) are higher than emissions from landfilling of fluoropolymers (RAC RF 0.0036% (0.000036)) or emissions from manufacturing of fluoropolymers (RF 0.35% (0.0035)), because the latter two release factors have been derived differently.

The two release factors for hazardous waste incineration, 0.01% (0.0001) proposed by the Dossier Submitter and 1% (0.01) set by RAC, do not necessarily contradict each other. Rather, they could be seen as a low and high endpoint of an interval in which the true release factor probably lies.

For non-hazardous waste incineration the situation is different. Since there is currently no study comprehensively characterising PFAS input and output from a moving-grate type of incinerator (normally used for incineration of municipal solid waste), both emission factors (1% (0.01) proposed by the Dossier Submitter and 2% (0.02) set by RAC) are highly uncertain. The only way to get at least a rough, order-of-magnitude estimate is to relate the RF to hazardous waste incineration. The available studies collectively suggest that temperatures around 800-850 °C for 2 seconds probably represent a breakpoint for PFAS incineration below which the formation of PICs (including PFAS) considerably increases (cf. Shields et al., 2023; Gehrmann et al., 2024). The difference between 850 °C and 1100 °C is currently less obvious, but a certain difference is expected given the known impact of temperature on reaction kinetics. The setup of the incinerator (rotary kiln vs moving grate) is also likely to affect the mineralisation efficiency. RAC selected a factor of 2 (RF for non-hazardous waste incineration 2 times higher than for hazardous waste incineration), which implies a relatively small difference, but this needs to be seen in the context of a relatively conservative RF for hazardous waste incineration. The actual difference may be larger than 2, but most likely lower than the factor of 100 implied in the Dossier Submitter's proposed release factors.

The RAC emission estimates in the sector- specific evaluations s have been calculated using the RAC proposed RFs for incineration. Still, due to the uncertainties and possible overestimation of PFAS emissions from incineration, RAC performed a sensitivity analysis comparing two types of estimates:

(1) emission estimates fully based on the RFs proposed by RAC;

(2) emission estimates based on the RF's proposed by RAC except for incineration, for which the emissions have been calculated using the Dossier Submitter's RFs.

The sensitivity analysis showed that lowering the RFs for incineration would affect particularly the uses of fluoropolymers. For example, the emissions from uses of fluoropolymers in the "Transport" sector, non-food plastic packaging or fuel cells would be lower by ca. 50% and in "Medical devices" by ca. 60% when using the Dossier Submitter's RFs for incineration instead of the RAC's proposed RFs. A more pronounced impact has been identified for industrial bakeware (decrease by 95%), but this appears to be an exception.

However, overall the difference is less than half an order of magnitude, and therefore still within the typical uncertainty levels regarding volume and/or emission estimates in this dossier.

Landfilling

The EU Landfill Directive (Directive 1999/31/EC) distinguishes three classes of landfills: landfill for hazardous waste, landfill for non-hazardous waste (including municipal waste), and landfill for inert waste (typically from construction and demolition).

The base and sides of a non-hazardous waste landfill, according to the requirements of the Landfill Directive, consist of a mineral layer covered with a plastic liner (geomembrane). The geomembrane is the primary barrier preventing contamination of soil and groundwater below the landfill with landfill leachate (leachate results mainly from rain). Still, a certain amount of leachate (up to 2%) leaks through the liner due to holes and imperfections (US EPA, 2024). Landfill leachate has been shown to contain PFAS, e.g. PFCAs (e.g. Zhang et al, 2023; Miljösamverkan Sverige, 2022). The liner and the overlying drainage layer are part of leachate collection system. The collected leachate is treated on site or in a municipal wastewater treatment plant. The common wastewater treatment methods generally do not efficiently remove PFAS (see below).

Municipal waste delivered to the landfill is compacted and covered by soil. The biodegradable fraction of municipal waste (e.g. food, paper) starts decomposing mostly via anaerobic processes, producing landfill gas (mostly methane and CO_2), which may contain volatile PFAS (e.g. fluorotelomer alcohols; Zhang et al., 2023; Lin et al., 2024). Landfill gas must be collected from all landfills receiving biodegradable waste. It is used to produce energy or flared. As the temperature in flares and power-generating engines is generally below 850 °C (US EPA, 2024), PFAS contained in the landfill gas are probably partly converted to products of incomplete combustion, part of which are still PFAS. A fraction of the landfill gas is emitted directly to the environment e.g. through the surface of the landfill. Fugitive losses at sites actively collecting landfill gas have been estimated at ca. 25% (US EPA, 2024).

Once a landfill cell reaches its capacity, it is capped with a cover system, which typically consists of a combination of soil and membrane materials. The cover is primarily intended to reduce infiltration of rainwater and thus minimize leachate generation, and also to reduce uncontrolled gas emissions. Generation of leachate and landfill gas may continue for decades after the closure of the landfill (the Landfill Directive envisages an at least 30-year after-care period).

Hazardous waste landfills generally have more stringent requirements for sealing and leak detection. Inert waste landfills, on the other hand, may not have leachate and gas collection systems.

Although there are numerous studies reporting occurrence of PFAS in leachate and landfill gas, there is currently no study providing PFAS release factors specifically from landfills. Therefore, the Dossier Submitter proposed to use the following release factors partly derived from the ECHA guidance R.18 (Appendix R.18-2):

- For PFAAs and PFAA precursors: 3.36% (0.0336) (3.2% (0.032) to water, 0.16 % (0.0016) to soil)
- For fluoropolymers and PFPEs: 0.16% (0.0016) (to soil, previously used in the microplastics restriction)
- For fluorinated gases: 0.5% (0.005)

The R.18 guidance specifies that this scenario covers both hazardous and non-hazardous waste landfills operated according to the Landfill Directive. This assumption may not be valid for some old landfills.

The release factor to water for PFAAs and PFAA precursors has been derived from the same data as the ERC 10A release factor, i.e. 0.16% (0.0016) per year from the OECD emission scenario document on plastic additives (OECD, 2009). According to the R.18 guidance, this value should be multiplied by an average residence time of 20 years (until closure of the landfill), yielding an RF of 3.2% (0.032). RAC supports this value, while acknowledging the uncertainty due to the fact that generation of leachate may continue for more than 20 years (this has also been mentioned by the Dossier Submitter in the text below Table B.120 in Annex B of the Background Document).

The release factor to soil of 0.16% (0.0016), according to the R.18 guidance, also originates from ERC 10A, but in this case is not multiplied by 20 years. Although the rationale for that approach is not clearly explained in the R.18 guidance, it is plausible that emissions to soil are much lower than to water as landfills generally have a plastic bottom liner (collection efficiency estimated at ca. 98%; US EPA, 2024). Therefore, RAC agrees to use an overall release factor of 3.36% (0.0336). A certain fraction of these emissions partitions to air rather than water or soil (e.g. fluorotelomer alcohols; cf. Tolaymat et al., 2023), but this does not make any difference to the current assessment given the use of a one-compartment model.

In the view of RAC, the RF of 3.36% (0.0336) for landfilling should be applied wherever PFAAs or their precursors are incorporated into articles/matrices (or bound to a solid substrate, like in the case of side-chain fluorinated polymers). For PFAA and PFAAs precursors not included in articles, RAC proposes a release factor of 100%. Such a situation is however rare since PFAS not included in articles are generally emitted already during the production and service life (ski wax is an exception, in that case the Dossier Submitter used a range of 3.36%

(0.0336) to 100% (1)).

For landfilling of fluoropolymers, RAC has used the same approach as for service life, i.e. quantification of emissions of non-polymeric PFAS within the polymeric matrix. The approach is in principle the same as the one for PFAAs and their precursors, but the RF of 3.36% (0.0336) is applied only to the non-polymeric fraction, not to the whole fluoropolymer volume. RAC agreed to set the non-polymeric content at 1 000 ppm (see section 3.1.2.4 above) and that value has been used for emission quantification throughout sectors.

Particle emissions from landfilled fluoropolymers may be emitted e.g. via leachate. Fluoropolymers are generally highly resistant to chemical and thermal degradation (e.g. Henry et al., 2018; Korzeniowski et al., 2023) but can break down to microplastics e.g. due to abrasion. Nevertheless, the physical processes that lead to abrasion are expected to be relatively low in landfills, so the bulk of stable fluoropolymers would be expected to be retained for a long duration (US EPA, 2024). The release factor proposed by the Dossier Submitter (0.16% (0.0016)) is not specific to particles nor fluoropolymers, and therefore highly uncertain. Based on this, RAC has not quantified particle emissions from landfilled fluoropolymers.

As explained earlier, RAC proposes to distinguish between fluoropolymers and PFPEs. For PFPEs RAC proposes to use the same release factor as for PFAAs and PFAA precursors and to apply it to the whole volume of PFPE, unless sector-specific information is available. RAC acknowledges that this approach may lead to overestimation of bioavailable emissions given the low solubility and polymeric nature of PFPEs.

End of life emissions from major applications of fluorinated gases have been quantified using sector-specific information (mostly GHG inventory). The generic release factor of 0.5% (0.005) listed in Table B.120 of Annex B of the Background Document was rarely used by the Dossier Submitter (mentioned in “Electronics and semiconductors” and “Broader industrial uses”). RAC notes that the release factor in ECHA guidance R.18 is 0.05% (0.0005) (not 0.5% (0.005)) and originates from the OECD emission scenario document on plastic additives (OECD, 2009). Its use for landfilling of volatile solvents and gases is not considered appropriate. Instead, RAC proposes to consider the specific application of the fluorinated gas or solvent, the likelihood that it reaches a landfill in significant amounts (given that acceptance of liquid waste is prohibited by the Landfill Directive) and the likely magnitude of release.

In conclusion, for landfilling RAC supports the proposed RF of 3.36% (0.0336) for PFAAs and PFAA precursors. In the case of fluoropolymers, RAC proposes – contrary to the Dossier Submitter’s proposal – to apply the RF only to the non-polymeric residue. Emissions of fluoropolymer particles are thus not quantified. For PFPEs, RAC proposes to apply the same RF as for PFAAs and PFAA precursors. Should fluorinated gases enter the landfill in significant amounts, RAC recommends a case-by-case assessment for the specific application in question.

Wastewater treatment

Wastewater treatment plants (WWTPs) can be divided into two main categories: municipal WWTPs (also known as sewage treatment plants, STPs) and industrial WWTPs. STPs, besides wastewater from homes, institutions, and businesses, might also receive landfill leachate and wastewater pre-treated in industrial WWTPs.

Since the major components of sewage are human urine and excrements, STPs are primarily designed to efficiently remove these. After pretreatment to remove coarse materials, the wastewater enters primary settling tanks. Sludge (so-called ‘primary sludge’) is pumped away and the wastewater continues to the next step, ‘secondary treatment’ to remove biodegradable contaminants. In the commonly used activated sludge process, a consortium of microorganisms digests organic matter and clumps into flocs. The flocs are removed in the next step, final sedimentation, are partly returned back to the aeration tanks. Cleared water is then released into the environment (e.g. river or sea).

Due the persistence of PFAS, they are generally not assumed to be mineralised in STPs. The available studies on the fate of PFAS in STPs are limited regarding analytical characterisation, but so far they suggest that if any chemical transformation of PFAS occurs, it is mainly transformation of PFAA precursors to PFAAs (Lenka et al., 2021). Depending on their physico-chemical properties, PFAS distribute between water and sludge. Longer-chain PFAS have higher affinity to sludge whereas shorter-chain PFAS largely remain in water. Certain volatile species (e.g. fluorotelomer alcohols) may also be released to air.

The sludge from primary and secondary settling tanks is stabilised in anaerobic digesters and then they may be applied to agricultural soil, landfilled or thermally treated for energy recovery (incineration, pyrolysis, gasification). Application of PFAS-containing sewage sludge to agricultural soil may lead to contamination of the environment and crops. The fate of PFAS during thermal treatment of sewage sludge has not been specifically assessed by RAC.

Some STPs may have additional treatment steps, such as filtration, disinfection or adsorption to activated carbon. The latest recast of the Urban Wastewater Treatment Directive (Directive (EU) 2024/3019) introduces a requirement for quaternary treatment to reduce the concentrations of micropollutants (by at least 80% for selected indicator substances), which will be gradually implemented by 2045. However, it is noted that PFAS are not among the indicator substances. Some of the quaternary treatment techniques may reduce concentrations of longer-chain PFAS but the efficiency for short-chain PFAS might be low.

Unlike sewage, industrial wastewaters are very diverse in composition, and so are the technologies applied for their treatment. The primary purpose of industrial WWTPs is to decrease the levels of selected contaminants below a certain limit imposed e.g. by a regulatory authority. This means that if there is no limit for a specific substance in a given stream, it is likely that there will be no or limited emission reduction for that particular substance. For example, if the primary goal of the wastewater treatment is to remove heavy metals, the treatment may include precipitation and adsorption to activated carbon. Such kind of treatment may be of limited efficiency for reduction of PFAS levels, particularly short-chain PFAS.

In contrast, efficient PFAS removal techniques may be in place if there are specific regulatory obligations to reduce r PFAS content in a given WWTP effluent. This has been documented e.g. for fluorinated polymerisation aids in the fluoropolymer manufacturing industry (comment #6337). However, RAC has no evidence of widespread use of PFAS removal techniques for industrial WWTPs.

Established wastewater treatment techniques that can be used to reduce PFAS concentrations include granular activated carbon (GAC), ion exchange (IX) resin, foam fractionation and reverse osmosis. These are separation/concentration techniques and have to be followed by destruction techniques (e.g. incineration).

Adsorption to GAC or IX resin is efficient for longer-chain PFAS but generally not for short-chain perfluorocarboxylates. Adsorption of PFAS may be negatively affected by high organic load, particles, and in the case of IX also inorganic salts. Thus, pre-treatment may be needed (for further details see ITRC, 2026). Regeneration of sorbents generates liquid residues that have to be further treated.

Foam fractionation and reverse osmosis are examples of concentration techniques. Reverse osmosis is effective in removing most organic and inorganic contaminants from aqueous solutions. However, the membrane is susceptible to fouling, so pretreatment is usually needed and the technique is not suitable for highly concentrated liquids. In contrast, foam fractionation usually does not require pre-treatment but typically needs to be followed by GAC to remove residual PFAS. Both technologies produce PFAS-laden concentrate which has to be further treated.

There are also several emerging technologies (e.g. supercritical water oxidation). The information on their performance for various matrices and on generation of fluorinated by-products is still limited.

The Dossier Submitter proposed a release factor of 87% (0.87) for PFAAs and their precursors and 50% (0.50) or 20% (0.20) for fluoropolymers. However, they very rarely used them (one occurrence can be found in "Construction products"). In fact, in practically all cases involving emissions to (waste)water the Dossier Submitter applied no correction for wastewater treatment efficiency (that is, a RF of 100% (1) for wastewater treatment is applied in almost all Dossier Submitter's calculations).

RAC is of the view that a release factor for wastewater treatment should be based on PFAS mineralisation in a typical WWTP. Given that commonly used wastewater treatment systems are generally not able to efficiently remove PFAS, RAC proposes a release factor of **100%** (1) for PFAAs and PFAA precursors. Particle emissions have not been quantified by RAC, but the release factor of 50% (0.50), previously used in the restriction ofmicroplastics, is in principle applicable also here.

Overview of waste stage release factors

Table 6 below provides an overview of the waste stage release factors used by the Dossier Submitter, and the modifications agreed by RAC.

Table 6: Overview of waste stage release factors

	Dossier Submitter	**RAC**
Incineration, hazardous waste	0.01% (0.0001)	1% (0.01)
Incineration, non-hazardous waste	1% (0.01)	2% (0.02)
Landfilling, PFAAs and PFAA precursors	3.36% (0.0336)	3.36% (0.0336)
Landfilling, fluoropolymers	0.16% (0.0016) (applied to the whole volume of fluoropolymer)	0.00336% (0.0000336) (i.e. 3.36% applied to the non-polymeric fraction 1000 ppm) Particles not quantified
Landfilling, PFPEs	0.16% (0.0016)	3.36% (0.0336)
Landfilling, fluorinated gases	0.5% (0.005)	Case-by-case
Wastewater treatment, PFAAs and PFAA precursors	87% (0.87)	100% (1)
Wastewater treatment, fluoropolymers	50% (0.50) / 20% (0.20)	Particles not quantified

3.1.2.7. Spare parts

The Dossier Submitter has assessed the implications of the proposed restriction on spare parts as an overarching issue as there are similarities across different sectors and applications. According to the Dossier Submitter, a spare part is considered to be an article, or a complex object (i.e., an object made up of more than one article, which have been assembled or joined together). A spare part is used for the maintenance and repair of another article or complex object.

RAC notes that several comments provided during the Annex XV consultation emphasise the importance of the continued supply of spare parts especially for energy, electronics and semiconductors, sealing and machinery applications and transport-related uses. Some of those also refer to other EU legislation, including EU Ecodesign for Sustainable Products Regulation (Regulation (EU) 2024/1781) and Right to Repair Directive (Directive (EU) 2024/1799). Derogation for spare parts is also considered to be in line with some sector specific legislations like End-of-life Vehicle (ELV) Directive (Directive 2000/53/EC) and Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS) Directive (2011/65/EU). Environmental benefits (in terms of e.g. generation of less waste) of access to spare parts is also emphasised. According to the comments provided, the need for PFAS-containing spare parts depends on the availability of suitable 'PFAS-free' spare parts, their technical feasibility and price. In addition, for several uses there are industry standards, certification requirements and legislation which may limit/slow down the introduction of PFAS-free spare parts for specific uses. However, as pointed out by the Dossier Submitter, quantitative information on the demand for spare parts containing PFAS is not available. This makes the estimation of emissions related to the production and use of spare parts in various sectors impossible. The Dossier Submitter states in Annex E that "it seems likely that the amount of PFAS used for spare parts is substantial. However, it might also be possible that PFAS emissions resulting from these uses are limited." This reflects the limited information available on the actual demand of the spare parts in various uses. RAC, however, agrees with the Dossier Submitter that based on the information received on the demand of the spare parts, most of the spare parts used are polymeric in nature and are predominantly used in professional and industrial uses. Although acknowledging this, RAC notes that since it is not specified which types of spare parts are proposed to be derogated, RAC cannot exclude that some types of spare parts are used also by consumers. Thus, the main associated emissions are rather likely to occur in the manufacturing and in the end-of-life stage if not disposed appropriately. However, since it is not possible to estimate volumes of spare parts needed, no emission estimates are possible to be made for spare parts. Since the need for spare parts containing PFAS will decrease with time, related emissions will also gradually decrease after the restriction enters in force.

3.1.2.8. Reuse, secondary use and recycling

The Dossier Submitter has discussed reuse, secondary use and recycling mainly under other impacts (chapter E.3 of the Annex E of the Background Document). Articles can be sold as second-hand articles for the purpose for which the article was originally used or for secondary use, meaning a different purpose than the one for which the article was originally used. The term 'recycling' means material recycling i.e. any recovery operation by which waste materials are ultimately reprocessed into materials and products, whether for the original or other purposes.

A wide variety of articles can be reused for the original purpose or for a different purpose. These include textiles, cars, construction/building elements (e.g. wood, concrete, bricks, tiles, windows, lamps, etc, see comment from the Annex XV consultation #8921), electronics etc. The Dossier Submitter did not make any quantitative emission estimate related to the reuse/secondary use of PFAS-containing articles but notes that a longer service life obtained by reuse or by secondary use would only have an impact on the effectiveness of the restriction if the sum of emissions resulting from the additional emissions related to an extended service plus the remaining emissions from the waste lifecycle stage would be significantly higher in comparison to those that would have occurred at the waste lifecycle stage without reuse/secondary use. The Dossier Submitter also notes that, for the several articles containing fluoropolymers, it is likely that additional emissions resulting from a prolonged service life are limited. RAC agrees with this - as can be noted from sector-specific evaluations, service-life of fluoropolymers containing articles is generally resulting in insignificant emissions. In the case of PFAAs and PFAA precursors, including side-chain fluorinated polymers, there is a potential for more significant service life emissions. For example, textiles coated with PFAAs precursors form a large volume of articles potentially reused in second-hand markets. They have also been shown to release significant amount of PFAAs and their precursors during their use, especially during washing (e.g. Danish Environmental Protection Agency, 2015). This was reflected in relatively high (40%) emission factors applied for the calculation of service life emissions for textiles (see sector specific text on "TULAC" sector). However, it can be anticipated that a major proportion of PFAS is already emitted during their initial use although e.g. further washings during the reuse may still result in release of e.g. PFAS side-chains from SCFPs (Danish Environmental Protection Agency, 2015). Thus, RAC agrees with the Dossier Submitter that additional emissions caused by reuse are likely to be limited also in these cases. RAC also agrees that it is not possible to make any quantitative estimate on these emissions.

Regarding fluorinated gases, recovery of fluorinated gases from HVACR applications at the end of the service life is currently a common practise required by existing legislation (Waste from Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU) (see Fluorinated Gases sector specific text). After recovery, they are either reused or destructed. For example, one industry comment (#8285) states that the main refrigerants in use today for mobile air conditioning (MAC) applications (R-134a and R-1234yf) can be reused many times at the end of the life of the vehicle and estimated that 12 million vehicles leaving the road would equate to roughly 6 000MT of refrigerant for potential reuse (0.5kg/vehicle). Since the Dossier Submitter proposes a time-unlimited derogation for the use of fluorinated gases in existing refrigerants, clean fire-suppressing agents and insulation gases for maintenance and refilling of existing HVACR and fire-suppressing and switchgear equipment put on the market before 18 months after entry into force of the restriction , recovery and reuse of used fluorinated gases for these purposes instead of using virgin (e.g. non-recycled) fluorinated gases is not considered to increase overall PFAS emissions. The situation would be different in case proposed derogations for the use of fluorinated gases in existing equipment are not supported by the decision maker: Allowing the use of recovered fluorinated gases instead of virgin (e.g. non-recycled) non-PFAS gases would result in the additional emissions during the use stage. Based on the available data, these cannot, however, be quantified. RAC notes that technologies for effective reuse/recycling of fluorinated gases, including separation techniques for F-gas mixtures, are currently developing (see, e.g. Jovell et al., 2021).

For the recycling of PFAS-containing materials, the Dossier Submitter indicates that there is a concern of PFAS being released during the recycling process itself, and through recycled material incorporated into new articles.

Specific recycling of PFAS is limited. RAC notes that while recycling and reuse of fluoropolymers, especially PTFE, is performed on some industrial waste, there are limited options for their recycling from consumer articles. For example, fluorinated polymers applied to metal articles (e.g., non-stick frying pans) may not be recycled as it is difficult to separate them from metal wastes during metal recycling. In addition, as highlighted in the UN Basel Convention technical guidelines on Plastic waste (UNEP 2023), the recycling of waste fluorinated polymers is not well established inter alia as they may contain additives (e.g., glass fibres, glass beads, graphite, and soot) to an extent that renders the waste hazardous or problematic (Schlipf et al., 2014).

On the industrial scale, recycling of clean PTFE waste or scraps generated during production does occur, although according to the Dossier Submitter it accounts only for about 3% of total fluoropolymers waste. Specific information on recycling methods is provided e.g. by the reports by Schmidt-Rodenkirchen, A et al., (2022) (Chemical recycling of PTFE (as a model for other polymers) and Améduri and Hori (2023, Recycling and End of life assessment of Fluoropolymers: Recent Developments, Challenges and Future Trends) submitted as part of Annex XV report consultation (comment #6056). Unfilled PTFE-scrap resins from manufacturing can be recycled by three means: it can be cleaned from contaminants and milled into certain particle size classes, which can be reused and e.g. mixed with virgin PTFE. Secondly, unfilled PTFE can be thermally degraded into low-molecular-weight PTFE and further milled into particles a few microns in size, producing PTFE micropowders. Alternatively, PTFE micropowder can be produced by high-energy radiation. According to Schmidt-Rodenkirchen, A et al., 2022 degradation of high-molecular-weight PTFE by electron beam irradiation is currently widely used, but it produces significant amounts of perfluorinated carboxylic acid, which is a major concern. Instead of producing PTFE from recycled PTFE waste, there are techniques used to produce fluorine-containing monomers from PTFE waste (chemical recycling/upcycling). These techniques are based on thermal degradation of fluoropolymer as monomeric fluorocarbons (like tetrafluoroethylene) that can be further used for the production of virgin fluoropolymers. According to Korzeniowski et al. (2023) this type of upcycling treatment is applicable to some articles containing fluoropolymers, such as pipe liners in chemical plants, as well as other plant components such as pumps, tank liners, seals, hoses, compensators, and many other fluoropolymer components and systems. These are the products for which high quantities of fluoropolymers are used. This upcycling needs to be co-located to a fluoropolymer manufacturing plant that can use tetrafluoroethylene (Korzeniowski et al, 2023).

In addition, the most advanced methods are able to crack fluoropolymers even further as fluorine and carbon ions that are available for the production of any other fluorine containing compounds (see e.g. Yu et al., 2025). These approaches are, however, still under development and not used at industrial scale.

RAC notes that the Dossier Submitter considers that emissions related to the recycling in manufacturing industry are covered by the emissions estimates calculated for PFAS manufacturing. RAC however notes that on-site recycling is not specifically considered in the emission factors applied for fluoropolymer manufacturing (see sector-specific evaluation on PFAS manufacturing). RAC does not have enough information to estimate the impact of on-site recycling processes to the emissions from fluoropolymer manufacturing. Related to the recycling of fluoropolymers, RAC would like to express a concern on the production of very fine PTFE micropowders from recycled PTFE. These PTFE micropowders might be more bioavailable and more toxic when compared to larger fluoropolymer particles (see section 3.1.1 Hazards). RAC also notes that there is a possibility for occupational exposure to PFAAs in the recycling processes using heat or radiation to degrade fluoropolymers. No information on exposure levels is however available.

As noted above, PFAS are often difficult to separate from other materials present in various articles/products. Therefore, PFAS presence is anticipated in various waste streams, particularly textiles, paper, plastics, and metals. The Dossier Submitter has evaluated the data on the presence of PFAS in these waste streams typically collected for recycling. A summary is provided below.

Plastics

Although the recycling of fluoropolymer plastics is limited, PFAS are present in feedstocks for plastic recycling due to the intentional use of PFAS in the production of various plastics or plastic articles. For example, in the production of PE and PP films, PFAS are commonly used as processing aids in concentrations of around 0.1% w/w (1 000 ppm) (industry comment ID #9387). In addition, PFAS may be present in plastic articles, for example due to their use in inks and lacquers. As described by the Dossier Submitter plastic waste streams contain various types of plastics, including PP, PE (low, medium, high density), PS, PVC, PET, PUR and other thermoplastics. The Dossier Submitter notes that the concentration of PFAS in waste streams are generally associated with uncertainties and potentially large variations also within particular waste streams. In addition, the concentration of PFAS in recycling feedstocks over time is influenced by the service life of articles and complex products that will contain them. The Dossier Submitter refers to the systematic review by Pivato et al. (2024), which provides data on a total of 613 analyses of plastic waste from six different publications. Only 2.17% of analyses exceeded the proposed 25 ppb concentration limit value for PFOS, with no measurement exceeding the limit value for PFOA, C9-C14 PFAS, PFHxS or 'other PFAS'. Altogether, 112 analyses were made using TOP assay resulting in median PFAA concentrations of 1.52 ppb and 95th percentile of 23.09 ppb. Total fluorine measurements were not included in the review. Several companies commented that it is not possible to ensure that waste recyclates will comply with the concentration limits although generally average PFAS levels remain below the given limits in plastic waste recyclates. Some measurement data, summarized under chapter E.3.5.2.1.7 in Annex E were also provided to support these comments and show that although in many cases total fluorine or total oxidizable precursors levels were below the given concentration limits, there were also instances (covering various waste streams/plastic types), in which these levels were exceeded. The Dossier Submitter did not estimate the emissions related to the recycling of plastic waste but concluded that emissions are likely, especially because recyclers are generally not aware which waste plastics contain PFAS and in what concentration and therefore it is difficult to apply appropriate risk management measures in the recycling process. Data on actual emissions during the recycling of plastics is limited. One Annex XV report consultation comment notes that emissions to air are expected due to the high vapor pressure of short chain non-polymeric processing aids and the heat applied in the extrusion processes in plastics recycling. Although the Dossier Submitter did not calculate any emissions, RAC notes that ECHA R.18 Guidance gives some default emission factors for recycling activities covering emissions related to the substances which are included in plastic materials or have been added as a finishing to a plastic article (e.g. coating, firm attachment of other materials onto the surface of an article). These release factors are 0.025 to air and 0.0025 to water, meaning an overall release factor of 0.0275. Using these emission factors and considering Pivato et al. (2024) data on PFAA levels measured using TOP assay (showing 95th percentile of 23 ppb), and 59 million tonnes of plastics produced in EU, of which 19.7% is recycled plastics, it can be calculated that emissions of PFAAs are insignificant (below 1 kg). Overall, RAC considers that since in the majority of cases the PFAS levels in recyclates seem to be below the concentration limits, the overall emissions are likely to be minimal and are decreasing further as a result of the phase-out of PFAS from products.

One specific aspect related to plastic recycling is the release of fluorinated gases from low-pressure spray polyurethane foams at the end of life. According to the stakeholders, a significant proportion of the fluorinated gases used as blowing agents remain in the foam and can be released at the end of life. However, according to one Annex XV report consultation comment (#7379) post-treatment of foam using the matrix degassing method may reduce residual content to as low as 0.2%.

Paper and board

In addition to plastics, PFAS may be present in end-of-life products ultimately serving as feedstocks for paper and board recycling. Sources of PFAS in paper and board recyclate may include e.g., food and feed packaging paper and board in which PFAS have been intentionally added to repel fat, stains or water, and to provide heat resistance or non-stick properties or inks and lacquers (see Annex E and e.g., comments #6702, #9523). The systematic review of Pivato et al. (2024) included data from 17 individual studies measuring PFAS-levels in paper and board waste. Significantly higher numbers of exceedances of concentration limits were seen when compared to the plastic waste described above. From a total of 2 680 observations from 17 studies, 6.51% exceeded the 25 ppb limit for PFOA, 5.35% for C9-C14 PFAS, 0.65% for PFOS, 5.35% for PFHxS and 6.98% for 'other PFAS'. No data on TOP assay results on paper and board waste were presented in the review. Exceedances in recyclate and paper and board products made of recycled materials were also reported by Langberg et al. (2024) (see Annex E of the Background Document).

RAC notes that according to some Annex XV report consultation comments, paper and board manufacturers in some countries have already started to reduce or phase out the use of PFAS in food-contact materials (see Annex E). RAC agrees with the Dossier Submitter that the service life duration of paper and board products is relatively short, but they may become recycled up to seven times on average prolonging the time PFAS remain in the cycle after the restriction. There are limited data on the PFAS emissions from paper and board recycling process. RAC however notes the study by Arcedis (2021) submitted during the Annex XV report consultation and suggesting high levels of PFAA precursors (e.g. fluorotelomersulfonates) and perfluoropropanoic acid in pulp samples from factories handling recycled paper. This may result in emissions from these facilities to air and water and also to the direct exposure of workers (Reinhart et al., 2023). Regarding worker exposure there is no specific data available from paper and board recycling industry. However, a Dutch study shows elevated levels of PFAS in wastewater from companies processing recycled paper (Rijkswaterstaat, 2020). Again, although the Dossier Submitter did not calculate any emissions, RAC notes that ECHA R.18 Guidance gives some default emission factors for recycling activities covering emissions related to the substances which have been added to a paper article in the course of finishing or other uses of paper (coating, printing etc.) and are contained in the material as contamination. The worst-case default release factor to water given in R.18 Guidance for paper recycling is 0.9014. Considering this, and that approximately 44 million tonnes of paper are recycled in Europe (according to year 2023 statistics, see Annex E, Table E.498 of the Background Document), this may result in emissions of 1 t/y if 25 ppb is used as an average PFAA level in recyclate. Overall, RAC agrees with the Dossier Submitter that recycling of paper and board is likely to result in additional PFAS emissions, which are however likely to decrease progressively as a result of the phase-out of PFAS in products made of virgin materials. It cannot, however, be concluded how long it will take for the levels in paper and board recyclate to stay consistently below the limits given in the restriction. Similarly, it is not possible to make any quantitative estimate on the emissions related to the recycling process.

Textiles

Textile waste is the third type of waste streams which may contain PFAS due to their use in various textiles. Although some PFAS-treated technical textiles used in professional and industrial uses are incinerated in the end-of-life stage, many PFAS-treated textiles e.g. from consumer uses may enter the normal textile recycling processes. Systematic review by Pivato et al. (2024) identified altogether 7 papers with a total of 1 488 observations on PFAS in textile and leather waste. According to the results, 8.14% of the measurements exceeded the concentration limit of 25 ppb for 'other PFAS', 2.97% for PFOA, 0.87% for C9-C14 PFAS and PFHxS, and 7.41% for PFOS. TOP assay showed median levels of 1.95 ppb and P95 levels of 37.91 ppb for PFAA concentrations in textile and leather waste. Similarly, the Dossier Submitter cites the study by Arcadis (submitted as part of the Annex XV report consultation) (Arcadis, 2021) which showed elevated individual PFAS' levels and organic fluorine levels in recycled carpet fluff. In addition, a study by Bartolini et al. (2019) (submitted by comment #6395 of the Annex XV consultation), provided information on PFAS levels in the recycled woollen- and cotton-type fibres . As described by the Dossier Submitter, according to this study, concentrations of telomers (incl. 4:2 FTOH, 6:2 FTOH, 8:2 FTOH) exceeded 33 ppb in 38 out of 39 post-consumer samples and 13 out of 13 pre-consumer samples.

Recycling methods have an impact on whether the PFAS that are present in end-of-life textiles remain in recyclate at levels above the proposed concentration or not. RAC agrees with the Dossier Submitter that mechanical recycling does not destroy PFAS and only mixing with virgin (non-PFAS containing) fibres can decrease their concentration in products made of recycled material. Chemical recycling may break fibres as polymers and even monomers and fluorinated polymers might be processed in chemical recycling, but it is not known to what extent the process destroys PFAS and to what extent it may cause volatile emissions (WSP, 2024, see Annex E of the Background Document). The WSP report (2024) notes that textile recycling can result in occupational exposure to PFAS through dermal contact and through air when handling the materials. RAC notes that there is, however, no actual data available on occupational exposure in textile recycling. Similarly, no data is available on air or wastewater emissions related to textile recycling. No default emission factors have been defined for textile recycling in ECHA Guidance R.18.

Overall, based on the evidence described above, RAC agrees with the Dossier Submitter that textile recyclate may contain PFAS above the concentration limits given in the restriction and, depending on the recycling process, PFAS may enter the market in new textile products manufactured from the recyclate. In addition, the recycling process may result in wastewater and air emissions, as well as on occupational exposure, but it is not possible to make any quantitative estimate on emissions. The emissions may vary depending on the type of the recycling process. Emissions and levels of PFAS in recyclate are, however, likely to decrease gradually after the restriction enters in force, but how fast this will happen will depend on the length of the service life of various textiles, which has been described to be four years on average (Laitala and Klepp, 2020; Laitala et al., 2017) but may vary greatly depending on the type of textile.

Metals

PFAS may also enter in metal waste streams since they are used in various metal-containing products which are commonly collected for metal recovery and recycling. Systematic review performed by Pivato et al (2024) identified only two papers and 55 measurements covering the category metal waste. About 11% of the metals' data exceeded the 25 ppb limit for PFAS other than PFOA, C9-C14 PHAS and PFHxS. For the latter three PFAS, no exceedances were recorded. TOP assay showed median PFAAs levels of 7.71 and P95 levels of 107.66 ppb in 51 tested samples. These data support the assumption that PFAS are entering into the metal waste streams. RAC notes the several comments provided in the Annex XV report consultation related to the recycling of metals from electronic waste and from e.g. batteries. These comments were cited by the Dossier Submitter in Annex E, chapter E.3.5.5 of the Background

Document. As described by the Dossier Submitter, metals can be recycled by using either pyrometallurgical or hydrometallurgical techniques. Although mechanical recycling is also possible, RAC notes that it was not further considered by the Dossier Submitter as no related information was provided in the Annex XV report consultation.

RAC agrees with the Dossier Submitter that pyrometallurgical techniques used for metal recycling and occurring at high temperatures (>1 000 °C) are likely to fully mineralise PFAS, leaving no traces in recycled metals. However, hydrometallurgical techniques, occurring at lower temperatures, may result in emissions of shorter chain PFAS and require e.g. high-temperature post-processing steps to fully mineralize PFAS. Similarly, pyro- and hydrometallurgical techniques are currently utilized to recover metals from batteries. As described above, the pyrometallurgical technique is likely to fully mineralise PFAS but is not favoured because e.g. of its higher energy demand and lower metal yield compared to hydrometallurgy (Rensmo et al., 2023). Hydrometallurgical techniques require several steps, including the production of the so-called "black mass" from the active materials in batteries. This black mass still contains PFAS (Annex E of the Background Document) but is further processed by heating steps and hydrometallurgy to remove the PVDF binder. Although final recycled metals do not contain PFAS, emissions of PFAS formed during the recycling process are possible, especially when lower temperature hydrometallurgical processes are utilized. This applies also to battery recycling (Rensmo et al., 2023) and all these releases may not be captured by the targeted analyses. These emissions may also lead to occupational exposure, although there are no measured data currently available. RAC notes that several Annex XV report consultation comments were provided by the industry describing the recycling processes, and available techniques to minimise emissions during the recycling process (see Annex E of the Background Document). Many of those emphasise the effectivity of pyrometallurgy over the hydrometallurgy to destroy the remaining PFAS. RAC agrees with this and considers technique important in minimising PFAS emissions in metal recycling process. The Dossier Submitter did not make any quantitative estimate on emissions related to the metal recycling. RAC notes that ECHA R.18 Guidance gives some default release factors for recycling activities covering emissions related to the substances added to the metal after the forming process in the primary production. This default release factor for organics is 1% (0.001), which can be considered applicable to PFAS in pyrometallurgical processes (see also the discussion related to the hazardous waste release factor) but which is not considered conservative enough to describe PFAS emissions in hydrometallurgical processes, in which emissions may rather resemble those observed in non-hazardous waste incineration. RAC did not, however, make an attempt to calculate the potential emissions related to metal recycling.

3.1.2.9. Existing operational conditions and risk management measures

Existing operational conditions and risk management measures to reduce PFAS emissions and exposure have been described for several sectors of use. In general, RAC acknowledges that in some cases such measures do exist and may have a significant emission/exposure reduction potential. However, it is not always clear whether the described measures (e.g. provided in Annex XV report consultation comments) are widely applied in practice. Further, there are cases where reduction of PFAS emissions is inherently difficult and significant residual emissions may still occur despite such measures (e.g. short-chain PFAAs in wastewater, use of fluorinated gases in HVACR equipment). In some cases, it may be very challenging to implement risk management measures for certain life cycle stages (e.g. use of propellants).

As to fluoropolymers, RAC notes that the potential for non-polymeric emissions is highest during fluoropolymer manufacturing and possibly also during incineration under suboptimal conditions; non-negligible non-polymeric emissions may also occur during hot processing (for details see sections 3.1.2.4 and 3.1.2.6).

Based on the available information and the emission estimates presented by the Dossier Submitter and re-calculated by RAC (see Table 5), RAC agrees that the existing operational conditions and risk management measures are not sufficient to control the risks resulting from the manufacture, use and disposal of PFAS and PFAS-containing products and articles More specific information and conclusions can be found in the RAC sector-specific evaluations.

3.1.2.10. Environmental monitoring data

Environmental monitoring and biomonitoring data from different species may give further insights related to the PFAS emissions to the environment although it needs to be noted that these might not be possible to link to specific point sources. In addition, considering the persistence of PFAS, monitoring data is not necessarily representing the current uses and emissions but may be related to already ceased use. The Dossier Submitter has summarised available environmental monitoring data mainly under section B.4.2, in particular in B.4.2.6 and B.4.2.7 and in Appendixes B.4.2.1.3., B.4.2.3. and B.4.2.7 of the Background Document. The summary is not fully exhaustive and RAC recognises that new scientific studies and other environmental monitoring data are becoming constantly available. Therefore, RAC also does not aim for any exhaustive evaluation but rather summarises the main points related to the current knowledge. When it comes to the extent of environmental PFAS contamination, RAC notes the recent paper by Cordner et al. 2024, which used both scientific methods and investigative journalism techniques such as open-source intelligence (OSINT) and freedom of information (FOI) requests to map PFAS contamination across Europe. The study identified 22 934 known contamination sites, including 20 PFAS manufacturing facilities, and 21 426 “presumptive contamination sites”, which included industrial facilities, and facilities handling PFAS-containing waste (wastewater treatment plants, landfills and incinerators) or aqueous firefighting foams discharge and storage sites. The data highlights the role of PFAS producing and using industries in local PFAS contamination – in addition to PFAS manufacturing industries, especially pulp, paper and paperboard facilities were associated with PFAS contaminated sites (Cordner et al., 2024). The authors of this paper consider the true extent of contamination in Europe may remain significantly underestimated due to a lack of comprehensive geolocation, sampling, and publicly available data.

Many environmental monitoring studies have used targeted methods for the monitoring of specific PFAS in environmental samples and often the focus has been on PFAS that are covered already by existing or proposed restrictions under REACH and/or the POPs Regulation. Regarding other PFAS, data on environmental levels in different environmental matrixes are available especially on TFA (data on other ultrashort C1-C3 PFAAs is however more limited), ≥C4 PFCAs and PFSAs that are not subject to existing or proposed restrictions, PFECHS and PFAEs like HFPO-DA, ADONA and Cl-PFESA. Some of these PFAS have been detected next to known point-sources. TFA have been found at high levels and constitute a large part of the total PFAS content in aquatic matrices such as drinking water, WWTP effluents, waters close to point-sources, and precipitation (Aro et al., 2021; Björnsdotter et al., 2019; Chen et al., 2019; Freeling et al., 2020; Neuwald et al., 2022; Wang et al., 2020).

The levels of polymeric PFAS in the environment are poorly described, mainly due to analytical limitations. There are however increasing amounts of data on the levels and distribution of fluoropolymer microparticles in the environment. The levels of fluoropolymer microparticles are often lower compared to more common plastic types, PP, PE, PS.

Since there are targeted analysis methods available only for a limited number of PFAS (typically <50 compounds), untargeted approaches have been applied to estimate total PFAS levels in different environmental matrixes. Studies on Extractable Organic Fluorine (EOF) or Adsorbable Organic Fluorine (AOF) in environmental samples and mass balance analysis show that varying but significant fractions of organofluorine originates from PFAS molecules that are not captured by targeted PFAS analysis during monitoring (see e.g. Figure B.60 in t Annex B). The Dossier Submitter also reported that organisms at higher trophic levels display a lower fraction of unknown organofluorine, possibly due to metabolism of precursors into the stable PFAAs which are often included in the targeted analyses. Studies of abiotic and biotic samples utilizing TOPA[13] demonstrate that considerable fractions of PFAS in the samples may consist of unknown oxidizable PFAS that are not detected in routine targeted analyses, including precursors to the rarely analysed C1-C3 PFCAs (Göckener et al., 2021; Joerss et al., 2020; Simonnet-Laprade et al., 2019). Some studies have also used non-target and suspect screening approaches for qualitative or semi-quantitative identification of unknown PFAS which have identified hundreds of different PFAS in various environmental samples. As pointed out by the Dossier Submitter these remain undetected if only targeted analyses with available reference standards were performed.

RAC also notes the trend-data presented by the Dossier Submitter under section B.4.2.7. Remarkable is the increasing time trend observed for the fluorinated gases that have been increasingly used after the implementation of the Montreal Protocol. In addition, although the levels of PFOA and PFOS are declining in humans and the aquatic environment in Europe, no clear trend has been demonstrated in biota (Land et al.,2018). PFOA and PFOS are still dominating PFAS found in the environment highlighting their high persistence in the environment.

RAC concurs with the Dossier Submitter's conclusion that the targeted analyses of individual PFAS do not provide the full picture of PFAS contamination, and while most of these studies have analysed a limited number of compounds, there are data from targeted and non-targeted approaches demonstrating occurrence of wide range of different PFAS in different environmental compartments. Data also 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's concern on the increasing TFA levels in the environment, which is in line with the significant emissions of fluorinated gases predicted by emission estimates.

3.1.2.11. Human exposure and supporting human biomonitoring data

The Dossier Submitter has included a general discussion on human exposure and human biomonitoring data in Annex B of the Background Document, sections B.9.29 and B.9.30, respectively. RAC notes that human exposure to PFAS has been extensively studied through biomonitoring. In addition, intake estimates via different routes of exposure have been made considering the environmental levels in different matrixes (dust, air, food). Observed indoor air and dust levels have been summarised by the Dossier Submitter in Appendix B.9.29 of the Background Document. As discussed by the Dossier Submitter, the main exposure routes vary greatly for different PFAS; for hydrophobic and bioaccumulative long-chain PFAAs (like PFOA, PFOS), dietary intake especially via fish and meat consumption is typically the most

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[13] The Total Oxidisable Precursor Assay (TOP assay or TOPA) is a standardised pre-treatment of water samples or sample extracts (soil and water) designed to expose underlying PFAS not amenable to standard analysis.

important exposure route. For water-soluble short-chain PFAS, drinking water may dominate (for drinking water levels, see section B. 4.2.1.3 of the background Document). However, RAC notes that there are limited data available on the exposure sources of other PFAS; it has been considered that for precursor compounds, exposure via consumer products (e.g. textile impregnation products) directly or via the indoor environment (house dust) is probably the major exposure route (Vestergren et al., 2008) but the actual data on this is limited partly due to the limitations in monitoring approaches (see e.g Dewapriya et al., 2023). In addition, main exposure sources and substances may differ between populations depending for example on the proximity to industrial facilities or contaminated sites.

Human biomonitoring has been used to evaluate total exposure to several PFAS in different populations covering general population, people living next to industrial facilities or contaminated sites or occupationally exposed population groups. Human biomonitoring data on PFAS exposure in Europe have been evaluated earlier by EFSA (2020) as part of dietary risk assessment. In addition, the available data from general population biomonitoring studies in Europe have been collected in EU HBM dashboard[14] as part of EU project, HBM4EU. There are also several scientific publications and reviews presenting PFAS levels in different populations across the world in the literature. These demonstrate world-wide human exposure to several PFAS, even in remote areas. For example, a study by Sonne et al. (2023) showed that the indigenous population of East Greenland Inuit who rely on traditional marine food have high blood serum concentrations of four legacy PFAS (PFOA, PFOS, PFNA, PFHxS) highlighting the long-range transport potential of these PFAS.

However, as noted by the Dossier Submitter, substances most frequently analysed in these studies include substances already covered by the Stockholm Convention on POPs or by existing or proposed REACH restrictions (PFOS, PFOA, PFHxA, PFHxS, C9-C14 PFCAs). Limited data is available on the PFAS which have not been covered by these earlier restrictions. In addition, often the measured levels of these non-restricted PFAS have been at least one order of magnitude lower than those observed for PFOS and PFOA, and in many cases below the detection limit of targeted analyses (see e.g. data available in the HBM dashboard). The Dossier Submitter has compiled in Annex B in Tables B.124 and B.125 of the Background Document available data on the biomonitoring of non-regulated PFAS. PFHpA, PFHpS and PFBS are the most detected non-regulated PFAAs in human biomonitoring studies (Table B.124 and EU HBM dashboard). Some PFAAs have been studied only sparsely, like TFA has been studied only in two studies. Some studies have included also analysis of some PFAEs (6:2 Cl-PFESA, ADONA, and HFPO-DA), and e.g. 6:2 Cl-PFESA, ADONA, HFPO-DA and PFECHS. RAC notes that although these levels have been in many cases low compared to for example levels of PFOA and PFOS in the general population, continued and increasing use may result in gradual increase of levels in the population. RAC also notes that the data presented in Annex B of the Background Document and e.g. in the HBM dashboard is in many cases from populations sampled >10 years ago and emphasises the importance of continuous surveillance of population levels for potential increasing trends of currently non-restricted PFAS. In addition, RAC wants to highlight the limitations of these targeted human biomonitoring analyses, which can currently cover typically <50 different compounds. RAC notes that extractable organic fluorine (EOF) has been applied only in a few human biomonitoring studies and the unidentified organic fluorine (UOF) to the total EOF varied substantially between these studies (see Annex B, section B.9.30). RAC agrees with the Dossier Submitter that currently a considerable fraction of the extractable organofluorine detected in human samples may not be covered by the targeted analyses and this proportion

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[14] https://www.hbm4eu.eu/

of unknown PFAS in relation to known PFAS in humans may increase over time partly due to decreasing levels of restricted, legacy PFAS but potentially also substitution of restricted PFAS with newer compounds for which no targeted analysis methods exist. Overall, RAC considers that the current biomonitoring data covering also non-restricted PFAS is currently limited and emphasises the importance of continued monitoring using both non-targeted and targeted approaches to cover also these PFAS.

The Dossier Submitter has also reviewed the biomonitoring data concerning occupationally exposed populations. RAC has indicated the available data on occupational exposure in their sector-specific evaluations. Although there are some data available demonstrating occupational exposure of workers in different sectors including fluoropolymer manufacturing, ski waxing, metal plating and e.g. construction sector RAC considers that overall, the data on occupational exposure is extremely limited considering the wide-spread use of PFAS in various sectors. Thus, there is a clear need for further monitoring data on occupational exposure to PFAS in various sectors as pointed out recently by Lucas et al., 2023.

3.1.3. Risk characterisation

Relevant sections of the Background Document:

The risk characterisation is available in section 1.1.6 of the Background Document.

RAC conclusion(s):

- The Dossier Submitter performed a risk assessment according to REACH Annex I, paragraph 0.10, also referred to as a case-by-case assessment. RAC considers this approach appropriate for the risk assessment of PFAS.
- RAC agrees with the Dossier Submitter that quantitative risk assessment is not appropriate or even possible and the aim of the risk characterisation is therefore to demonstrate the magnitude of releases from different uses and determine whether releases have been minimised. All environmental compartments are relevant to consider.
- RAC also concurs with the Dossier Submitter with the use of the one compartment model for determining emissions. This model has been consistently applied throughout all the sectors evaluated in the restriction proposal and is consistent with the overarching persistence concern with PFAS, which is independent of the compartment PFAS are emitted to.
- RAC concurs with the Dossier Submitter that PFAS should be treated as non-threshold substances for the purpose of risk assessment in a similar manner to PBT/vPvB substances, whereby releases are taken to be a proxy for risk and ultimately, that releases should be minimised.
- RAC recognises that there is no certainty on the environmental and human health hazards of all different types of PFAS and some PFAS may be of low toxicity. However, considering their very high persistence, increasing environmental concentrations, ubiquity, and available (although limited) evidence on adverse effects of different PFAS, RAC concludes that uses of PFAS that result in releases to the environment are not adequately controlled and pose a potential health or environmental risk that needs to be addressed.
- According to RAC estimations, overall emissions of PFAS in the EEA are approximately

70 000 t/year[15] (excluding sectors not specifically evaluated by RAC). Fluorinated gases are major contributors to the emissions (ca. 60 000 t/y), followed by the application of side-chain fluorinated polymers (considered as PFAA precursors), especially in the "TULAC" sector. RAC has not made a quantitative estimate on the polymeric particle emissions derived from the use of fluoropolymers although RAC recognises the concern related to the formation of fluoropolymer micro- and nanoplastics in the environment.

- Overall, RAC agrees that PFAS releases present a risk and that the risk increases with continued use due to PFAS persistence and other properties of concern and the consequent build-up of environmental stocks over time. RAC concludes that there is no evidence that the release of PFAS from the manufacturing, use and disposal of PFAS, PFAS-containing mixtures and articles is adequately controlled and, therefore, it should be minimised.
- Considering that the sectors specifically evaluated by RAC represent ca. 90% of the volumes in use of PFAS in the EEA (see Table 4) and taking into account the emission estimates from the Dossier Submitter for those sector of use not specifically evaluated by RAC (see Table 5), RAC considers that the above conclusion can be applied for all sectors of use of PFAS within the scope of this restriction proposal.

Key elements underpinning the RAC conclusion(s):

RAC acknowledges that the conducted risk assessment according to REACH Annex I, paragraph 0.10, also referred to as a case-by-case assessment methodology has been already applied before in the case of the PFAS in firefighting foams restriction proposal. The case-by-case assessment approach is intended to cover risks for which the chemical safety assessment procedure outlined in Sections 1 to 6 of Annex I of REACH is 'impracticable' for quantitative and PBT/vPvB assessments.

RAC considers that a quantitative assessment is not applicable because of the large number of implicated substances and their persistence, the mobility of some and the irreversible nature of the releases. A PBT/vPvB assessment is not directly applicable because - although essentially all PFAS are persistent and many are bioaccumulative - the group as a whole has not been demonstrated to fulfil the PBT/vPvB criteria. The examples given in REACH Annex I, paragraph 0.10 are sufficiently diverse for RAC to have confidence that the risks posed by PFAS are well suited to a 'case-by-case' assessment as carried out by the Dossier Submitter.

Due to their very persistent properties, any releases of PFAS will contribute to the environmental stock over time. Therefore, RAC considers that PFAS should be assessed as non-threshold substances in a similar way to PBT/vPvB substances. The releases are then used as a surrogate for risk. RAC recognises that ecotoxicological and toxicological hazards of PFAS covered under this restriction vary and some individual PFAS have shown low (eco)toxicological potency meaning that, regardless of their persistence, risks may (in some cases) take very long to manifest and their magnitude are uncertain. This would not, however, eliminate the key fundamental issue arising from the very long-term persistence of PFAS whereby any potential (eco)toxicological threshold may eventually be exceeded over time due to the cumulative nature of the exposure. Therefore, RAC agrees with Dossier Submitter that a restriction under REACH should minimise releases of PFAS to the environment meaning that for risk characterisation, the PFAS emissions are used as a proxy for risk.

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[15] RAC estimation does not include emissions from those sectors of use not specifically evaluated (see section 2.2). According to the Dossier Submitter, PFAS emissions from these additional sectors of use represent about 5 000 t/y.

The presence of PFAS has been reported in almost all environmental compartments, including in the aquatic and terrestrial environment as well as air. Ecotoxicity studies with a range of organisms have demonstrated that exposure to PFAS results in adverse effects and in addition, PFAS can be transferred to humans through the food chain. There is growing scientific evidence that many PFAS may pose irreversible and long-term (eco)toxicological risks in water and terrestrial organisms as well as in humans.

RAC has estimated PFAS emissions per sector in sector-specific evaluations annexed to this opinion. According to RAC estimate, overall emissions of PFAS in the EU are approximately 70 000 t/year (excluding sectors not assessed in detail). Although RAC has not made an evaluation of the emissions related to the new 8 sectors identified in the Background Document after the Annex XV report consultation (see section 2.2), it can be noted, that based on Dossier Submitter release estimations, the inclusion of these 8 new sectors would not change the order of magnitude of the total emissions. Fluorinated gases are major contributors to the emissions (ca. 60 000 t/y), followed by the application of side-chain fluorinated polymers (considered as PFAA precursors) especially in the "TULAC" sector. RAC concludes that estimated emissions demonstrate that the risks are currently not adequately controlled and should be minimised.

Considering that the sectors specifically evaluated by RAC represent ca. 90% of the volumes in use of PFAS in the EEA (see Table 4) and taking into account the emission estimates from the Dossier Submitter for those sector of use not specifically evaluated by RAC (see Table 5), RAC considers that the above conclusion can be applied for all sectors of use of PFAS within the scope of this restriction proposal.

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

Relevant sections of the Background Document:

The Dossier Submitter has provided their justification in section 1.2 of the Background Document.

RAC conclusion(s):

- 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.

Key elements underpinning the RAC conclusion(s):

As demonstrated above in section 3.1.2 Emissions and exposures and in the sector-specific evaluations, PFAS are used in large quantities in a variety of products all over the world, including in all EU Member States. Emissions due to the use of PFAS occur during the manufacturing of PFAS, production of PFAS-containing mixtures or articles, during the use stage and when PFAS-containing products are disposed – the latter three life-cycle stages being relevant for all EU Member States. As discussed in section 3.1.1 Hazards, 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 as demonstrated by several environmental and biomonitoring studies observing PFAS pollution even in very remote locations. The findings of Cordner et al (2024) further highlight the European-wide challenge caused by environmental PFAS contamination. All these aspects emphasise the need for a common, union-wide action.

RAC notes that, in addition to European production, a significant proportion of various products/articles containing PFAS are imported into the EU region. As emissions are not restricted to the production stage of these articles, and PFAS can be transported across global borders via air and water, RAC supports EU-wide action restricting also the import of PFAS containing products/articles. RAC agrees with Dossier Submitter that restricting the placing on the market and use of PFAS in imported articles in EU may present the first step in reducing the overall global environmental burden caused by PFAS.

SEAC conclusion(s):

See SEAC Opinion

Key elements underpinning the SEAC conclusion(s):

See SEAC Opinion

3.3. ANALYSIS OF ALTERNATIVES

3.3.1. Availability and technical and economic feasibility of alternatives

See SEAC Opinion

3.3.2. Risk of alternatives

Relevant sections of the Background Document:

The Dossier Submitter’s approach to the risk of alternatives assessment is described in Annex E.2 of the Background Document.

RAC conclusion(s):

- RAC analysis of alternatives is based on the data provided by the Dossier Submitter and supplemented by additional information from literature or Annex XV report consultation comments.
- The Dossier Submitter’s approach to the analysis of risks of alternatives is based on the evaluation of hazardous properties, including persistent and bioaccumulative properties, of the alternatives.
- RAC considers that based on this information, the first comparison of their hazard properties with those of the PFAS used can be performed. RAC however notes that this information is not sufficient to fully characterise the possible risks of alternatives proposed for various PFAS uses. This is especially relevant in the case of alternatives for fluoropolymer uses, which are often high-molecular weight polymers and – like fluoropolymers – have main concerns related to their manufacturing and end-of-life phases. To fully compare the risks of different polymers, a risk assessment covering the whole life-cycle would have been needed but is not feasible.
- Because of these limitations, RAC’s analysis is therefore limited mainly to the

hazardous properties of the alternative substance itself. However, if possible serious hazards from substances involved or created in their manufacturing have been recognised by RAC, these have been considered in the evaluation.

- RAC has categorised alternative substances as follows:
    - **Likely of lower concern**:
        - Well characterised substances not known to exert any severe hazards; RAC however emphasises the uncertainties related to the fact that the assessment is based mainly on the analysis of hazardous properties of the alternative substance itself.
        - Alternatives with some known severe hazards which can likely be addressed by proper risk management measures during the manufacture, use or disposal of these alternatives.
        - Alternatives suggesting a low concern but with some significant data gaps in the available hazard data.
    - **Comparable concern**: These alternative substances have well characterised severe hazards (substances with SVHC properties, EDCs or PBT/vPvB or PMT/vPvM) which can be considered to cause risks comparable to or more severe than PFAS which may not be fully controlled by the known or possible risk management measures. Also, high GWP substances regulated by the F-gas Regulation (Regulation (EU) 2024/573) can be considered as causing a comparable concern and are not recommended as alternatives.
    - **Insufficient information**: RAC notes that under various uses, several alternative substances that lack hazard information or detailed characterisation have been identified. This limited information is hampering the evaluation. In these cases, no conclusion is provided by RAC.
- Detailed evaluation of alternatives for various uses has been presented in sector specific evaluations. RAC notes that there are a number of sub-uses in various sectors, for which no alternatives were proposed by the Dossier Submitter for RAC analysis. RAC highlights that conclusions on the risks of alternatives include uncertainties due to the methodological limitations in the Dossier Submitter's approach.

Key elements underpinning the RAC conclusion(s):

The Dossier Submitter approach to the assessment of alternatives has been described in Annex E of the Background Document. It is based on the evaluation of the available information on the hazardous properties of the potential alternatives on the basis of available hazard classification under CLP and an evaluation of bioaccumulation potential and PBT/vPvB (and PMT/vPvM) and endocrine disrupting properties.

According to the Dossier Submitter, the substance would be considered as an unsuitable alternative, if risks resulting from the hazard are considered to be comparable or even greater than the risks resulting from the use of PFAS. The Dossier Submitter presents an adapted German GHS column model[16] for the assessment of alternatives and their hazardous properties. In this model, substances are categorised as very high, high, medium, low and negligible risk categories according to their hazardous properties.

RAC notes that although these categories are named as "risk categories", they are rather

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[16] https://publikationen.dguv.de/widgets/pdf/download/article/3737

"hazard categories" and do not yet inform on actual risk.

In addition, RAC notes that this model has not actually been applied in the assessment of alternatives. The Dossier Submitter states that due to the outstanding persistence of PFAS together with their other hazardous properties, PFAS pose the highest risk according to the GHS Column Model. RAC notes that this was done regardless of the fact that some of the alternatives may cause, for example, severe human health risks in the short term. However, if they are less persistent, environmental concentrations decrease more rapidly than for PFAS and therefore, according to the Dossier Submitter, they can be considered as better alternatives than PFAS.

Overall, the Dossier Submitter approach to the assessment of alternatives is based on the evaluation of hazardous properties of the proposed alternatives with a special focus on persistent and bioaccumulative properties, which may result in long-term environmental contamination.

RAC acknowledges the challenges and limitations related to the analysis of a high number of different compounds that have been suggested as alternatives for PFAS in various uses. As a result of this, the assessment of the risks to human health and the environment has not been done. In addition, RAC notes that although Dossier Submitter acknowledges the importance of the evaluation of the whole life-cycle especially in the case of polymers, this has not been done. RAC notes that this approach is limited and not sufficient to fully identify the possible concerns related to the substitution, especially in the case of alternatives for fluoropolymers. RAC recognises that some alternatives may result in various (environmental or occupational) concerns during their life cycle, even though the alternative itself can be considered of low concern based on its known specific hazardous properties. Especially in the case of polymers (commonly proposed as alternatives for fluoropolymers), focusing only on the hazard classification of the polymer itself, without considering possible additives, impurities or releases of hazardous constituents during the manufacturing or end-of-life stage of the polymer is not sufficient to fully compare their safety (for instance in the case of fluoropolymers, for which the main concerns are often related to the manufacturing and end-of-life stage of their life-cycle).

RAC also notes that some Annex XV report consultation comments emphasise that the use of alternative substance for some uses could result in higher carbon footprint or higher amounts of plastic waste due to shorter lifespan of the products. These are also aspects that were not considered by the Dossier Submitter, and thus not assessed by RAC.

RAC's qualitative assessment of alternatives is based on the information provided by the Dossier Submitter in the Appendix E of the Background Document. These alternatives and the accompanying hazard information were listed and cross-checked against additional literature sources available to RAC as well as to Annex XV consultation comments. RAC's analysis is also limited, mainly to the hazardous properties of the alternative substance itself.

However, if potential serious hazards from the manufacturing of the substance were recognised by RAC, these were considered in the evaluation. However, this analysis was not systematic and therefore it needs to be interpreted with caution. Also, possible additional information from Annex E were noted when available. Where possible, a categorization of alternatives according to the concern they cause compared to PFAS were made (see below). In addition to concluding on the concern related to individual alternatives, RAC has indicated whether alternatives of lower concern were identified for the specific sub-use. It needs to be noted that RAC's conclusions are based on RAC's assessment on the potential health and environmental risks, and they do not consider feasibility aspects and technical performance which are instead evaluated by SEAC. RAC takes however note of the SEAC assessment of the feasibility of various alternatives.

RAC has categorised alternatives when compared to PFAS either as:

1. likely of lower concern,
2. comparable concern or
3. insufficient information

Alternatives of likely of lower concern include substances which are:

1) well characterised and are not known to exert any severe hazards (substances with e.g. SVHC properties, EDCs or PBT/vPvB or PMT/vPvM). However, RAC would emphasise that also in these cases there might be some uncertainties related to the fact that the assessment is limited to hazard assessment of the alternative, without further assessment or consideration of the whole life cycle, which might become for instance relevant in case of the polymers (suggested as alternatives for fluoropolymers).
2) Known to have some severe hazards but it has been shown (or it is anticipated) that these can be addressed by proper risk management measures applied during manufacture, use or disposal. These include for example cases where raw materials have severe hazards, but those materials are not entering in relevant concentrations into the final products, and the exposures and emissions during the manufacturing, use and disposal can be controlled.
3) of low concern as suggested by available data but with some data gaps/uncertainties in the hazard database (e.g. limited data on long-term effects).

In two latter cases (2-3), RAC has highlighted the identified concerns related to these alternatives. Therefore, the identified concerns are recommended to be addressed in case those substances are used to replace PFAS.

Alternatives of comparable concern are:

1. Substances with well characterised severe hazards (e.g. SVHC, PBT/vPvB properties), which may not be fully controlled by the known or possible risk management measures. This is for instance the case for those proposed alternative substances for which no threshold for their hazardous properties can be given and which have a potential for wide-spread exposure of the population due to emissions that cannot to be fully controlled.

   RAC acknowledges that this approach differs from the Dossier Submitter's approach. The Dossier Submitter has not necessarily considered a substance as of comparable concern even if the substance has some non-threshold CMR or EDC properties unless the substance is highly persistent or bioaccumulative. Exposure-related aspects were not considered by the Dossier Submitter.

Alternatives with insufficient information:

1. In some cases, no information on the hazardous properties of the suggested alternative is available or the lack of detailed characterization of the alternative hampers the analysis. In these cases, no conclusion is provided by RAC.

Examples of some alternatives and their analysis by RAC is provided below.

For some specific uses, alternatives such as lithium salts or boron compounds have been suggested. In case of boron compounds (cat 1B reproductive toxicants), RAC has recently concluded that a threshold can be assumed for their reproductive toxic effects (ECHA, 2024).

The same may apply for lithium salts (cat 1B for their reproductive toxicity) which have been proposed as alternatives in some specific applications. These risks can therefore be managed by applying proper risk management measures and are therefore categorised as likely lower concern alternatives.

The situation becomes more complex in the case of various polymers suggested as alternatives for fluoropolymers.

Polypropylene and polyethylene plastics have been proposed as alternatives for fluoropolymers in many applications. They are widely used plastic types, and no severe hazards related to these plastics have been identified. Based on this, these are classified as lower risk alternatives by the Dossier Submitter and likely a lower concern alternatives by RAC. RAC however notes that – as commented in some Annex XV report consultation comments (e.g. #8346) – also PE and PP plastics can form micro- and nanoplastics (MNP) during their life-cycle. Potential formation of MNPs and related concerns on the bioavailability and toxicity of MNP particles due to their small size applies to many different types of plastics, including PE, PP, PS, PVC as well as to fluoropolymers like PTFE. As discussed under section "Hazards", the health and environmental hazards of MNPs are currently under active research and currently majority of the data on the hazards of MNPs comes especially on polystyrene particles and less data is available specifically on the hazards of fluoropolymer particles. Although RAC notes this, the general effects of plastics pollution have not been considered in the analysis of alternatives.

In addition to PE and PP, epoxy-based polymers, polyurethanes, polystyrene and PVC are polymeric alternatives that have been suggested as alternatives for fluoropolymers for various applications but are associated with some severe concerns during their life-cycle.

- Epoxy-based coatings (suggested especially for some construction applications) are well-known causes of occupational skin allergies in the construction sector. In addition, manufacturing of epoxy-resin is typically based on the reaction between epichlorohydrin (carcinogen) and endocrine disruptor bisphenol-A (BPA). If emissions of these compounds during the manufacturing are controlled, these coatings can be considered as likely lower concern alternatives. Occupational sensitization risks can be managed by good working practises and proper personal protection.
- Manufacturing and use of polyurethanes, on the other hand, may lead to exposure to diisocyanates, causing occupational asthmas. No threshold for this hazard has been identified. To manage these risks, a binding occupational exposure limit value (BOELV) and REACH restriction defining obligatory training of workers on safe working practises have been implemented in the EU.
- PVC requires carcinogenic precursors (vinyl chloride and 1,2-dichloroethane) that need to be carefully controlled during their manufacturing phase. In the case of PVC, the recent ECHA evaluation concluded that the risks from PVC resin to workers and the environment are adequately controlled with the current operational conditions and companies' safety measures (ECHA, 2023c). However, ECHA (2023c) concludes that various additives, like reprotoxic phthalate plasticizers, organotin heat stabilizers and halogenated flame retardants, used in PVC may need further regulatory action due to their potential health and environmental risks. If no above-mentioned substances are used in the manufacturing of PVC, it could be considered as a likely lower concern alternative. Otherwise, PVC could be considered as of comparable concern. In addition, RAC notes that there are concerns related to the formation of dioxins if PVC is incinerated in poorly-controlled conditions when disposed.

Various rubbers have also been suggested as alternatives for fluoropolymers in different sub-uses. In rubber manufacturing, various substances are used, including fillers, vulcanizing agents, vulcanization accelerators and activators, vulcanization inhibitors, softeners, antioxidants etc (see SCOEL, 2016). Rubber fumes formed in the process may include several carcinogens, like aromatic amines (o-toluidine), N-nitrosamines, aromatic solvents (benzene) and polycyclic aromatic hydrocarbons (PAHs), which can be released in the process to the workplace or to the environment. Also, styrene and 1,3-butadiene may be released in processing of styrene-butadiene-rubber. Silicone rubber may contain traces of cyclic siloxanes, such as D4, D5 and D6. IARC has evaluated Occupational exposures in the rubber-manufacturing industry as carcinogenic to humans (Group 1). However, the classification is based on epidemiological data which may not fully reflect the exposures in the modern rubber industry (see SCOEL, 2016). Overall, the categorization of various types of rubbers either as lower or comparable concern depends on the type of rubber, residues and additives used in manufacturing process and cannot be fully concluded based on information available to RAC.

In addition to the individual metal compounds discussed above, also various metal alloys have been proposed for various applications. These include e.g. different grades of steel, including stainless steels. RAC recognises there are different grades of steel and release of metal components from steel varies between grades and is a central factor for assessing the risks of various steels. Specific grades of stainless steel used e.g. in cooking applications release only minimal amounts of hazardous metals (like nickel) and can on that basis be considered as a likely of lower concern alternative. In addition, RAC notes the occupational health risks related to steel manufacturing process, which includes exposure to e.g. hexavalent chromium fumes. These are controlled by occupational health legislation, which sets binding occupational exposure limit values for hexavalent chromium and nickel oxides. Overall, various steels can be considered as likely of lower concern alternatives depending on the grade and release of hazardous components from them. RAC notes some consultation comments highlighting the high carbon footprint of stainless steels. Although RAC acknowledges the importance of full life-cycle analysis considering also these aspects, this is an issue which cannot be considered in current analysis.

RAC notes that siloxanes and siloxane-based substances, including polymers, copolymers, and additives, are among the most frequently used alternatives to PFAS across different sectors. ECHA has recently concluded an assessment of regulatory needs (ARN) for a group of hydrocarbyl siloxanes, covering 52 substances. The ARN concluded that, all substances within the group have potential vPvB/PBT properties. Furthermore, a few substances in the group may also be persistent, mobile and toxic. In addition, for some substances, potential health hazards were identified, including STOT RE (liver, kidney, thyroid), and/or - reproductive toxicity (development, and/or fertility), and/or - endocrine disrupting properties (thyroid weight, and thyroid hormones levels) (ECHA, 2022).

It is also noted that polymer preparations (whether in mixtures or articles) derived from these monomer substances can also contribute to the release of monomers into the environment. For certain substances within this group (e.g., D4 (EC 209-136-7), D5 (EC 208-764-9), and D6 (EC 208-762-8)), it is well-documented that unreacted monomers remain in polymers in significant amounts and/or may be released from polymer-based articles (ECHA 2022). ECHA (2022) report concluded that there exists potential for exposure to professional workers, consumers and the environment, including via article service life, and/or concern for substitution. A restriction of the substances as such, as a constituent in other substance, as unreacted monomers in polymers and/or in mixtures (>0.1 %) used by consumers, professional workers and industrial workers was suggested after SVHC identification and/or CLH, with the aim to minimise exposures and emissions to humans and the environment.

RAC notes that in most occasions the specific siloxane substance identified as an alternative to PFAS (including both non-polymeric and polymeric PFAS) has not been identified, nor the amount of residues, impurities or unreacted monomers present in a mixture or in polymer. Based on this, and without a clear on conclusion on the scope of future risk management on hydrocarbyl siloxanes, RAC notes the concerns associated with siloxanes and siloxane-based substances, which may lead (depending on e.g. type and residues) comparable or lower concern as PFAS.

Finally, there are many less well-described alternatives, including polymers suggested for various applications. Some of these have been mentioned only as a trade name or only a chemical group have been mentioned. Lack of detailed information on the chemical identity of the alternative hampers the evaluation and prevents making conclusions on their hazardous profile compared to PFAS. In these cases, RAC has indicated that there are too limited data to draw any conclusions on their hazards/risks. Examples of these cases include above-mentioned rubbers or hydrocarbon elastomers, polyacetyl resins, phosphorus, sulfur or nitrogen containing flame retardants, various (unspecified/poorly specified) nanomaterials. These may include alternatives of lower concern, but lack of more specific information prevents making conclusions on their possible hazards.

Some examples of alternatives identified for various uses of PFAAs/PFAA precursors and fluoropolymers and categorised as likely of lower concern, comparable concern or insufficient information categories are presented in Table 7.

Table 7: Some examples of RAC categorisation

Category	Proposed Alternatives
Likely of lower concern	No severe hazards identified: PE, PP, polyester, glass
	Severe hazards which are likely manageable with risk management measures or substances with no severe hazards but some data gaps related to their hazardous properties identified: epoxy-based coatings, polyester melamine, polyurethanes, polystyrene* and PVC*, Lithium salts, boron nitride, siloxanes#, stainless steel
Comparable concern	PVC**, siloxanes#
Insufficient information	rubbers or hydrocarbon elastomers, polyacetyl resins, phosphorus, sulfur or nitrogen containing flame retardants, various (unspecified/poorly specified) nanomaterials

* depending on the amount of monomers released and potential exposure in different exposure scenarios, in most cases likely a lower concern, see text for further explanation

** depending on additives and incineration method (PVC), see text for further explanation

depending on the specific type of siloxane and residue levels, see text for further explanation

It needs to be noted that although RAC has tried to consider for example the source materials used to produce polymeric alternatives, or possible residues/impurities, the analysis is not comprehensive, includes significant uncertainties and may miss some relevant concerns related to specific alternatives. Therefore, it should be considered only as indicative.

Alternatives for fluorinated gases

Many alternatives for fluorinated gases display flammable properties (hydrocarbons like propane, butane, isobutane; ethanol) and sometimes acutely toxic (ammonia, CO2, SO2). Although RAC considers these as likely of lower concern than PFAS, RAC highlights that in certain applications there is a need for controlling flammability risks and, in case of for example ammonia, need for controlling the risk of acute poisonings due to incidental releases. Alternatives such as water and air are considered of no concern alternatives.

In addition, some HFC-substances (HFC-32, HFC-152a) have been identified as alternatives. RAC notes that these are regulated under the F-gas Regulation due to their global warming potential. In the F-gas Regulation, more severe restrictions are applied to the substances with a GWP of 150 or above. Especially HFC-32 (mentioned as a potential alternative in some applications) has a Global Warming Potential (GWP) of 675 and is therefore more severely regulated under the F-gas Regulation than another proposed alternative, HFC-152a, which GWP is 124. Therefore, for example HFC-32 and SF6 (GWP 23500) mentioned in some uses are not recommended as alternatives and can be considered of comparable concern as PFAS.

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

3.4.1. Regulatory risk management options other than restriction

Relevant sections of the Background Document:

The Dossier Submitter has assessed regulatory risk management options other than a restriction in section 2.2 of the Background Document.

RAC conclusion(s):

- RAC agrees with the Dossier Submitter that a restriction on manufacturing, placing on the market and use of PFAS and PFAS-containing articles and mixtures is the most appropriate way to limit the risk to human health and the environment and to avoid regrettable substitution.
- RAC considers other EU legislation (Water Framework Directive, Industrial Emissions Directive, etc) to be important in complementing the risk mitigation of the proposed restriction.
- RAC also considers that a REACH restriction is in accordance with the risk management approach selected for some individual PFAS that are already regulated under REACH.
- RAC considers CLH and SVHC identification followed by authorisation to be less suitable options to address the broad nature of the identified risk.
- 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 exempted from the proposed ban on the manufacture, placing on the market and use of PFAS since they are covered under their own legislation. RAC considers that the current legislations on BPs, PPPs and MPs do not fully address the concern associated with the emissions to the environment of PFAS and considers it important that, in case the decision-maker supports a derogation for these uses, measures to minimise PFAS emissions are incorporated into the respective sector-specific regulations.

Key elements underpinning the RAC conclusion(s):

The Dossier Submitter has made a detailed evaluation of the existing legislation covering the different use of PFAS and other risk management options under REACH or other EU legislation.

In chapter 2.2.1 an overview of the regulatory measures currently applicable to PFAS in the EU have been given covering:

- Stockholm Convention and Regulation on Persistent Organic Pollutants (POP) Regulation (Regulation (EU) 2019/1021)
- Existing restrictions under REACH Regulation (Regulation (EC) 1907/2006) and Substances of very high concern (SVHC) identification
- Montreal protocol and F-Gas Regulation (Regulation (EU) 2024/573)
- Mobile air-conditioning systems (MAC) Directive (Directive 2006/40/EC)
- EU Drinking Water Directive (Directive (EU) 2020/2184)
- Water Framework Directive (Directive 2000/60/EC)
- Cosmetic Product Regulation (Regulation (EC) No 1223/2009)
- Regulation on plastic materials and articles intended to come into contact with food (Regulation (EU) 10/2011)
- Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food.

These existing regulations either focus only on specific PFAS or specific hazards (like ozone layer depletion or GWP) and therefore cover only some specific (groups of) PFAS or address only specific concerns.

In chapter 2.2.2, other risk management options than restriction under REACH are considered. Other risk management options under REACH are SVHC identification, authorisation and CLH classification. RAC agrees with the Dossier Submitter that CLH alone is not effective in limiting the use of the substances for article/product manufacturing although it is recognised that specific hazard classifications (CMR, PBT, vPvB) restrict the use of classified substances in specific uses e.g. in consumer products. However, as discussed in section 3.1.1 Hazards, both CLH and SVHC identification may require additional testing of individual PFAS for their (eco)toxicological properties since there is limited information on the properties of the majority of PFAS. Although persistence is a common property for PFAS, other properties vary, and persistence alone is currently not a property resulting in CLH classification or SVHC identification. CLH and SVHC identification followed by authorisation are also time-consuming, would not prevent regrettable substitution and would not cover imported articles. In contrast, a group restriction based on structural similarity and equivalent hazard will prevent regrettable substitution and future exposure to those PFAS which are not currently in use. This is considered to be a more effective measure than regulating PFAS individually, especially when considering the high number of PFAS. Restriction can include the ban of the manufacturing, placing on the market or use of a chemical substance, or a group of substances. Thus, it applies also to imported products. Additionally, it can use other requirements to address the risks (use of RMMs, reporting requirements etc).

In addition, the Dossier Submitter considered the potential of the following EU legislations to address the risks caused by PFAS:

- **Water Framework Directive, EU Soil monitoring law (Directive (EU) 2025/2360) (approved in EU Parliament in October 2025) and Sewage Sludge Directive (Directive 86/278/EEC):** RAC agrees with the Dossier Submitter that the main constraint in these legislations is that they can only regulate PFAS in their specific target media (water, soil etc.). Thus, any of those is not considered sufficient alone nor as effective as a REACH restriction in reducing emissions at their source. However, RAC acknowledges that introducing PFAS emission limits in these specific legislations could result in reducing industrial emissions to the wastewater or to the environment, therefore, RAC strongly supports it.

- **Industrial emissions Directive (IED) (Directive 2010/75/EU) and Volatile Organic Compounds (VOC) Directive (Directive 2004/42/CE)**: The IED concerns emissions from large industrial instillations, waste incineration and landfills. Within the IED, emission limit values can be set considering the best available techniques. RAC considers IED important complementary legislation but not as effective as PFAS restriction under REACH to address the risks of PFAS from all uses and during their whole life cycle. Considering the scope of VOC-Directive, it could potentially cover only a limited number of volatile PFAS.
- **Regulation on materials and articles intended to come into contact with food (Regulation (EC) 1935/2004), and Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food**: RAC considers that this legislation has a limited focus in food contact materials only and therefore does not address the identified risk sufficiently.
- **Waste Framework Directive (Directive 2008/98/EC) and Packaging and Packaging Waste Regulation (Regulation (EU) 2025/40):** This legislation has a main emphasis on effective recycling and reuse of waste. However, specific requirements can be given for hazardous chemicals in waste under these legislations. The revised packing and packaging waste regulation gives limit values for PFAS in food packaging. RAC agrees with the Dossier Submitter that these legislations can be considered to support and complement the planned restriction under REACH but have limited effectiveness since they can address only one life-cycle stage.

Overall, although some existing EU legislation may have an impact on the risk management of PFAS, these were assessed as insufficient to address all the sectors, life-cycle stages and substances contributing to the identified risk. RAC, however, considers them as important complementing the proposed restriction.

RAC agrees with the Dossier Submitter that a REACH restriction is the most appropriate measure to minimise the risks to human health and the environment resulting from the widespread use of PFAS in industrial products and processes and in products placed on the market for use by professionals and consumers.

The Dossier Submitter has proposed a time-unlimited derogation for PFAS used as active substances in Plant Protection Products (PPP; paragraph 4.b) and Biocidal Products (BP; paragraph 4.a), and in human and veterinary Medicinal Products (MP; paragraph 4.c). The Dossier Submitter also proposes a derogation for starting materials and intermediates used in the production of these active substances (paragraph 4.g). RAC understands that paragraph 4.g of the proposed entry text is intended to also cover process chemicals required for the production of active substances. The Dossier Submitter justifies these derogations by the existing legislations (Biocidal Products Regulation (BPR) Regulation (EU) 528/2012, Plant Protection Products (PPPR) (Regulation (EC)1107/2009), Directive 2001/83/EC on human medicinal products (MP) and Regulations (EC)726/2004 and Regulation (EU) 2019/6 concerning human and veterinary MPs), which include also an assessment of risks for the environment. Since intermediates and process chemicals are considered in the approved manufacturing processes of the active substances in PPP, BP and MP, the Dossier Submitter proposes also their derogation (paragraph 4.g of the draft entry text). RAC notes that several comments were provided during the Annex XV consultation on active substances, and intermediates and process chemicals used to produce active substances (comment numbers listed in the chapter 2.2.3 of Background Document). The Dossier Submitter has not estimated emissions from these derogated uses but only describes annual use tonnages for

PPPs and for human MPs, which are 5 479 and >500 t/y, respectively (see also section 3.4.2.1). No volume estimates were made for active substances in veterinary medicine or biocides. Although each of these regulations include an environmental risk assessment, according to RAC, information on the formation of persistent arrowhead PFAS (like TFA) and potential risks related to the environmental accumulation of these persistent degradation products are not fully considered there. There is literature showing that several PPP currently used in Europe can be significant contributors to TFA levels in the groundwater (Joerss et al., 2024). The paper calls for more information on the ability of different pesticides to form TFA and it emphasises that actual TFA formation rates are lacking for most PPP and are urgently needed to better assess the actual formation potential of individual products. Similarly, for example fluranes used as inhalation anaesthetics (regulated by the MPR) can form TFA and other persistent PFAS degradation products in the environment (Kalmar et al., 2024).

Although the Dossier Submitter has recognised the issue of TFA (and other arrowhead PFAS) formation from PPPs, BPs and MPs in the Background Document, no further consideration on how the issue could be addressed is provided. RAC is concerned that current legislation and practise on BPs, PPPs and MPs is not sufficient to fully address the risks of environmental accumulation of persistent PFAS on these uses. RAC however notes that Directive 2001/83/EC and Regulation (EC) 726/2004 (on MPs) are currently under revision and the intention is to better consider environmental risks in the decision-making process, and to perform environmental risk assessments also for those active ingredients which were in the market before year 2006 when environmental risk assessments were introduced in MP legislation.

The Dossier Submitter recommends that measures to minimise emissions from the use of PFAS as active substances in PPP, BP and MP are taken in the context of the respective sector-specific regulations. RAC agrees with the Dossier Submitter that in case of derogation, there is a need to consider measures strengthen the requirements for the management and minimization of the emissions under their sector-specific legislation. The Dossier Submitter has also proposed specific reporting obligations for the manufacturers and importers of these active substances. These are discussed further under section 3.4.2.1 Effectiveness in reducing the identified risk.

Finally, the Dossier Submitter proposes (see paragraph 9 of the draft entry text proposed by the Dossier Submitter) that the proposed restriction should not affect existing entries of REACH regulation Annex XVII, apart from entries 28 to 30, as well as substances listed in the EU POPs Regulation (Regulation (EU) 2019/1021). Other Union legislation addressing substances within the scope of this restriction shall be adhered to notwithstanding this restriction.

According to RAC’s understanding, the Dossier Submitter’s intention is not to interfere with any existing substance- or use-specific PFAS restrictions and instead aim to ensure that the strictest EU regulation applies. Since entries 28-30 of Annex XVII of REACH covering restrictions of use of substances classified as carcinogenic, mutagenic or reproductive toxic are less stringent than the proposed restriction, PFAS restriction would overrule them. RAC notes that Forum commented on the wording of the first sentence in paragraph 9, which was considered ambiguous. Also, RAC has doubts whether the current expression in paragraph 9 of the restriction proposal is clear enough to ensure that in cases of existing specific restrictions, the most stringent condition always applies and considers that this may need further clarification by the decision maker.

SEAC conclusion(s):

See SEAC Opinion

Key elements underpinning the SEAC conclusion(s):

See SEAC Opinion

3.4.2. Restriction options

Summary of the restriction options proposed by the Dossier Submitter

The Dossier Submitter assessed the following restriction options:

- Restriction option 1 (RO1): Full ban with an 18-month transition period; and
- Restriction option 2 (RO2): Ban with use-specific and (mainly) time-limited derogations.
- For specific sectors, a third restriction option (RO3) was introduced by the Dossier Submitter, which provides additional conditions for specific (sub-)uses instead of a ban or to complement a time-limited derogation. The conditions mainly relate to emission control and reporting measures for (sub-)uses where derogations are foreseen. RO3 was introduced only after the Annex XV report consultation, based on information provided by stakeholders, for the following sectors: i) "PFAS manufacturing", ii) "Transport", iii) "Electronics and semiconductors", iv) "Energy", v) "Sealing applications", vi) "Machinery applications" and vii) "Technical textiles". Depending on the sector affected, the design of RO3, as well as its conditions, differ.

The restriction proposed by the Dossier Submitter (see Table 1) corresponds to RO2 for all sectors except for "PFAS manufacturing", for which RO3b[17] is proposed.

The conditions of the proposed restriction also include reporting requirements, for derogations with a 12-year derogation period or time-unlimited and all applications of fluorinated gases (following the 18-month general transition period), labelling requirements (for certain plastic articles or complex objects) and the establishment of site-specific PFAS management plans (for manufacturers, importers and downstream users of fluoropolymers and perfluoropolyethers making use of a derogation). Further details on the proposed restriction are given in Table 1 of this opinion.

3.4.2.1. Effectiveness in reducing the identified risk(s)

Relevant sections of the Background Document:

The effectiveness of the proposed restriction is assessed in section 2.4 of the Background Document and in Annex E of the Background Document.

RAC conclusion(s):

- RAC concludes that RO1, i.e., a full ban for all uses of PFAS, is an effective measure to minimise PFAS emissions and exposure of humans and the environment. RAC calculates a total emission reduction potential of 96 % (excluding uses not evaluated in detail), corresponding to approx. 3 300 000 tonnes of avoided emissions over the 30-year assessment period for RO1.
- RAC notes that uses of PFAS as active substances under the Plant Protection Products, Biocidal Products and Medicinal Products Regulations, are excluded from the proposed ban and this may still result in relevant emissions of PFAS, which are not fully

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[17] RO3b corresponds to a ban with a time-unlimited derogation for the manufacturing of PFAS conditional upon emission limits.

addressed by the current legislation

- Similarly, spare parts, second-hand articles and recycled materials are proposed to be derogated by either time-limited or time-unlimited derogations. The impact of these derogations on the effectiveness of the restriction cannot to be quantified. However, additional emissions related specifically to second-hand articles and some recycling activities are considered negligible to low.
- RAC considers the impact of the proposed reporting requirements for these derogated uses on overall risk reduction to be low.
- RAC notes that RO2 includes several additional derogations for specific uses. The effectiveness of the restriction is reduced to 76% due to these derogations. RAC concludes that RO2 leads to additional estimated emissions of around 700 000 tonnes compared to RO1 (excluding uses not evaluated in detail) and results in an uncontrolled risk.
- For some sectors, an RO3 including specific additional risk management measures for uses derogated under RO2 is presented by the Dossier Submitter. RAC notes that the additional risk management measures proposed are not sufficiently defined for RAC to conclude on their effectiveness and implementability under the proposed restriction.
- RAC considers that the implementation of site-specific PFAS management plans to control PFAS emissions can be an appropriate risk management measure to minimise emissions at industrial sites for those derogated uses. However, RAC considers that the requirements for site-specific PFAS management plans proposed by the Dossier Submitter are not sufficient to provide a significant risk reduction.
- RAC has proposed relevant improvements to the site-specific PFAS management plan, which aims for the minimisation of emissions. In this plan, industry needs to describe the measures taken and planned to minimise the emissions to the environment covering the emissions arising during the process, measures taken to prevent accidental emissions, and measures taken to ensure safe disposal of the waste produced during the process. Monitoring arrangements and results need to be described.
- RAC also recommends requirements for the manufacturers and importers of PFAS-containing materials/products for derogated uses need to ensure effective supply-chain communication, which may occur via labelling of products, safety datasheets/technical datasheets or product passports. In addition, RAC proposes the requirement to provide instructions for safe use and disposal of PFAS and PFAS-containing mixtures and articles.
- RAC considers that requirement of this site-specific PFAS management plan should apply to all types of PFAS and to all industrial sites where manufacturing and downstream uses of PFAS and PFAS-containing mixtures are allowed to continue; this is to ensure that minimisation of emissions could be achieved also in these sectors. RAC notes that this also should apply for example to active substances with a time-unlimited derogation.
- RAC notes that it is uncertain which PFAS uses can be derogated by REACH SR&D exemption and by the derogation proposed by Dossier Submitter for PPORD activities and what the resulting emissions resulting from these proposed derogations will be.

Key elements underpinning the RAC conclusion(s):

3.4.2.1.1. Overall effectiveness of RO1 and RO2

As discussed above, PFAS are treated as non-threshold substances for the purpose of risk assessment and their releases are used as a proxy for risk. As a result, emissions should be minimised as all emissions pose a risk and adverse effects for human health and the environment cannot be ruled out below a specific threshold. The risk assessment therefore focuses on estimating emissions only and does not include any quantitative health or environmental risk assessment. RAC notes the Annex XV consultation comments related to the potential public health benefits and recognises the available research studies on the potential public health impacts of PFAS [e.g. a recent study by Plass et al., 2025 on burden of disease of PFOS and PFOA in several European countries. However, RAC points out that a human health and environmental risk assessment related specifically to this restriction would be difficult due to the qualitative and quantitative variation in toxicological and ecotoxicological properties of thousands of PFAS covered under this restriction and due to the availability of data only on limited number of PFAS, many of which are already covered by the existing substance-specific restrictions (see further discussion under Chapter "Hazards").

As discussed above under "Emissions and exposure", RAC has focused in its emission estimates on the emissions of PFAAs and their precursors. This means that in the case of fluoropolymer uses, emissions are calculated only considering of non-polymeric compounds, used in the production or degradation products and residues. Particle emissions are not quantified.

Effectiveness of the restriction has been quantified by comparing baseline emissions over the period from 2025 to 2055 versus emissions under various restriction options (RO1, RO2, in some cases RO3) over the same period. The 18-month transition period was originally expected to start in 2025, corresponding to cessation of emissions from 2027 under RO1. Although now it is clear that the transition period will start later, 2025 was retained as the beginning of the transition period for the purpose of effectiveness calculations.

In order to be able to model future emissions, the Dossier Submitter had to estimate growth rates for various sectors and uses. RAC used for its calculations the growth rates proposed by the Dossier Submitter without any modifications (assessment of growth rates is in the remit of SEAC). Assumptions about growth rates represent an additional source of uncertainty. Consequently, estimates of effectiveness, as well as the corresponding estimates of additional emissions due to derogations, are even more uncertain than estimates of yearly emissions as of 2020. RAC points out that although the values presented in Table 8 below have many significant digits, their actual accuracy is much lower. The figures should be used only as an indication of the order of magnitude of emissions.

Using the RAC emission estimates for year 2020 and the proposed growth rates, the baseline emissions over the assessment period (2025-2055) have been estimated by RAC at about 3 400 000 tonnes. This estimate does not include the eight sectors not evaluated in detail. Emissions for RO1 (full ban) are about 150 000 tonnes, corresponding to 96% effectiveness (RAC noted that the effectiveness is lower than 100% due to the 18-month transition period).

For the restriction as proposed by the Dossier Submitter (i.e. RO2 except for "PFAS manufacturing", where RO3b is proposed) the emissions have been estimated at about 800 000 tonnes (effectiveness 76%). Thus, additional emissions due to the proposed derogations compared to a full ban are approximately 700 000 tonnes. Out of this, approx. 590 000 tonnes come from various derogations for uses of fluorinated gases in sectors "Transport" and "Applications of fluorinated gases". Other proposed derogations with relatively high additional emissions are e.g. those for batteries, lubricants or immersion cooling.

Effectiveness of the restriction and emissions from the proposed derogations for the sectors added after the Annex XV report consultation have not been assessed by RAC. According to the Dossier Submitter’s assessment, the baseline emissions for the newly assessed sectors are approx. 250 000 tonnes over the assessment period and the proposed derogations result in approx. 50 000 tonnes of additional emissions compared to full ban.

In several sectors (“PFAS manufacturing”, “Transport”, “Electronics and semiconductors”, “Energy”, “Sealing applications”, “Machinery applications”, “Technical textiles”) the Dossier Submitter additionally assessed RO3, a derogation with specified additional conditions. For assessment of RO3 in sectors assessed by RAC please refer to the sector-specific opinions.

As an overarching principle, RAC generally considers a full ban (RO1) to be more effective than a ban with derogations (RO2 and RO3) in reducing PFAS emission and related uncontrolled risks. An exception is a targeted derogation for certain types of PPE proposed by SEAC to avoid risks to workers.

RAC acknowledges that, decision maker may decide to implement sector-/use specific derogations as proposed by the Dossier Submitter. In case the decision maker decides to implement these derogations, RAC proposes additional RMMs to ensure associated emissions are minimised (see additional conditions considered by RAC below).

Table 8: Effectiveness in emission reduction compared to baseline emissions (2025 to 2055)

Manufacturing and use sectors	Effectiveness					
	Baseline emissions [t/y] (2025 - 2055)		Emission reduction - full ban [t/y]		Emission reduction-restriction as proposed by the Dossier Submitter [t/y]	
	Total PFAS emissions as presented by the Dossier Submitter	Total PFAS emissions as calculated by RAC	Total PFAS emission reduction as presented by the Dossier Submitter	Total PFAS emission reduction as calculated by RAC**	Total PFAS emission reduction as presented by the Dossier Submitter	Total PFAS emission reduction as calculated by RAC***
PFAS manufacturing	50 532	51 736	48 795	49 961 (97%)	45 324	44 950 (87%)
Sectors of use						
Textiles, upholstery, leather, apparel and carpet	664 871	387 185	634 277	369 369 (95%)	627 490	363 040 (94%)
Food contact materials and packaging	50 224	42 061	48 497	40 615 (97%)	48 117	40 480 (96%)
Metal plating and manufacture of metal products	1 013	1 161	948	1 087 (94%)	899	1036 (89%)
Consumer mixtures and miscellaneous consumer articles	912	642	853	600 (94%)	853	600 (94%)
Cosmetics	1 165	1 326	1 092	1 244 (94%)	1 092	1 244 (94%)

Manufacturing and use sectors	**Effectiveness**					
	Baseline emissions [t/y] (2025 - 2055)		**Emission reduction - full ban [t/y]**		**Emission reduction-restriction as proposed by the Dossier Submitter [t/y]**	
	Total PFAS emissions as presented by the Dossier Submitter	**Total PFAS emissions as calculated by RAC**	**Total PFAS emission reduction as presented by the Dossier Submitter**	**Total PFAS emission reduction as calculated by RAC**[**]	**Total PFAS emission reduction as presented by the Dossier Submitter**	**Total PFAS emission reduction as calculated by RAC**[***]
Ski wax	14	15	13	13 (88%)	13	13 (88%)
Applications of fluorinated gases	1 804 914	1 804 914	1 718 883	1 718 883 (95%)	1 498 108	1 494 396 (83%)
Medical devices	387 686	11 507	376 454	11 174 (97%)	375 657	10 971 (95%)
Transport	738 478	725 524	697 397	685 165 (94%)	446 904	316 857 (44%)
Electronics and semiconductors	94 277	64 517	92 231	63 116 (98%)	74 890	52 187 (81%)
Energy	470 241	254 581****	467 843	253 282**** (99%)	426 972	218 849**** (86%)
Construction products	241 400	26 125	231 094	25 010 (96%)	230 314	24 554 (94%)
Lubricants	100 108	49 932	95 834	47 801 (96%)	62 102	30 975 (62%)
Petroleum and mining	59	59	56	56 (94%)	56	56 (94%)
Total emissions	***4 605 895***	***3 421 286***	***4 414 267***	***3 267 375 (96%)***	***3 838 791***	***2 600 208 (76%)***

Manufacturing and use sectors	**Effectiveness**					
	Baseline emissions [t/y] (2025 - 2055)		**Emission reduction - full ban [t/y]**		**Emission reduction-restriction as proposed by the Dossier Submitter [t/y]**	
	Total PFAS emissions as presented by the Dossier Submitter	**Total PFAS emissions as calculated by RAC**	**Total PFAS emission reduction as presented by the Dossier Submitter**	**Total PFAS emission reduction as calculated by RAC[**]**	**Total PFAS emission reduction as presented by the Dossier Submitter**	**Total PFAS emission reduction as calculated by RAC[***]**
(14 sectors + PFAS manufacturing)						
Printing applications[*]	722	Not evaluated in detail	696	Not evaluated in detail	580	Not evaluated in detail
Sealing applications[*]	29 086	Not evaluated in detail	27 905	Not evaluated in detail	19 147	Not evaluated in detail
Machinery applications[*]	1 265	Not evaluated in detail	1 214	Not evaluated in detail	833	Not evaluated in detail
Other medical applications[*]	76 626	Not evaluated in detail	70 036	Not evaluated in detail	56 256	Not evaluated in detail
Military applications[*]	69 099	Not evaluated in detail	67 232	Not evaluated in detail	49 860	Not evaluated in detail
Explosives[*]	1 664	Not evaluated in detail	1 604	Not evaluated in detail	1 581	Not evaluated in detail
Technical Textiles[*]	62 464	Not evaluated in detail	60 755	Not evaluated in detail	52 518	Not evaluated in detail

Manufacturing and use sectors	**Effectiveness**					
	Baseline emissions [t/y] (2025 - 2055)		**Emission reduction - full ban [t/y]**		**Emission reduction-restriction as proposed by the Dossier Submitter [t/y]**	
	Total PFAS emissions as presented by the Dossier Submitter	**Total PFAS emissions as calculated by RAC**	**Total PFAS emission reduction as presented by the Dossier Submitter**	**Total PFAS emission reduction as calculated by RAC******	**Total PFAS emission reduction as presented by the Dossier Submitter**	**Total PFAS emission reduction as calculated by RAC*******
Broader industrial uses*	9 618	Not evaluated in detail	9 228	Not evaluated in detail	6 556	Not evaluated in detail
Total emissions (8 additional sectors)	*250 544*	*Not evaluated in detail*	*238 670*	*Not evaluated in detail*	*187 331*	*Not evaluated in detail*
Total emissions	**4 856 439**	**3 421 286**	**4 652 937**	**3 267 375 (96%)** (excluding additional sectors)	**4 024 164**	**2 600 208 (76%)** (excluding additional sectors)

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

** Full ban corresponds to RO1. The effectiveness is lower than 100% due to the general 18-month transition period. Emission values recalculated by RAC, polymeric particles not quantified

*** Proposed restriction by the Dossier Submitter corresponds to RO2, except for PFAS manufacturing, for which RO3b is proposed. Emission values recalculated by RAC, polymeric particles not quantified

**** It is noted that RAC has evaluated two additional scenarios for this sector (see sector specific evaluation for the Energy sector, section R-1.3): (i) RAC calculated values assuming the lower point emission estimate for batteries use, (ii) RAC calculated values assuming the lower point emission estimate for batteries use and 90% adequate collection and management of batteries.

3.4.2.1.2. Site-specific management plans and labelling requirements

To minimise emissions from the continued use of PFAS in derogated uses, the Dossier Submitter has proposed that 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 PFAS management plan which shall include:

i. information on the identity of the substances and the products they are used in

ii. a justification for the use;

iii. details on the conditions of use and safe disposal.

This management plan shall be reviewed annually and kept available for inspection by enforcement authorities upon request.

According to the Dossier Submitter's proposal, the site-specific management plan covers all life cycle stages of fluoropolymers and PFPEs: manufacturing, use and disposal. It should be noted that PFAS manufacturing is covered separately by the Dossier Submitter elsewhere, including a separate set of proposed emission reduction measures (see derogation 4.m of the draft entry text and RAC opinion on PFAS manufacturing).

There are several main groups of PFAS, and their potential for use stage and waste stage emissions generally increases in the following order: fluoropolymers < PFPEs < PFAAs and PFAA precursors < fluorinated gases. The Dossier Submitter has not explained the reasons to propose limiting the applicability of management plans to groups with relatively low emissions (fluoropolymers and PFPEs), and to exclude groups with relatively high emissions.

RAC understands that by "justification for the use" the Dossier Submitter meant an analysis of alternatives to PFAS. Despite the fact that the use will be derogated for a certain period of time, the Dossier Submitter expects that an annual analysis of alternatives will motivate users to substitute the industrial use already before the end of the derogation period. However, RAC is unsure whether such a measure in itself will bring the desired effect of earlier substitution.

The Dossier Submitter refers to several examples of established management plans. First, the recent amendment of the Industrial Emissions Directive (IED), Art. 14a(2)(d), sets an obligation for certain operators (specified in Annex I to IED) to prepare an inventory of the hazardous substances present in or emitted from the installation with special regard given to the substances meeting SVHC criteria and substances restricted under REACH. For such substances, the operator must prepare a risk assessment and an analysis of the possibilities for substituting them with safer alternatives or reducing their use or emissions. Since PFAS are proposed to be restricted under REACH, some equivalent of PFAS management plan will – according to the Dossier Submitter - be required by the IED at least for some facilities even without a specific requirement for such a plan in the proposed restriction.

The IED (Annex VII) also outlines details of a 'solvent management plan'. RAC considers that at least some elements of the solvent management plan under the IED could in principle be applicable also to fluorinated solvents. However, as mentioned above, fluorinated solvents have not been included in the PFAS management plan by the Dossier Submitter, despite their particularly high potential for emissions.

Another relevant example of existing obligation to produce a management plan is the "PFAS-containing firefighting foams management plan" in the recently adopted restriction on PFAS in firefighting foams (Commission Reg. (EU) 2025/1988 of 2 October 2025).

RAC notes that the type of PFAS concerned in this case is PFAAs and PFAA precursors (i.e. not fluoropolymers or PFPEs), and the potential for emissions and exposure in the use stage (i.e. during firefighting) is very high (this may not be the case for fluoropolymers). The Dossier Submitter also referred to existing PFAS management plans reported by industry. Comment #7993 from an industry association mentions (1) recycling, recovery destruction of certain fluorinated gases; (2) incineration or recycling of lubricants and greases; (3) incineration, recycling or landfilling of solid PFAS.

Most importantly, RAC notes that the management plan proposed by the Dossier Submitter does not explicitly require minimisation of emissions. In addition, the management plan would not be reported/collected and assessed by authorities but should only be available for inspection by enforcement authorities upon request; therefore, according to RAC the effectiveness of this approach in achieving PFAS substitution and emission reduction is questionable and overall weak.

Considering all these aspects, RAC concludes that the site-specific PFAS management plan (as proposed by the Dossier Submitter) is not sufficient to achieve a significant risk reduction. Therefore, RAC has outlined below its own proposal to improve the site-specific PFAS management plan, which is considered more effective in minimising the emissions and subsequent risk.

Furthermore, the Dossier Submitter's proposal does not include any requirements for supply-chain communication on e.g. information on PFAS content, safe waste disposal practices etc.

As an exception, RAC notes the requirement proposed under paragraph 4 of the restriction entry for suppliers of plastic articles or complex objects falling under the scope of the Waste from Electrical and Electronic Equipment (WEEE) Directive (Directive 2012/19/EU)) or End-of-life Vehicle Directive (ELV) (Directive (2000/53/EC)[18] or for suppliers of PVC articles listed in paragraph 18 of Regulation (EU) 2023/923 on lead and its compounds in PVC containing intentionally added PFAS. In this case, before placing in the market these articles shall be marked with a statement "Contains intentionally added PFAS". The main aim of this requirement is to facilitate the removal of PFAS-containing products from plastics recycling feedstocks once the products reach the end of their service lives. RAC considers this measure as effective and finds it important to clearly inform downstream users on the use of PFAS in these products. However, RAC considers that this requirement on the use of PFAS should be extended also to other articles/products, which may contain intentionally added PFAS due to the multiple use-specific derogations proposed by the Dossier Submitter.

3.4.2.1.3. RAC view on the additional risk management measures in case of derogations

RAC takes note that the Dossier Submitter proposed several derogations for uses of PFAS; most of them will result in significant additional emissions, overall reducing the effectiveness of the restriction. In case some of these derogations would be considered appropriate by the decision maker, RAC recommends adopting additional risk management measures (RMMs) to minimise emissions from the derogated uses.

For most of the derogations the Dossier Submitter did not propose specific emission abatement and monitoring measures besides reporting requirements and site-specific

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[18] RAC notes there is a proposal for an updated and more comprehensive legislation for ELV (proposal for a Regulation 2023/0284)

management plans. They explained (in a written response to a RAC request for clarification) that additional conditions would require companies to invest in emission reduction measures for a relatively short period of time (as most of the derogations are time-limited), whilst also investing in development and implementation of alternatives. Thus, the Dossier Submitter expects that lack of additional conditions would allow for an earlier substitution.

However, RAC considers the requirement for additional RMMs justified, particularly for 12-year and time-unlimited derogations (following the 18-month general transition period), given that for many of the derogated uses no suitable alternatives may currently be available. It is not clear whether alternatives will become available within the derogation period and the decision-maker could grant an even longer time for derogations. Thus, the emissions may continue longer than anticipated by the Dossier Submitter.

Some specific additional RMMs applicable in individual sectors have been mentioned in the RAC sector-specific evaluations, under restriction option RO3. However, RAC has not been able to evaluate these specific RMMs in detail enough to conclude on whether they would be effective and implementable. RAC proposes instead to apply more generic RMMs for all uses of PFAS that are allowed to be continued after a transition period of 18 months after the restriction enters into force. These generic RMM would apply to all time-limited or unlimited continued uses and for all sectors of use, including those sectors not specifically evaluated by RAC The potential for emissions depends on the type of PFAS. As mentioned above in section 3.4.2.1.2 on site-specific management plans, the highest emission potential is expected for fluorinated gases and for PFAAs and PFAA precursors due to their volatility or mobility, whereas in the case of fluoropolymers the potential for significant non-polymeric emissions is generally limited to processing (if there is no capture and destruction of volatile emissions) and incineration (under suboptimal conditions). In addition, RAC notes that applicability of the site-management plans for activities other than industrial uses is very limited and therefore considers those should be limited to industrial sites where manufacturing and industrial downstream uses of PFAS and PFAS-containing mixtures (including formulation and uses of mixtures and production of articles) take place. Industrial uses of PFAS-containing articles are expected to lead to lower level of emissions and therefore the potential effectiveness of PFAS management plans for these activities is considered low. The type and efficiency of any additional RMMs will also depend on the type of user (industrial, professional and/or consumer).

3.4.2.1.3.1.Additional RMMs for industrial uses

RAC takes note that for fluorinated gases, a range of RMMs is already prescribed by the F-gas Regulation (Regulation (EU) 2024/573), such as containment, leak checks and end-of-life recovery. Additional measures (e.g. setting maximum leak rates) have been proposed in the Annex XV report consultation (comment #8285). Management of fluorinated solvents can be modelled according to the ‘solvent management plan’ outlined in Annex VII of the Industrial Emissions Directive. However, in certain cases, such as propellants, it might be difficult to propose effective RMMs.

Uses of PFAAs and PFAA precursors (including side-chain fluorinated polymers) are very diverse, and this applies also to the proposed derogations. Attention should generally be paid to minimisation of emissions in all life cycle stages. Prevention of emissions to water is critical because most wastewater treatment plants (including industrial ones) are not able to efficiently remove PFAS (see also section 3.1.2.6).

For fluoropolymers, the most important RMMs are (1) capture and destruction of volatile emissions during hot processing, and (2) appropriate disposal. Since fluoropolymers are chemically stable and immobile, non-polymeric emissions from their landfilling are assumed to be very low. The mineralisation efficiency of incineration depends on the conditions; for further details see section above.

Therefore, RAC considers it important that as a condition of use of PFAS for industrial uses including PFAS manufacturing and downstream uses of PFAS and PFAS-containing mixtures (i.e. activities with the highest potential for emissions) that are derogated by the decision-maker, a site- specific PFAS management plan for the industrial site where the use takes place must be implemented and made available to competent authorities on demand. According to RAC this condition would also apply to PFAS uses covered by a time-unlimited derogation, such as in Plant Protection Products (PPP), Biocidal Products (BP), and in human and veterinary Medicinal Products (MP).

3.4.2.1.3.1.1. Content of PFAS Management Plan for all derogated industrial uses

In the site-specific management plans, special attention should be given to the above-mentioned life-cycle stages mostly contributing to the PFAS emissions. RAC considers that minimisation of emissions should be the main aim, and PFAS management plans should clearly define measures taken and planned to minimise the emissions to the environment.

This should cover the emissions arising during the process, measures taken to prevent accidental emissions, and measures taken to ensure environmentally sound and safe disposal of the waste produced during the process. Monitoring arrangements and results need to be described. Considering the high number and variety of derogated uses, RAC could identify the following RMMs to be included in a site-specific ‘PFAS management plan’:

- a justification for the use of PFAS when greater than the concentration indicated under section 3.4.2.3 (including an assessment of the technical feasibility of alternatives);
- report the conditions of use and disposal of PFAS used on site to minimise emissions to the environment and direct and indirect human exposure (including plans for the treatment and appropriate disposal of PFAS containing wastes arising in production, routine cleaning and maintenance of equipment etc.);
- report 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);
- regularly review the site-specific PFAS management plan (at least annually) and keep it available for inspection by enforcement authorities on request.

The results of the monitoring activities on PFAS should be reported to the Agency (see section 3.4.2.1.4 on reporting requirements).

3.4.2.1.3.1.2. Supply chain communication requirement

In addition, RAC considers supply-chain communication essential to ensure minimisation of emissions in all relevant stages of life cycle. Therefore, conditions for manufacturers and importers of PFAS-containing materials/products for derogated uses need to include also requirements ensuring effective supply-chain communication. This may occur via safety datasheets/technical datasheets, labels or product passports. RAC notes that Dossier Submitter proposes under paragraph 4 of the restriction a labelling requirement for suppliers of plastic articles or complex objects falling under the scope of the WEEE Directive (Directive

2012/19/EU) or ELV Directive (2000/53/EC) or for suppliers of PVC articles listed in paragraph 18 of Regulation (EU) 2023/923 on lead and its compounds in PVC containing intentionally added PFAS. According to this requirement these articles shall be marked with a statement "Contains intentionally added PFAS". In addition, in some sectors where RO3s have been developed by the Dossier Submitter, mention of communication requirements is given. For example, in the Energy sector, the Dossier Submitter puts forward that:

- A product passport or technical datasheet shall be available, which includes information on the quantities of PFAS, their generic identity and location in the battery/fuel cells/electrolysers
- A packaging/technical datasheet shall include the following statement: "This product contains PFAS" or "This product contains PFAS; ensure appropriate handling, storage and disposal" and provide instructions for the safe use and disposal.

RAC considers that a requirement to ensure effective supply-chain communication should be introduced for manufacturers and importers of PFAS and PFAS-containing mixtures and articles for all derogated industrial uses, with an exception of materials/articles produced from recycled/recovered plastics, textiles or paper and board or articles which were already in end-use in the Union (reuse of articles). Depending on the type of material/product, it could include a labelling of products with the statement "Contains PFAS; ensure appropriate handling, storage and disposal" or indicating this in the packaging or technical datasheet, material data sheet or product passport. RAC considers also important that this labelling is accompanied with specific information on the safe use and waste disposal.

Overall, when compared to the Dossier Submitter proposal on site-specific PFAS management plans, which aims primarily to motivate the industry for substitution already before the end of the derogation period rather than to effective control of emissions, RAC emphasises the need for minimisation of emissions and effective communication along the supply chain.

3.4.2.1.3.2. Additional RMMs for professional and consumer uses

RAC does not consider site-specific PFAS management plans nor supply-chain communication as discussed above to be effective in reducing associated emissions for professional and consumer uses. Instead, RAC notes the requirements in the restriction of synthetic polymer microparticles [microplastics] (Entry 78 of Annex XVII). In the case of the microplastics restriction, products need to be labelled with a statement: "This product contains microplastics." and the following information – and more - needs to be provided:

- instructions for use and disposal explaining to downstream users how to prevent releases and ensure appropriate disposal;
- the statement: "The synthetic polymer microparticles supplied is subject to conditions laid down by entry 78 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council";

RAC considers that for articles and mixtures subject to derogated professional and consumer uses and containing PFAS above the concentration limits defined in the restriction clear labelling as well as clear and easy-to-follow guidance for safe use and disposal can be critical to minimise emissions during such uses.

3.4.2.1.4. Reporting requirement for derogated uses

In paragraph 7 of the restriction proposal, the Dossier Submitter proposes that manufacturers, importers of PFAS or PFAS-containing articles as well as downstream users formulating PFAS-containing mixtures making use of derogations for 13.5 years or longer and for derogations relating to applications of fluorinated gases, report to ECHA on the derogation that the intended use belongs to and on the identity and quantity of the substances placed on the market in the previous year.

RAC understands that the main aim of this requirement is to collect information at EU level, and it that sense it would be useful. RAC also recommends that reporting should apply to importers of PFAS-containing mixtures. RAC notes that this reporting requirement could be extended to cover also reporting of the monitoring data on emissions, which has been proposed to be collected by industrial users as part of the PFAS management plan. RAC also notes that information on the products containing PFAS, and on the exact identity of PFAS they contain, may facilitate the implementation of PFAS monitoring requirements in updated Urban Wastewater Treatment Directive (Directive (EU) 2024/3019) and the development of analytics for PFAS in wastewater. Practicality-aspects of this requirement are discussed under section 3.4.3.2 Practicality, including enforceability.

3.4.2.1.5. Proposed derogations for active substances

The Dossier Submitter has proposed time-unlimited derogations for PFAS used as active substances in Plant Protection Products (PPP), Biocidal Products (BP), and in human and veterinary Medicinal Products (MP). No estimates on the emissions for the derogation on manufacturing and using these active substances have been provided by the Dossier Submitter. According to the Dossier Submitter annual use tonnages for PPPs and for human MPs are 5 479 and >500 t/y, respectively. No estimates are available on BPs or veterinary MPs. In addition, it is unclear how large a proportion of these are manufactured in the EU versus imported. RAC notes that considering, for example, the use of PPPs with intentional environmental release, emissions are significant and are likely to correspond to use volumes. The significant emissions from PPP use are supported by e.g. Joerss et al., 2024, which demonstrates that several widely used pesticides may form relevant amounts of TFA and agricultural uses of PPPs may be a dominant source of TFA in groundwater in many agricultural areas in Europe. Similarly, the use of inhalation anaesthetics may result in significant environmental emissions since the majority of e.g. sevoflurane used in anaesthesia either escapes into the operating room, is exhaled by the patient, or is collected by a Waste Anaesthesia Gas Scavenging System before being vented into the atmosphere (Kalmar et al., 2024). In addition, it is released to wastewater after excretion either as a parent compound or as metabolite HFIP (which is a PFAS as well). RAC however recognises the current trend of moving towards the use of intra-venous (non-PFAS-based) anaesthetics instead of PFAS-based inhalation anaesthetics. Overall, RAC notes that exclusion of active substances may result in significant continued emissions of PFAS into the environment, which need to be addressed. Therefore, the Dossier Submitter recommends that measures to minimise emissions from the use of PFAS as active substances in PPP, BP and MP are addressed in the context of the respective sector-specific regulations. The Dossier Submitter has however not specified the risk management measures recommended to minimise emissions from these uses.

RAC acknowledges that the concerns related to these active substances should be primarily addressed under their own sector-specific legislation. RAC is however concerned whether these legislations are sufficient to fully address the concerns related to the persistence of PFAS. RAC considers that there is a need to strengthen these legislations: the emissions of PFAS and formation of persistent arrowhead PFAS (like TFA) should be better considered and used in decision-making concerning PPPs, BPs and MPs. In addition, in case of continued use under the sector-specific legislations, RAC recommends that conditions related to the minimization of emissions in the manufacturing of these active substances (site-specific management plans, see above) and conditions on the informing users on the minimisation of emissions during the use (e.g. anaesthetics) and on the safe disposal are considered under these sector-specific legislations.

In addition, RAC would like to highlight specific concern related to the release of PFAS-based pharmaceuticals to wastewater. Medicinal products are an important chemical pollutants observed in municipal wastewaters and PFAS-based pharmaceuticals or their PFAS-metabolites are likely to enter to sewage treatment plants e.g. via the human excreta. Although the updated Urban Wastewater Treatment Directive (Directive (EU) 2024/3019) introduces a requirement for quaternary treatment to reduce the concentrations of micropollutants (like pharmaceuticals) in wastewater, RAC notes that there are no specific limits for PFAS, and as discussed under chapter 3.1.2.7 on Wastewater, the current wastewater treatment techniques are likely not efficient in removing short-chain PFAS (like fluranes and their metabolites).

Overall, RAC considers that in case of the derogation for active substances in Plant Protection Products (PPP), Biocidal Products (BP), and in human and veterinary Medicinal Products (MP), there is a need to strengthen their sector-specific legislations to better address the concerns related to the persistence of PFAS. The Dossier Submitter has also proposed specific reporting obligations for the manufacturers and users of these active substances who need to report to ECHA on the derogation that the intended use belongs to and on the identity and quantity of the substances placed on the market in the previous year. As discussed above, the main aim of such a requirement is to collect information at the EU level. Although this may not directly affect the emissions, this information may facilitate the implementation of monitoring requirement in updated Urban Wastewater Treatment Directive and the development of PFAS analytics in wastewater.

3.4.2.1.6. Impact of derogations for spare parts, reuse, secondary use and recycling

The Dossier Submitter proposes a derogation for spare parts

1) 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 (paragraph 4.e of the proposed entry text);

and

2) for spare parts used in articles or complex objects for which legal obligations related to the use of specific spare parts exist until the end of service life for the specific object (paragraph 4.f of the proposed entry text).

The suggested maximum timeline of 20 years is based on the durations given for the restrictions for decaBDE and Dechlorane plus under the EU POPs Regulation, and on the input from Annex XV consultation, which suggests service life of complex objects from 10 years to above 50 years. As described in 3.1.2 Emissions and exposure, it is not possible to estimate additional emissions caused by the proposed derogation for spare parts. Since most of the PFAS required in these spare parts are likely to be fluoropolymers, the main emissions likely occur in the manufacturing stage and at end-of-life, if not disposed appropriately. In addition, the need for spare parts and related emissions are expected to decrease gradually over time after the restriction enters in force. RAC recognises the importance of spare parts in extending the service life of articles. Availability of spare parts would be in accordance with for example EU Ecodesign for Sustainable Products Regulation (Regulation (EU) 2024/1781) and Right to Repair Directive (Directive (EU) 2024/1799). Therefore, RAC can support the derogation for spare parts. RAC, however, emphasizes the need for careful control of emissions especially related to the manufacturing of spare parts, and the importance of the safe disposal of the spare parts in the end-of-life. RAC considers that a requirement on the site-specific management plan should apply also to the manufacturers of the spare parts making use of this derogation. About the site-specific management plan, see above. RAC also considers that companies making use of this derogation should inform the downstream users on the PFAS content and safe disposal of the products. In line with recycled products, a requirement to provide a certificate showing that the products are intended for spare parts to replace PFAS-containing articles in articles or complex objects would also be justified.

In addition, the Dossier Submitter proposes a time-unlimited derogation without any additional measures for the placing on the market of articles which were already in end-use in the Union (paragraph 4.d of the proposed entry text). RAC recognises the importance of reuse and recycling in the minimising of waste and the use of new resources and considers it important to increase the reuse and recycling of materials according to EU Clean Industrial Deal and Circular Economy Action plan. Therefore, RAC supports derogation for articles which were already in end-use in the Union. In addition, RAC considers that additional emissions caused by the prolonged service life of these articles are generally limited (see 3.1.2 Emissions and exposure).

Regarding recycling, the Dossier Submitter proposes a time-limited derogation for **plastic articles** containing recovered material, with the exception of food-contact material and food-contact packaging and toys, until 23.5 years after EiF (paragraph 4.i of the proposed entry text). This is based on the challenges in demonstrating compliance with the proposed concentration limits in plastic recyclates. In addition, the Dossier Submitter proposes to implement a labelling requirement for articles or complex objects falling under the scope of the WEEE Directive (Directive 2012/19/EU) and ELV Directive (Directive 2000/53/EC), as well as to the PVC articles listed in paragraph 18 (a to f) of Regulation (EU) 2023/923 on lead and its compounds in PVC. Furthermore, in analogy to Regulation (EU) 2023/923 on lead and its compounds in PVC, suppliers of plastic recyclate or articles produced using plastic recyclate benefitting from the derogation are required to be able to prove the origin of the recovered material by presenting documentary evidence. This is to facilitate the removal of PFAS-containing products from plastics recycling feedstocks. As discussed under 3.1.2 Emissions and exposure, levels of PFAS in plastic recyclate (consisting of e.g. PP, PE, LDPE, HDPE, PS, PUR, PET and PVC, in which PFAS may exist as impurities) vary depending on the source of the recyclate and may, in some instances, exceed the proposed concentration limits. RAC, however, estimates that the impact of these trace levels of PFAS in plastic recyclate in overall PFAA/PFAA precursor emissions is minimal and decreasing progressively as a result of the phase-out of PFAS in plastic products. RAC notes that 23.5 y after EiF (10 years after the expiration of the longest relevant time-limited use-specific derogation) is set to ensure a sufficient duration for most recycled plastic materials to achieve the proposed concentration limits before it expires. RAC also notes that some types of plastics (used e.g. in vehicles or construction) have rather long life-span, which could further support a need for a longer derogation. On the other hand, already now, many measurement results in various plastic recyclates showed compliance with the limits given in the restriction. Considering the importance of plastic recycling in minimising the build-up of plastic waste in the environment and in minimising the use of new resources RAC can support DS proposal on time-limited derogation for plastic recyclate combined with a labelling obligation. RAC cannot confirm whether labelling requirements for objects under the scope of WEEE or ELV Directives or for PVC articles listed in paragraph 18 (a to f) of Regulation (EU) 2023/923 will result in reduction of emissions related to the recycling since there is no legal obligation to lower concentrations in recycled plastics (or remove PFAS-containing articles from plastic recyclate) during the derogation period; nevertheless it may still facilitate the understanding whether PFAS in articles and recyclate is the result of intentional use or contamination This may also highlight the need for caution in case of handling objects with intentionally added PFAS. RAC can support this requirement.

The Dossier Submitter proposes a time-unlimited derogation for **paper and board articles** containing recovered material, with the exception of food-contact material and packaging. No labelling requirements are proposed. However, suppliers of paper and board articles benefitting from the derogation are required to prove the origin of the recovered material by presenting documentary evidence.

As discussed under 3.1.2 Emissions and exposure, paper and bulk recyclate may contain PFAS levels exceeding the limit values proposed in the restriction, which may result in additional emissions in case of a derogation for paper and bulk recycling. RAC estimate on emissions using default emission factors for paper recycling is in the order of magnitude of 1 t/y but includes uncertainties. RAC notes that the service life of paper and board is generally short and recycled material is typically mixed with 10%-30% of virgin material resulting in gradual reduction in additional emissions caused by the proposed derogation for paper and board recycling. RAC notes the Dossier Submitter’s justification for a time-unlimited derogation is based on the 12-year derogations (following the 18-month general transition period) for inks and toners emphasising the challenges related to implementing testing strategies after the derogation has expired to ensure that the general concentration limits are met. In addition, the Dossier Submitter proposes time-unlimited derogations for the placing on the market and use of toners and latex printing inks in equipment placed on the market before the end of the 12-year derogation period (following the 18-month general transition period).

RAC notes that in the Annex XV report consultation 6.5 years (5 years after the 18-month transitional period) were proposed by some industry stakeholders (comment #9523) but this was before the derogation for inks and toners were introduced. Although it is not possible to make an estimate of how long it might take to achieve PFAS levels consistently below the proposed concentration limits, RAC considers a time-limited derogation more appropriate and better in line with the time-limited derogations given for plastics and textiles recycling. In addition, food packaging, in which PFAS are intentionally used, are generally not recycled because of the food contamination limiting the amount of intentionally added PFAS entering the paper and bulk recyclate. RAC agrees with the Dossier Submitter that labelling requirements for paper and bulk products with intentionally added PFAS are not likely to result in any significant reduction in additional emissions due to the fact that those used for food packaging are not generally recycled. Unlike in the case of specific plastic products for which labelling requirements are proposed, RAC agrees that in the case of paper and bulk products, similar labelling requirements for intentionally added PFAS are more difficult to apply.

The Dossier Submitter proposes a derogation for **textile articles** containing recovered material, with the exception of toys as defined in Directive 2009/48/EC[19], until 13.5 years after EiF. No labelling requirements are proposed. However, suppliers of textile articles benefitting from the derogation are required to prove the origin of the recovered material by

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

presenting documentary evidence. As discussed under 3.1.2 Emissions and exposure, recycled textile fibres may contain PFAS levels exceeding the limit values proposed in the restriction, and the recycling process may involve direct emissions of PFAS (depending on the type of process). This may result in some additional emissions in case of a derogation for recycled textiles. It is, however, not possible to make any quantitative estimate on the additional emissions. RAC notes that the service life of consumer textiles is on average only four years and recycled material is typically mixed with virgin fibres. This is likely to result in progressive decline in the levels of PFAS in fibres and textiles produced from the recycled textiles after the restriction on the use of PFAS in textiles enters in force. RAC notes that the Dossier Submitter considered also an option for 6.5 years derogation, although their final proposal is 13.5 years. It cannot be concluded for sure whether a 6.5-year derogation would have sufficed, although RAC notes that already now PFAS have been substituted in many newly produced consumer textiles. Overall, considering the importance of recycling in minimising the waste and the use of new resources, RAC can support a time-limited derogation for textile waste.

RAC agrees with the Dossier Submitter that labelling requirements for textiles with intentionally added PFAS is not likely to result in any significant reduction in additional emissions since, after the restriction enters in force, new textiles will be PFAS-free (unless containing prints) due to the absence of use-specific derogations for these types of products.

The Dossier Submitter does not propose any derogation for recycled metals, since it considers that there is sufficiently strong evidence that recycled metals will meet the proposed concentration limits for PFAS. RAC agrees with this. However, RAC wants to point out that, if lower temperature metal recycling techniques are used, there is a potential for emissions of PFAS during the recycling process into the environment as well as potential for direct exposure of workers to PFAS, which needs to be recognized and managed by applying appropriate risk management methods. No quantitative estimate on emissions is made due to the limited data. Pyrometallurgical recycling techniques are considered effective in mineralising PFAS resulting in no additional emissions compared to disposal of the materials via incineration.

Overall, since some waste streams may contain relevant levels of PFAS, which may become emitted during the recycling process, RAC emphasises the need for monitoring and control of potential exposure and emissions during the recycling processes.

3.4.2.1.7. SR&D and PPORD

According to REACH Article 67, restrictions do not apply to manufacture, placing on the market or use of a substance in **scientific research and development (SR&D)**. The Dossier Submitter has interpreted this exemption to include also in vitro diagnostic devices and PFAS (e.g. fluoropolymers) used in equipment and instruments in research-related activities. The Dossier Submitter has not made any estimate on the potential volumes and emissions related to this exemption. In addition, according to RAC understanding all medical in vitro diagnostic devices do not fall under this general SR&D exemption. According to the REACH definition, SR&D refers to "scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year" (REACH Article 3 (23)). REACH guidance on SR&D and PPORD[20] states that examples of SR&D may include any experimental research or analytical activities at a laboratory scale such as synthesis and testing of

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[20] Guidance on Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD) Version 2.1 October 2017

applications of chemicals, release tests, etc. as well as the use of the substance in monitoring and routine quality control or in vitro diagnostics at a laboratory scale under controlled conditions. RAC points out that IVDs include (according to EU In Vitro Diagnostic Regulation (IVDR) Regulation (EU) 2017/746) also for example various home tests (glucose meters, pregnancy/fertility tests etc), for which the use is not occurring at a laboratory scale under controlled conditions. Therefore, RAC considers that these are not covered by the proposed derogation. Similarly, RAC considers it unclear whether PFAS-based sealings, hoses, lubricants etc. used in the manufacturing of complex laboratory devices are included in the REACH Article 67 SR&D exemption. RAC also notes that sometimes it might be difficult to differentiate whether these instruments are to be used in research or for example in the medical sector. On the other hand, RAC agrees with the Dossier Submitter that the use of PFAS for the calibration of measurement instruments and as analytical reference materials occurring in controlled conditions in laboratories can be considered to fall under this exemption.

The Dossier Submitter proposes a time-unlimited derogation for **product and process orientated research and development (PPORD**; Article 67(1) of REACH; see paragraph 4.i of the proposed entry text). PPORD is defined as "any scientific development related to product development or the further development of a substance, on its own, in mixtures or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance" (REACH Article 3 (22)). RAC notes the comments in the Annex XV report consultation from the pharmaceuticals industry (e.g., #4438, #4455, #5390, #6436, #7756, #7875, #8314, #8540, #8623, #9063) emphasising the need for this derogation in the development of active ingredients that are derogated from this restriction (see also above). Some consultation comments were also given concerning energy and electronics applications (e.g., #3991, #5969, #6708, #7142, #8363, #9453) to avoid unwanted consequences for the possibility to develop products for derogated uses.

RAC notes that the PPORD derogation proposed by the Dossier Submitter does not specify sectors or uses but applies to all PPORD activities. RAC also considers it unclear why a derogation for PPORD is needed for uses with time-limited (5 or 12 years) derogations (following the 18-month general transition period). According to the Dossier Submitter, this time-unlimited derogation for PPORD for derogated uses will cease once the derogation period for a specific use ends. This is however not specified in paragraph 4.i of the proposed entry text. In addition, Dossier Submitter is not proposing an upper limit for the quantities as required by Art 67(1). In RAC opinion, this should be reflected in paragraph 4.i., as well. Overall, according to RAC, the derogation should be more well defined and justified.

The Dossier Submitter refers to REACH Article 9(4), according to which conditions can be imposed by ECHA on the safe use and disposal on the level of an individual PPORD. RAC emphasises that if this derogation is accepted, these conditions need to include a site-specific management plan (as proposed by RAC under paragraph "RAC view on the additional RMMs in case of derogations") to minimise emissions during the derogated research and development project, and safe disposal of any PFAS waste in line with what has been described above under paragraph "RAC view on the additional RMMs in case of derogations".

It is not possible to estimate the impact of this PPORD derogation on the effectiveness of the restriction.

3.4.2.2. Socio-economic analysis

See SEAC Opinion

3.4.2.3. Practicality, including enforceability

Relevant sections of the Background Document:

Practicality, including enforceability is assessed by the Dossier Submitter in section 2.5 of the Background Document.

RAC conclusion(s):

- RAC considers that the concentration limits are generally appropriate, although the 25 ppb limit may not be currently achievable for certain PFAS with the available analytical methods. RAC notes that leaving an option in the restriction entry for the 250 ppb limit ("optionally with prior degradation") may complicate enforcement.
- Enforcement of the concentration limits will face many challenges with respect to sampling, sample pre-treatment and analytical methods. Although RAC considers that the concentration limits are in principle enforceable, there is a strong need for a harmonized enforcement strategy and for standardized analytical methods and methods for sample preparation.
- RAC considers reporting requirements proposed by the Dossier Submitter for derogated uses practical and enforceable.
- The Dossier Submitter has also proposed a labelling requirement for the plastics under WEEE and ELV Directives (Directives 2012/19/EUand 2000/53/EC, respectively) or PVC articles listed in paragraphs 18 (a to f) Regulation (EU) 2023/923. RAC considers that the labelling requirement could be extended to cover all derogated uses of PFAS in various materials or products with the exception of recovered materials and derogated articles containing recovered materials and articles already in end-use in the Union (reuse). RAC generally considers this requirement as practical and enforceable.
- Regarding the certificate required to prove the recovered origin of paper and board, textiles and plastic in articles manufactured from recycled materials, RAC notes that a similar requirement is given under Regulation (EU) 2023/923 on lead and its compounds in PVC. However, RAC also takes note of the potential challenges in enforcement of the proposed requirement 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.
- RAC identifies significant problems regarding practicality and enforceability of the site-specific management plan proposed by the Dossier Submitter, particularly with respect to downstream users. Given the questionable benefit in terms of emission reduction and the issues with practicality and enforceability of the management plan proposed by the Dossier Submitter, RAC proposes to focus instead on RMMs to minimise PFAS emissions at industrial sites where activities with the highest potential for emission takes place (PFAS manufacturing and downstream uses of PFAS and PFAS-containing mixtures) and to supply chain communication about the presence of PFAS and safe disposal practises in the end-of-life stage.
- Reporting requirements given for uses listed by the Dossier Submitter (i.e. uses with 13.5-years or longer derogations and for derogations relating to applications of fluorinated gases are considered practical and enforceable.

Key elements underpinning the RAC conclusion(s):

3.4.2.3.1. Concentration limits, analytical methods and strategy for enforcement of the limits

Given the non-threshold approach for risk characterisation applied in this restriction, there is no basis for setting a risk-based concentration limit. From a risk perspective, the limit should be set as low as possible. Thus, practicality (and sensitivity of the available analytical methods in particular) remains the only criterion in the remit of RAC to assess the appropriateness of the concentration limits proposed by the Dossier Submitter.

As pointed out by SEAC, a comprehensive overview of the current state of analytical methods for PFAS can be found in the Background Document (section 2.5 of the main report; section E.4.1.6 of Annex E; Appendix E.4.1 and E.4.2) and in NCM (2022).

The Dossier Submitter proposed three concentration limits, all of them have to be complied with. They apply as such; no distinction is made between intentionally added PFAS and PFAS unintentionally present e.g. due to contamination or as impurities. The rationale for setting the concentration limits is explained in section 2.5.2 of the Background Document.

The 25 ppb (µg/kg) limit for individual PFAS as measured by targeted analysis (polymeric PFAS excluded) is already set for several PFAAs in existing restrictions (e.g. PFOA restriction, PFHxA restriction). Although RAC can generally support this limit, it is noted that the substance scope of the current restriction proposal is much broader and includes substances for which the LOQ currently appears to be far above 25 ppb (cf. comment #4130). RAC notes that targeted analysis often captures only a fraction of PFAS present in a sample (depending on the sample).

The second limit, 250 ppb (µg/kg), is set for the sum of PFAS measured by targeted analysis, optionally with prior degradation of precursors (degradation products, e.g. from side-chain fluorinated polymers, included in the sum). Similar limits for the sum of PFAS have been set in previous PFAS restrictions. The requirement for degradation (e.g. by hydrolysis or oxidation) increases the proportion of PFAS in a sample that can be detected and is therefore supported by RAC. The fact that degradation is left optional has been recognized as a problem for enforcement by Forum. RAC recommends that degradation is set as a requirement in the restriction text (except cases where it is not feasible). A guidance for enforcement of this restriction should specify which degradation method is to be used for a given type of sample.

The third limit, 50 ppm (mg/kg) is set for total PFAS in a sample (including polymeric PFAS) and is based on the sensitivity of total fluorine methods (e.g. combustion ion chromatography). Although much lower limits can be achieved in certain cases, this restriction proposal encompasses a broad range for matrices, including those where the LOQ is close to 50 ppm. Therefore, the 50 ppm limit for total fluorine is considered appropriate by RAC.

One of the disadvantages of combustion ion chromatography and some other total fluorine methods is that they cannot distinguish between PFAS and non-PFAS fluorine. Therefore, the draft restriction entry stipulates that if total fluorine exceeds 50 mg/kg, the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFAS or non-PFAS. RAC notes that analytical verification may be challenging and this condition will probably often have to rely on supply chain communication.

Another problem of the total fluorine methods is that due to the relatively high LOQ they cannot be used as a screening for compliance with the 25 and 250 ppb limits. This needs to be taken into account in the enforcement strategy.

A general problem concerning all three limits is lack of harmonization and standardization of analytical methods, degradation methods and methods for sample preparation.

Given all the challenges and analytical limitations highlighted in the Forum advice, Annex XV consultation comments, NCM (2024), as well in the SEAC assessment, a practical and harmonized enforcement strategy is a prerequisite for successful enforcement of the proposed restriction. Such a strategy needs to cover not only the analytical measurements, but also the sample preparation step for various matrices including complex articles. The sample preparation step generally has a decisive impact on the final result.

The strategy published by Vestergren et al. (2024) is considered as a potentially feasible way forward by RAC, but it needs to be further developed, particularly with respect to sample preparation and selection of methods for various types of samples, before it can be used by enforcement authorities.

Further, any enforcement strategy needs reliable and harmonized analytical methods. Therefore, RAC highlights the importance of their further standardization.

RAC notes that due to the limitations of analytical methods, the enforcement strategy presented by Vestergren et al. (2024) partly relies on supply chain communication about the presence of PFAS in products. While the Dossier Submitter provided some general examples of measures that can improve supply chain communication (e.g. in Annex E, section 4.1.4), there is no clear proposal nor any assessment of its enforceability in the dossier.

Unfortunately, the current analytical methods will often not be able to determine whether a particular substance, mixture or an article complies with the proposed restriction. Because supply chain communication may not always be reliable, the availability of a harmonized enforcement strategy will also be important for various actors in the supply chain who may want to check for presence of PFAS in their products.

RAC notes that setting limit values for total PFAS under other legislations (e.g. Water Framework Directive, Industrial Emissions Directive) could also potentially facilitate harmonisation and standardisation of the analytical methods.

In conclusion, RAC considers that the proposed restriction is in principle enforceable but fully agrees with the conclusion of the Forum that "for the enforceability of the restriction proposal a general strategy of analysis must be developed and must become available," and that "there is a strong need for developing standardized analytical methods and methods for sample preparation."

3.4.2.3.2. Reporting/labelling requirements and site-specific management plans

The Dossier Submitter proposes reporting requirements concerning all uses with 13.5-years or longer derogations and for derogations relating to applications of fluorinated gases under paragraphs 5 and 6. According to the proposal, manufacturers and importers of PFAS or PFAS-containing articles as well as downstream users formulating PFAS-containing mixtures making use of any of those derogations need to provide by 31 May of each calendar year a report to the Agency containing:

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

In addition, manufacturers and importers of the active substances derogated under points 4

a) – c) of the restriction proposal shall submit to the Agency every two years the information listed above.

RAC considers these reporting requirements practical and enforceable. RAC also recommends that reporting should apply to importers of PFAS-containing mixtures. RAC notes that the reporting obligations apply only to manufacturers, importers and formulators, but not to downstream users of PFAS containing articles. RAC agrees with the Dossier Submitter that inclusion of down-stream users would have been impractical. It is however recognised that manufacturers, importers and formulators may have limited information on all the uses. RAC notes Forum's proposal to automatise reporting as much as possible to allow automated data analysis as well as to provide enforcement with online tools to facilitate their work. RAC supports this proposal.

In the case of paper and board, textile and plastic articles derogated under points 4j-l containing recovered materials, suppliers need to 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. This certificate needs to be issued by an independent third party. The reason for this requirement is to ensure that PFAS in articles is the result of contamination and not intentional use. A similar requirement is contained in Regulation (EU) 2023/923 on lead and its compounds in PVC. RAC notes that Forum identified several enforcement difficulties related to derogations defined under paragraphs 4j, 4k and 4l by the Dossier Submitter and pointed out in its advice that no concentration limit values for the recycled material is given, which may potentially lead to occurrence of materials with relatively high PFAS content. RAC acknowledges that a maximum concentration limit for PFAS in recycled material could be an effective risk mitigation measure that would facilitate gradual reduction of PFAS emissions. However, as mentioned in the Forum advice, this was not included in the Dossier Submitter's proposal and, therefore, RAC could not assess or establish such a limit.

Only labelling requirement given by the Dossier Submitter concern 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, which need to be labelled for "Contains intentionally added PFAS". This is aimed to facilitate the removal of PFAS-containing products from plastics recycling feedstocks once the products reach the end of their service lives. RAC supports this and considers this as practical and enforceable. However, as discussed under chapter 3.4.2.1 "Effectiveness", RAC considers that the labelling requirement should be extended to cover all derogated uses of PFAS, including e.g. spare parts and should identify the presence of PFAS independently of whether PFAS are intentionally added or the result of the production process (polymerisation aids, etc.) However, RAC recognises that derogated articles containing recovered material may contain traces of PFAS and the general labelling requirement as proposed by RAC is impractical. RAC proposes that in the case of derogated recovered articles the labelling requirement should not be applied. Similarly, the reporting requirement should not apply to the reuse of articles already in end-use in Union.

The Dossier Submitter has proposed 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 includes:

i. information on the identity of the substances and the products they are used in

ii. a justification for the use;

iii. details on the conditions of use and safe disposal.

These management plans shall be reviewed annually and kept available for inspection by enforcement authorities upon request. RAC has discussed on the effectiveness of this requirement under 3.4.2.1 Effectiveness in reducing the identified risk. Regarding practicability and enforceability, RAC has reservations concerning the practicality and enforceability of this requirement especially among the downstream users of fluoropolymers and PFPEs. Management plans are "site-specific" and are only required to be available for inspectors upon request. There are no requirements for sharing information on e.g. safe disposal practises with downstream users.

Considering the high number of derogated uses, the number of downstream users is likely to be high and supply chains might be long. This might create challenges for enforcement authorities to recognise companies required to develop such a management plans or to communicate on the PFAS content of their products especially when considering the high variety of PFAS and the fact that they do not often have any CLP classification. In addition, the management plan as proposed by the Dossier Submitter needs to only give details on the conditions of use and safe disposal but it does not contain requirements for measures to minimize emissions; this approach does not give enforcement authorities any tools to identify or take an action against improper practises. Furthermore, considering potentially long supply chains, it might not be fully clear for companies using articles with fluoropolymer content > 50 ppm whether these requirements apply to them and they may have limited knowledge to develop such a plan.

Overall, RAC identifies significant problems regarding practicality and enforceability of the site-specific management plan, particularly with respect to downstream users. Given the questionable benefit in terms of emission reduction and the issues with practicality and enforceability of the management plan proposed by the Dossier Submitter, RAC proposes to focus instead on RMMs to minimise PFAS emissions and to supply chain communication about the presence of PFAS and safe disposal practises in the end-of-life stage. RAC also proposes to extend the requirement to all PFAS, not only fluoropolymers and PFPE, and to those industrial uses with high emission potential including manufacturing and downstream uses of PFAS and PFAS-containing mixtures (e.g. formulation and production of articles). RAC proposal on risk management measures has been discussed under 3.4.2.1 Effectiveness in reducing the identified risk. RAC however recognises that challenges for example related to the difficulties of enforcement authorities to recognise companies required to have developed a site-specific management plan apply also to RAC's proposal.

SEAC conclusion(s):

See SEAC Opinion

Key elements underpinning the SEAC conclusion(s):

See SEAC Opinion

3.4.2.4. Monitorability

Relevant sections of the Background Document:

Monitorability is assessed by the Dossier Submitter in section 2.5 of the Background Document.

RAC conclusion(s):

- RAC agrees with the Dossier Submitter that the proposed restriction is monitorable.

Key elements underpinning the RAC conclusion(s):

There is an ongoing monitoring of PFAS in environmental matrices and in humans that can be used for monitoring of the effectiveness of the restriction (for further details see sections 3.1.2.8 and 3.1.2.9). Available analytical methods for monitoring are summarised in the Background Document (Appendix E.4.1 and section 2.5.6 of the main document).

Due to the persistence of PFAS, the long service life of some articles, the derogations and the extensive number of emission sources across multiple uses/sectors, it may take a long time before a decrease in concentrations is seen. RAC agrees with the Dossier Submitter's suggestion to monitor PFAS in emissions like wastewater and waste streams, where a reduction may occur within shorter timelines than in environmental and human samples.

The reporting and labelling requirements, site-specific management plans and enforcement of the concentration limits will also contribute to the monitorability of the effectiveness the restriction. Reporting requirements apply to all uses with 13.5-year or longer derogations and for derogations relating to applications of fluorinated gases under paragraphs 5 and 6, as well as to uses of active substances in biocidal, plant protection and medicinal products. As to the site-specific management plans, the Dossier Submitter proposed them to apply to derogated uses of fluoropolymers and PFPEs; RAC recommends extension to all types of PFAS (see section 3.4.2.1).

Labelling requirement was proposed by the Dossier Submitter only for 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, but RAC has proposed to require labelling of all PFAS containing materials/products covered by proposed derogations and communicate on the safe use and waste disposal in the supply chain. RAC recognises that enforcement authorities may have challenges to recognise companies required to develop management plans or to label and communicate on the PFAS content of their products especially when considering the high variety of different PFAS and the fact that they do not often have any harmonized classification according to CLP.

SEAC conclusion(s):

See SEAC Opinion

Key elements underpinning the SEAC conclusion(s):

See SEAC Opinion

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

3.4.3.1. RAC conclusion(s):

3.4.3.1.1. Substance scope (column 1)

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 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.

Regarding to the exclusion of certain PFAS sub-groups from the scope on the grounds that they are fully degradable, RAC considers the evidence provided by the Dossier Submitter is 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.

3.4.3.1.2. Scope of the proposed restriction (paragraphs 1 and 2)

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 the environment and human health. RAC agrees with the approach and highlights that also the technical challenges and limited effectiveness of remediation techniques used to remove PFAS from various environmental compartments; this underscores the necessity to regulate them to prevent further uncontrolled releases. RAC has followed a similar approach in the recent restriction of PFAS in fire-fighting foams (ECHA, 2023a), which covers the whole group of PFAS as defined by OECD (2021) although limits its application to that specific.

3.4.3.1.3. Concentration limits (paragraph 2)

The 25 ppb (μg/kg) limit for individual PFAS as measured by targeted analysis (polymeric PFAS excluded) is already set for several PFAAs in existing restrictions (e.g. PFOA restriction, PFHxA restriction). Although RAC can generally support this limit, it is noted that the substance scope of the current restriction proposal is much broader and includes substances for which the LOQ currently appears to be far above 25 ppb. RAC notes that targeted analysis often captures only a fraction of PFAS present in a sample (depending on the sample).

The second limit, 250 ppb (μg/kg), is set for the sum of PFAS measured by targeted analysis, optionally with prior degradation of precursors (degradation products, e.g. from side-chain fluorinated polymers, included in the sum). Similar limits for the sum of PFAS have been set in previous PFAS restrictions. The requirement for degradation (e.g. by hydrolysis or oxidation) increases the proportion of PFAS in a sample that can be detected and is therefore supported by RAC. The fact that degradation is left optional has been recognised as a potential issue for enforcement by Forum. therefore, RAC recommends that sample degradation is set as a requirement in the restriction text (except cases where it is not feasible). A guidance for enforcement of this restriction should specify which degradation methods are appropriate to be used for a given type of sample.

The third limit, 50 ppm (mg/kg) is set for total PFAS in a sample (including polymeric PFAS) and is based on the sensitivity of total fluorine methods (e.g. combustion ion chromatography). Although much lower limits can be achieved in certain cases, this restriction proposal encompasses a broad range for matrices, including those where the LOQ is close to 50 ppm. Therefore, the 50 ppm limit for total fluorine is considered appropriate by RAC.

3.4.3.1.4. General 18-month transition period (paragraph 3)

RAC emphasises the importance of acting swiftly to minimise PFAS emissions and to avoid further accumulation of permanent stocks of PFAS in the environment. The Dossier Submitter has set a general 18-month transition period based on the reasonable time-period for selling existing stocks of PFAS and PFAS-containing materials in the supply chain. RAC notes that this same transition period have been successfully used also in several previous restrictions. RAC can agree with this transition period.

3.4.3.1.5. Derogations (paragraphs 4, 5 and 6)

3.4.3.1.5.1. Active substances (paragraphs 4a, 4b and 4c)

RAC notes that active substances, used as biocides products (BPs), plant protection products (PPPs) and medicinal products (MPs), and process chemicals and intermediates used to produce these active substances are excluded from the ban on manufacturing, use and placing on the market since they are covered under their own legislation. RAC considers that current legislations on biocidal products (BPs) (Regulation (EU) No 528/2012), plant protection products (PPPs) (Regulation (EC) No 1107/2009) and medicinal products (MPs) (Regulation (EC) No 726/2004, Regulation (EU) 2019/6 and Directive 2001/83/EC) do not fully address the concern associated with PFAS emissions to the environment and may result in significant continued emissions. Therefore, RAC supports the Dossier Submitter recommendation that - in case derogations are granted for these uses- measures to minimise emissions from the use of PFAS as active substances in PPP, BP and MP are incorporated into respective sector-specific regulations. This means that formation of persistent arrowhead PFAS (like TFA) and emissions of PFAS into the environment are considered in the decision-making concerning active substances under PPPs, BPs and MPs.

In addition, in case of continued use, RAC recommends that conditions related to the minimisation of emissions in the manufacturing (requirement for the development of on site-specific PFAS management) should be implemented. RAC also considers that companies making use of this derogation should provide information to users (e.g. use of anaesthetics) on the PFAS content and safe use and disposal of the products (see section 3.4.2.1.3 of the RAC Opinion).

3.4.3.1.5.2. Second-hand articles (paragraph 4d)

The Dossier Submitter proposes a time-unlimited derogation without any additional measures for the placing on the market of articles which were already in end-use in the Union. RAC supports this derogation and considers that additional emissions caused by the prolonged service life of these articles will not have a significant impact on the effectiveness of the restriction in reducing the risks from PFAS.

3.4.3.1.5.3. Spare parts (paragraph 4e and 4f)

The Dossier Submitter proposes time-limited derogations for the spare parts intended to replace PFAS-containing articles in articles or complex objects. RAC notes the importance of the continued supply of spare parts especially for energy, electronics and semiconductors, sealing and machinery applications and transport-related uses as pointed out by SEAC. Since quantitative information on the demand for spare parts containing PFAS is not available, estimation of additional emissions related to this derogation is not possible. However, since most of the PFAS required in these spare parts are likely to be fluoropolymers, the main emissions occur in the manufacturing stage and at end-of-life, if not disposed appropriately. In addition, the need for spare parts and related emissions are expected to decrease gradually over time after the restriction enters in force. RAC can support the derogation for spare parts but emphasises the need for careful control of emissions especially related to the manufacturing of spare parts, and the importance of the safe disposal of the spare parts in the end-of-life. RAC considers that a requirement for the implementation of site-specific management plan should apply to the suppliers of the spare parts making use of this derogation. RAC also considers that companies making use of this derogation should provide information to users on the PFAS content and safe use and disposal of the products (see section 3.4.3.1.6 below).

RAC considers Dossier Submitter proposal on the requirement to provide a certificate showing that the products are intended for spare parts to replace PFAS-containing articles in articles or complex objects justified.

3.4.3.1.5.4. Upstream supply chain for derogated uses (paragraph 4g and 4h)

RAC recognises that in case derogations would be supported by the decision maker, starting materials and intermediates would be required in the manufacture of PFAS and production of PFAS-containing mixtures or articles in the upstream supply chain for the derogated uses. RAC considers that conditions related to the minimisation of emissions should apply to these processes. This includes the requirement for the implementation of on-site-specific PFAS management plans to minimise PFAS emissions at manufacturing sites and providing information to users on the conditions for safe use and disposal as described under section 3.4.3.1.6 below.

3.4.3.1.5.5. Product and Process Related Research and Development (PPORD) (paragraph 4i)

RAC notes that the PPORD derogation proposed by the Dossier Submitter does not specify sectors or uses but applies to all PPORD activities including those related to time-limited (5 or 12 years) derogations (following the 18-month general transition period). According to the Dossier Submitter, this time-unlimited derogation for PPORD for derogated uses will cease once the derogation period for a specific use ends. This is however not specified in paragraph 4.i of the proposed entry text. In addition, the Dossier Submitter is not proposing an upper limit for the quantities as required by Art 67(1). RAC therefore recommends that the derogation proposal should contain the above elements and be reflected in paragraph 4.i. RAC also emphasises that if this derogation is supported by the decision maker, there is a need for conditions to include a site-specific PFAS management plan to minimise emissions during the derogated research and development projects and the supply of information to users on the content of PFAS and instructions for the safe use and disposal of any PFAS waste (as proposed by RAC under section 3.4.2.1.3) of the RAC Opinion).

3.4.3.1.5.6. Recycling and labelling requirements (paragraphs 4j, 4k, 4l and additional requirements in paragraph 4)

The Dossier Submitter proposes a time-limited derogation (until 23.5 years after entry into force) for plastic articles containing recovered material, except for food-contact material and food-contact packaging and toys. For paper and board articles containing recovered material, the Dossier Submitter proposes a time-unlimited derogation (food-contact material and packaging being an exception), whereas for textile articles containing recovered material (with the exception of toys) a derogation until 13.5 years after entry into force is proposed.

Considering the practicality aspects and importance of plastic recycling in minimising the build-up of plastic waste in the environment and in minimising the use of new resources, RAC can support the Dossier Submitter proposal of a time-limited derogation for recycling of plastic. RAC also notes that the impact of trace levels of PFAS in recovered plastic in overall emissions is likely to be minimal.

In case of paper and board, RAC notes the Dossier Submitter's justification for a time-unlimited derogation emphasising the challenges related to implementing testing strategies. However, RAC considers this justification not sufficient to support a permanent derogation (overtime testing strategies will develop and possibly become available) and notes a time-limited derogation would be more appropriate and likely sufficient for paper and board products. It would also be better in line with the time-limited derogations proposed for recovered plastics and textiles. In addition, from 12 August 2026, PFAS will be banned from food-contact packaging (Reg. (EU) 2025/40 of 19 December 2024 on packaging and packaging waste), limiting its recycling.

For recovered textiles, the Dossier Submitter considered also an option for a 6.5 year derogation, although their final proposal is 13.5 years. It cannot be concluded for sure whether a 6.5-year derogation would have sufficed, although RAC notes that already now PFAS have been substituted in many newly produced consumer textiles. However, considering the importance of recycling in minimising the waste and the use of new resources, RAC can support a time-limited derogation for textile waste for 13.5 years, in line with the Dossier Submitter proposal.

The Dossier Submitter proposes that suppliers of plastic articles, paper and board articles and textile articles containing recovered material and benefitting from these derogations are required to present documentary evidence of the recovered origin of the material (this could be issued by an independent third party or by schemes to provide proof of traceability and recycled content such as EN 15343:2007). The reason for this requirement is to ensure that PFAS in articles is the result of the use of recycled material and not intentional use. A similar requirement is contained in Regulation (EU) 2023/923 on lead and its compounds in PVC. RAC notes that Forum identified several enforcement difficulties related the proposed requirement. RAC also acknowledges that a maximum concentration limit for PFAS in recycled material could be an effective risk mitigation measure that would facilitate gradual reduction of PFAS emissions. However, as mentioned in the Forum advice, this was not identified in the Dossier Submitter's proposal and, therefore, RAC could not assess or establish such a limit.

RAC notes that Dossier Submitter has proposed a labelling requirement for 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 containing recovered materials, which are proposed to be labelled for "Contains intentionally added PFASs".

RAC considers that a labelling requirement may facilitate the safe handling and disposal of all PFAS-containing products for derogated uses, and not only the ones specified by the Dossier Submitter above

Therefore, RAC proposes a labelling requirement for all PFAS-containing substances, mixtures and articles placed on the market for derogated uses. RAC considers that the label should apply to all PFAS-containing products independently of whether PFAS are present as the result of impurities from the production process (e.g. use of polymerisation aids) or have been intentionally added. However, this labelling requirement is not considered practical for derogated recovered materials and articles containing recovered material, or for reuse of articles already in end-use in the Union, which should be exempted. RAC considers this requirement enforceable.

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

Sector-/use-specific derogations are addressed and concluded on by RAC in sector-specific evaluations (with the exception of those eight new sectors[21] not evaluated in detail by RAC). As an overarching principle, RAC generally considers a full ban (RO1) to be more effective in limiting emission and uncontrolled risks than a ban with derogations (RO2 and RO3) that would result in continued emissions. An exception is the targeted derogation proposed by SEAC under "TULAC" for certain types of PPE to avoid possible serious risks to workers.

RAC acknowledges that the decision maker may decide to implement sector-/use specific derogations as proposed by the Dossier Submitter and/or SEAC. In such cases, RAC recommends adopting additional risk management measures to ensure associated emissions are minimised as described in section 3.4.2.1.3 of the RAC Opinion. This includes:

- The implementation of site-specific PFAS management plans to minimise PFAS emissions at industrial sites where PFAS and/or PFAS containing mixtures or articles above the concentration limits defined in section 3.4.3.1.3 are in use.
- The supply of information of the content of PFAS and instructions for safe use and disposal to downstream users (industrial and professional) and consumers of PFAS and/or PFAS containing mixtures or articles above the concentration limits defined in section 3.4.2.1.3.

RAC recognises that continued use of PFAS in (time-limited and unlimited) derogated uses as well as in spare parts would result in a need for continued manufacturing of PFAS. In such a case, RAC recognises that a derogation for PFAS manufacturing would be needed (see RAC sector-specific evaluation of PFAS manufacturing).

In this regard, the Dossier Submitter proposes a time unlimited derogation under 4m for the manufacturing of PFAS coupled with emission control measures reaching a specific minimum effectiveness (in the form of emission factors). RAC could not provide any view on the technical feasibility of the emission factors because this needs to be assessed specifically for each individual site. In addition, RAC has identified several challenges related to practicality of the calculation of the emission factors. RAC notes that in the case of a time-unlimited derogation, the emissions will continue beyond the assessment period.

Should the decision-maker consider a derogation for PFAS manufacturing is appropriate, RAC acknowledges that the establishment of emission limits (emission permits and environmental management system established by the Industrial Emissions Directive) is the most adequate measure to reduce the risk. This, if fully applied by local authorities and if supported by up-to-date BAT conclusions for PFAS manufacturing could offer a significant emission reduction potential; an effective enforcement would also be instrumental to achieve emission minimisation. However, at present and with the information available, RAC is not able to identify such emission limits.

RAC emphasises the importance of minimising emissions from PFAS manufacturing in case a derogation under 4 m is supported by the decision-maker. In view of the unfeasibility for RAC to define emission limits with the information available and the possible long time needed to develop BAT conclusions for PFAS manufacturing, RAC suggests to introduce requirements to implement site-specific PFAS management plans, including monitoring of emissions to the environment, for each PFAS manufacturing site. This is in line with the requirements proposed for other industrial sites, should their use of PFAS be allowed to continue. In addition, PFAS manufacturers should provide instructions for safe use and disposal to their downstream users

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[21] The eight new sectors not evaluated by RAC are Printing applications, Sealing applications, Machinery applications, Other medical applications, Military applications, Explosives, Technical textiles and Broader industrial uses. See Annex I for a short description.

to ensure PFAS emissions are controlled along the whole life cycle.

3.4.3.1.6. Conditions for continued use

3.4.3.1.6.1. Reporting requirements (paragraphs 4 and 7)

The Dossier Submitter proposes that manufacturers, importers of PFAS or PFAS-containing articles as well as downstream users formulating PFAS-containing mixtures making use of any of the 13.5-year or longer derogations and for derogations relating to applications of fluorinated gases report annually to the Agency on the derogation that the intended use belongs to and the identity and quantity of the substances placed on the market in the previous year. Similar reporting requirements are proposed also for active substances derogated under paragraph 4 of the restriction proposal.

RAC considers these reporting requirements practical and enforceable. Although they may not have any direct impact on risk reduction, they would provide EU-level data on the use of PFAS in these derogated uses; RAC considers this information very relevant e.g. for the future review of the restriction and its effectiveness. RAC notes that the reporting obligations apply only to manufacturers, importers of articles and formulators, but not to downstream users of PFAS-containing articles and mixtures. RAC agrees with the Dossier Submitter that inclusion of down-stream users (except for industrial formulators) would have been impractical. RAC also recommends that reporting should apply to importers of PFAS-containing mixtures.

It is recognised that manufacturers, importers and formulators may have limited information on all the uses. However, RAC notices that importers of PFAS-containing mixtures are not specifically mentioned in paragraph 7 and should also be included. RAC notes Forum's proposal to automatize reporting as much as possible to allow automated data analysis as well as to provide enforcement with online tools to facilitate their work. RAC supports this proposal.

3.4.3.1.6.2. Site-specific PFAS management plans (paragraph 8)

RAC has reviewed the Dossier Submitter proposal on site-specific PFAS management plans. RAC concludes that they are not sufficient to achieve a significant risk reduction. Therefore, RAC has outlined its own proposal to improve PFAS site-specific management plans, which are considered more effective in minimising the emissions and subsequent risk. They shall be made available to competent authorities on demand. The site-specific PFAS management plans should describe measures taken and planned to minimise the emissions to the environment (Section 3.4.2.1.3 provides additional details on RAC recommendations for PFAS site specific management plan). RAC proposes that monitoring data on emissions collected by industrial users as part of the PFAS management plan should be reported to the Agency. For those actors with reporting obligations on PFAS as discussed in section 3.4.3.1.6.1. above, this reporting could be done simultaneously.

Furthermore, RAC considers that:

- this requirement should apply to industrial uses of PFAS with high emission potential and in particular to the industrial use of PFAS and PFAS-containing mixtures (e.g. formulation of mixtures, production of articles, etc.) that will be allowed to continue (e.g. derogated) once the 18-month transition period comes to an end as well as to PFAS manufacturing.

- PFAS management plans should cover all type of PFAS and should not be restricted to fluoropolymers and PFPE, as proposed by the Dossier Submitter.

3.4.3.1.6.3. Additional conditions considered by RAC

RAC considers supply-chain communication on presence of PFAS essential to ensure minimisation of emissions in all relevant stages of life cycle. Therefore, conditions for manufacturers and importers of PFAS-containing materials/products for derogated uses should include also requirements ensuring effective supply-chain communication. This may occur via safety datasheets/technical datasheets or e.g. product passports. RAC notes that some sectors where RO3s have been developed by the Dossier Submitter, already contain a mention of such communication requirements.

RAC considers that a similar requirement ensuring effective supply-chain communication should be introduced for manufacturers and importers of PFAS-containing materials/products for all derogated industrial uses.

RAC recognises that for professional and consumer uses the above measures (site-specific management plans or supply-chain communication) would not be effective in reducing associated emissions. RAC notes the requirements in the restriction of synthetic polymer microparticles [microplastics] (Entry 78 of Annex XVII) which require products to be labelled with a statement: “This product contains microplastics.” following information e.g. on safe use and disposal.

Similarly, RAC considers that for professional and consumer uses of articles and mixtures containing PFAS, labelling requirements should be introduced; those labelling requirements should inform on the presence of PFAS and recommend disposal practices to minimise emissions during such uses.

3.4.3.1.7. Interaction with other relevant legislation (paragraph 9)

According to RAC’s understanding, the Dossier Submitter’s intention is to avoid overlap with any existing substance- or use-specific PFAS restrictions and instead aim to ensure that the strictest EU regulation applies. For instance, is noted that entries 28-30 of Annex XVII of REACH (covering restrictions of use of substances classified as carcinogenic, mutagenic or reproductive toxic) could partially overlap with the proposed restriction on PFAS

RAC notes that Forum commented on the wording of the first sentence in paragraph 9, which was considered ambiguous. Also, RAC has doubts whether the current text proposed by the Dossier submitter under paragraph 9 of the restriction proposal is clear enough to ensure that in cases of existing specific restrictions, the most stringent condition always applies and considers that this may need further clarification by the decision maker (e.g. guidance might be helpful in clarifying interactions across different restrictions).

3.4.3.2. SEAC conclusion(s)

See SEAC opinion.

3.5. SUMMARY OF UNCERTAINTIES

3.5.1. Uncertainties evaluated by RAC

RAC conclusion(s):

- Related to the hazard assessment, there are uncertainties related to the high number of PFAS falling under the scope of the restriction. Although persistence can be considered as a shared property of PFAS, other hazardous properties may vary qualitatively or quantitatively. This have not been considered in the assessment, but all PFAAs and PFAA precursors (including side-chain fluorinated polymers, PFPEs and fluorinated gases) have been considered as equal. RAC, however, has distinguished between PFAAs/PFAA precursors and fluoropolymer particles.
- RAC highlights several uncertainties related to the RAC assessment of emissions: the main uncertainties are related to the limited information on use volumes, unclear description of uses and to the fact that due to lack of detailed information, emission estimates are generally based on the use of default emission factors
- In addition, for many sectors, there is limited or lack of data on imports. In addition, RAC wants to emphasise the issue of cross-border pollution which have not been considered. For example, in the case of fluorinated gases, majority of manufacturing (and related emissions) occur outside EU and have not been covered in the assessment.
- RAC also points out that RAC emission estimates focus on PFAA/PFAA precursors and do not account for fluoropolymer particle emissions.
- However, although RAC recognises several uncertainties related to the assessment of emissions, RAC is rather confident on the order of magnitude of estimated emissions.
- The main uncertainties related to the assessment of the risks of alternatives are related to the fact that conclusions are based on hazard data only, which in some cases may have been limited.
- There are some uncertainties concerning the sensitivity and harmonisation/standardization of the analytical monitoring methods and related to the practical enforcement and monitoring of requirements related to the site-specific management plans and labelling/supply-chain communication.
- Regardless of these uncertainties, RAC is however confident that its overall conclusions are robust.

Key elements underpinning the RAC conclusion(s):

An overview of the main uncertainties identified are given below.

Table 9: Overview of uncertainties identified by RAC

Topic	**Uncertainty**	**Impact (minor/moderate/ major)**
Sector specific evaluations: Scope	Different terminology – of uses in the Background Documents and unclarities in the boundaries across categories and sub-uses	Minor
	For some sectors (e.g. "Medical Devices", "Construction Products") the linkages to other sectors may result in overlaps and double counting. On the other hand, some uses and niche applications may not have been fully covered under a certain sector.	Minor/Moderate

Topic	Uncertainty	Impact (minor/moderate/ major)
Scope and Hazards	The Dossier Submitter has excluded some PFAS groups from the scope as non-persistent. RAC was not able to ascertain non-persistence of these compound groups although RAC recognised that some compounds within those groups may be non-persistent. Exclusion of chemicals from the scope due to their non-persistence requires case-by-case evaluation.	Moderate
Scope and Hazards	The restriction includes an extensive number of compounds, whose hazardous properties may vary qualitatively and/or quantitatively. The impact assessment makes no distinction between PFCAs/PFSAs, side-chain fluorinated polymers, PFPEs and various groups of fluorinated gases, despite the fact that they differ in potency, ability to form persistent arrowhead compounds and type of adverse effects. The only difference taken into account in the RAC evaluation is the difference between the toxicity of PFAAs/PFAA precursors and fluoropolymer particles.	Moderate
Scope / Volumes / Emissions	For some sectors, the Dossier Submitter was not able to allocate quantities to each use/sub-use. It is therefore unclear to what extent volume data covers the sub-uses defined in the scope of the assessment. This will also impact the emissions' estimation.	Minor/Moderate
Volumes	For some sectors, there is lack of correspondence between the applications described in the scope (Annex A) and the uses for which volume data is provided (Annex A). It is not clear to what extent volume data provided represents the defined scope.	Minor/Moderate
	For some sectors, there is no specific data for several uses and the volume data is based on general statistics. In other cases, the volume is based on single company data, raising concerns about the representativeness of the figure across the entire sub-use.	Minor/Moderate
	For some (sub-)uses, in some sectors, there is incomplete information on the PFAS total tonnage, the tonnage per use and the PFAS type used. Moreover, some uses might have not been captured by the respective sectors. In such cases, RAC concludes that volumes are underestimated.	Moderate/Major

Topic	Uncertainty	Impact (minor/moderate/ major)
	For some sectors, the data received from stakeholders was for the products on the market (i.e. use stage). The volumes for the “production” stage were based on “reverse calculation”.	Minor
	For some sectors, there is limited or lack of data on imports.	Moderate
Volumes / Emissions / Effectiveness	Assumptions on the growth rate. RAC acknowledges that the growth rate is difficult to predict, given the various influences and challenges to take those into account (e.g. impact of legislative measures, technological developments).	Moderate
Emissions: release factors for waste	The available data on PFAS mineralisation during incineration are still limited and do not even allow to conclude about the order of the magnitude of the release factor. It is assumed that the RFs for incineration used in the RAC assessment probably represent the upper range of the true RF (and therefore do not underestimate emissions) but even this is uncertain given the scarcity of data on municipal waste incinerators.	Moderate/Major
Emissions	RAC has focused in its fluoropolymer emissions assessment on the emissions of monomeric leachables (PFAAs/PFAA precursors). There are uncertainties related to the RAC assumptions on the levels of leachable fractions in fluoropolymers. In addition, in the assessment of emissions from the use of fluoropolymers for the manufacturing of articles, RAC could not fully account for the emissions from hot processes.	Moderate
Emissions	The life-cycle stages considered by the Dossier Submitter partially differ from those established in ECHA Guidance R.12, R.16 and R.18 and the processes involved in each life stage are not described in detail. The difference in terminology of life cycle stages and the lack of detail descriptions of the processes associated to each life stage makes it challenging for RAC to determine whether all relevant stages have been thoroughly evaluated.	Moderate
	Use of default release factors, due to lack of monitoring data. The use of default release factors represents a worst-case approach that may lead to an overestimation of emissions.	Minor/Moderate

Topic	Uncertainty	Impact (minor/moderate/ major)
	However, in the absence of more specific data, default release factors are considered adequate.	
	The Dossier Submitter modified some release factors of standard ERCs, based on assumptions, which are difficult to verify. RAC understands modifications were made based on expert judgment and generally agrees with them.	Minor
	For some sectors, there are uncertainties related to volume and scope. In combination with the lack of a detailed description of the processes covered during the life-cycle stages and the potential omission of emissions from certain life-cycle stages (e.g., article manufacturing), there is uncertainty in the emission estimates.	Moderate
	For some sectors, the Dossier Submitter was not able to apply release factors to individual uses/sub-uses and merged them into broader categories. This approach reduces the granularity of the analysis and limits the accuracy that a use-specific application of release factors would provide.	Minor/Moderate
	Emissions from PFAS manufacturing were not considered in individual sectors. Emissions from manufacturing of PFAS used in the PFAS sector have not been quantified (are assessed horizontally under 'PFAS manufacturing' sector).	Moderate
Risk of alternatives	Limited information on identity, chemical composition and hazard of some alternatives. No assessment is possible in such cases.	Moderate
	For a substantial number of alternatives, the Dossier Submitter did not perform a hazard assessment. The relevance of these alternatives (included in Annex E but not in Appendix E2) is unknown to RAC.	Minor/Moderate
	Conclusions are mainly based on hazard data and CLP classification which was often based on notified classifications which is considered uncertain. No risk assessment was performed	Moderate
Effectiveness	For some sectors, the Dossier Submitter was not able to evaluate the impact on the effectiveness of the restriction of new legislation or recent regulatory measures (e.g. F-Gases Regulation, Batteries Regulation, ELV Regulation, WEE Directive, recently adopted PFHxA restriction).	Minor/Moderate

Topic	Uncertainty	Impact (minor/moderate/ major)
	The new legislation will impact the overall emissions estimate, which would probably be lower. The same applies with the new technological developments (e.g. rapid development of battery technologies). However, in many cases the overall conclusion is that emissions are underestimated due to data gaps in subuses/subsectors.	
Effectiveness and derogation analysis	RAC is not able to properly assess the possibility to implement the RO3 options presented by the Dossier Submitter for some sectors.	Moderate
Enforceability/ Monitorability	Proposed targeted concentration limits may not be currently achievable for certain PFAS with the available analytical methods.	Moderate
Enforceability/ Monitorability	There is lack of harmonisation/standardization of sampling, sample pre-treatment and analytical methods, which makes enforcement challenging.	Major
Enforceability/ Monitorability	There are uncertainties related to the practical enforcement and monitoring of site-specific management plans and proposed labelling/communication requirements.	Moderate

3.5.2. Uncertainties evaluated by SEAC

See SEAC Opinion

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Other references are included in the Background Document.

ANNEX I

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

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

Sector	Description
01. PFAS manufacturing	The assessment of the PFAS manufacturing sector covers all process steps in the manufacture of PFAS compounds at the manufacture site, including the processing of PFAS at the manufacturing site. This category also covers the use of PFAS as polymerisation aids in the manufacture of fluoropolymers. Note that processing PFAS into articles or mixtures offsite (e.g., foam moulding or fluoropolymer extrusion) is excluded and considered as part of other relevant sectors (e.g., Transport or Food contact materials and packaging).
02. Textiles, upholstery, leather, apparel and carpets (TULAC)	The assessment of the TULAC sector covers the uses of PFAS in home textiles, consumer apparel, professional apparel and personal protective equipment (PPE), leather and home fabric treatment sprays. PFAS uses related to TULAC but NOT considered as part of this sector: • Packaging (considered as part of the Food contact materials and packaging sector) • Optical fibre weaving (considered as part of the Electronics and semiconductors sector) • Latex printing inks, including inks for printing on textile (considered as part of the Printing applications sector) • Components related to textile industry e.g., conveyor belts (considered as part of the Machinery applications sector) • Outdoor technical textiles, architectural membranes, other tensile fabrics and other construction applications, filtration and separation media, removable covers for industrial process equipment, medical applications, technical textiles in transport vehicles (considered as part of the Technical textiles sector) • Textiles in engine bays (considered as part of the Technical textiles sector)
03. Food contact materials (FCM) and packaging	The assessment of the Food contact materials and packaging sector covers the uses of PFAS in food and non-food packaging applications, non-stick coatings in consumer cookware and domestic appliances, and non-stick coatings in industrial bakeware. PFAS uses related to Food contact materials and packaging but NOT considered as part of this sector: • Packaging of medical devices (considered as part of the Medical devices sector) • Immediate/primary packaging of medicinal and pharmaceutical products for human and veterinary uses (considered as part of the Other medical applications sector) • Inks, lacquers and waxes used in non-FCM applications (considered as part of the Printing applications sector) • Non-intentionally added substances in (recycled) packaging materials (considered and discussed in the Impacts on Recycling and Circular Economy section, please see e.g. section E.3.4. of Annex E) • Advanced semiconductor packaging (considered as part of the Electronics and semiconductors sector) • Sealings, gaskets, piping and linings used in food and feed production (considered as part of the Sealing applications sector)

	• Conveyor belts, production/assembly line equipment, bearings and rollers used in food and feed production (considered as part of the Machinery applications sector) • Lubricants in industrial settings (considered as part of the Lubricants sector) • Membranes and filtration materials used in drinking water treatment (considered as part of the Technical textiles sector)
04. Metal plating and manufacture of metal products	The assessment of the Metal plating and manufacture of metal products sector covers the uses of PFAS in metal plating processes as well as in the manufacture of other metal products. Examples include wetting agents, mist/fume suppressing agents and processing aids in metal plating baths, coating of metal products and solvents in metal manufacturing. PFAS uses related to the manufacture of metal products but NOT considered as part of this sector: • Production of parts for engines and other applications in technical components (considered as part of the Transport sector) • Production of parts in machinery, as well as other industrial applications, such as sealings (considered as part of the Sealing applications or Machinery applications sectors) • Production of parts for military equipment (considered as part of the Military Applications sector) • Coatings and paints for metal components specifically used in construction and machinery (considered as part of the Construction Products and Machinery applications sectors) • Cover gases for use in magnesium casting (considered as part of the Applications of fluorinated gases sector) • Precision cleaning fluids (considered as part of the Broader industrial uses sector)
05. Consumer mixtures and miscellaneous consumer articles	The assessment of the Consumer mixtures and miscellaneous consumer articles sector covers the uses of PFAS in various mixtures and articles intended specifically for consumer use. Examples include cleaners and cleaning products, waxes and polishes, automotive windscreen care products, anti-fogging agents for eyewear, fishing lines, synthetic turf as well as lubricants and string materials used in musical instruments. PFAS uses related to Consumer mixtures and miscellaneous consumer articles but NOT considered as part of this sector: • Cosmetics (considered as part of the Cosmetics sector) • Ski waxes (considered as part of the Ski wax sector) • Home fabric treatments e.g. sprays used for stain repellence purposes (considered as part of the Textiles, upholstery, leather, apparel and carpets (TULAC) sector) • Consumer uses of lubricants, except for piano keys and strings of musical instruments (considered as part of the Lubricants sector) • Razor blade coatings (considered as part of the Metal plating and manufacture of metal products sector) • Electrical components for musical instruments (considered as part of the Electronics and semiconductors sector) • Spare parts are assessed as an overarching issue (please see Annex E, Section 3.3, of the Background Document)
06. Cosmetics	The assessment of the Cosmetics sector covers the uses of PFAS in cosmetic products and the use of trifluoroacetic acid (TFA) in the synthesis of peptides as cosmetic ingredients. PFAS uses related to Cosmetics but NOT considered as part of this sector: • Applications in manufacturing equipment used for the manufacture of cosmetics (depending on the application, these may be considered as

	part of e.g., the Sealing applications or Machinery applications sectors) • Packaging of cosmetics products (considered as part of the Food Contact Materials and Packaging sector) • Analytical instruments and equipment parts used in the cosmetics sector e.g., valves, tubing and connectors (considered as part of the Sealing applications sector. Analytical equipment in general is assessed as an overarching issue, please see the explanatory notes of the main report of the Background Document and in particular the sub-heading '*Scientific research and development*'). • Uses of PFAS in excipients, immediate packaging and drug delivery devices (considered as part of Other Medical Applications) • Active substances in human and veterinary medicinal products are exempted from the restriction proposal (please see in particular Section 2.2.3 of the Background Document main report)
07. Ski wax	The assessment of the Ski wax sector covers the uses of PFAS in ski wax that can be applied to traditional skis, snowboards and skin skis across different kinds of snow sports. Examples include blocks of wax, liquid wax, paste wax, powder wax, spray wax or mixtures for cleaning and impregnation. PFAS uses related to Ski wax but NOT considered as part of this sector: • Shoes and textiles for skiing (considered as part of the Textiles, upholstery, leather, apparel and carpets (TULAC) sector)
08. Applications of fluorinated gases	The assessment of the Applications of fluorinated gases sector covers uses of PFAS gases in various applications and uses. Examples include refrigeration, air conditioning and heat pumps, foam blowing agents, propellants, cover gases, clean fire suppressants, preservation of cultural paper-based materials and insulating gases. PFAS uses related to Applications of fluorinated gases but NOT considered as part of this sector: • Mobile air conditioning (MAC) (considered as part of the Transport sector) • Transport refrigeration (considered as part of the Transport sector) • Heat transfer fluids (i.e. fluids that guide heat/cold away from an application but do not actively cool the application) for immersion cooling and indirect cooling of electronics and semiconductors (considered as part of the Electronics and semiconductors sector) • Semiconductor manufacture (considered as part of the Electronics and semiconductors sector) • Solvents for cleaning (considered as part of the Broader industrial uses, Electronics and semiconductors, or Metal plating and manufacture of metal products sectors) • Carrier solvents for lubricants (considered as part of the Lubricants sector) • Metered dose inhalers (MDI) (considered as part of the Other medical applications sector) • Use of fluoropolymers in equipment e.g. O-rings, gaskets, or similar components (considered as part of the Sealing applications and Machinery applications sectors) • Use of fluorinated gases in various military both mobile and stationary applications (considered as part of the Military applications sector)
09. Medical devices	The assessment of the Medical devices sector covers uses of PFAS in various instruments, appliances and other articles intended for medical purposes in humans. Examples include implantable medical devices, invasive medical devices, non-implantable/non-invasive medical devices and packaging of medical devices. PFAS uses related to Medical devices but NOT considered as part of this sector:

	• Electronic equipment for medical imaging, MRI, X-ray, etc. (considered as part of the Electronic and semiconductors sector) • Medical electronics (considered as part of the Electronic and semiconductors sector), except electronics in implantable and invasive medical devices (considered as part of the Medical devices sector) • Diagnostic laboratory testing (considered as an overarching issue, please see the explanatory notes of the Main report of the Background Document and in particular the sub-heading '*Scientific research and development*') • Excipients in pharmaceutical products (considered as part of the Other medical applications sector) • Drug delivery devices where the device is part of a drug-device combination product, e.g. pressurized metered-dose inhalers (pMDIs), pre-filled syringes, pre-filled injection pens, autoinjectors and pre-filled on-body delivery system, transdermal patches (considered as part of the Other medical applications sector) • Immediate packaging for medicines (considered as part of the Other medical applications sector) • Engineered fluids for diagnostic laboratory (considered as an overarching issue, please see the explanatory notes of the Main report of the Background Document and in particular the sub-heading '*Scientific research and development*') • Fluorinated gases used in industrial processes related to medical applications e.g. medical lasers (considered as part of the Broader industrial uses sector) • Medical textiles, including blood filtration filters, transducer membranes, membranes for venting, and virus and contaminant filters and membranes from water, air and other media (considered as part of the Technical textiles sector) • Personal protective equipment (PPE) e.g., clothing and drapes (considered as part of the TULAC sector) • Construction applications in hospitals (considered as part of the Construction products sector) • Parts of analytical and medical equipment e.g. valves, tubing, connectors (considered as part of the Sealing applications sector) • Packaging other than for medical devices and medicines (considered as part of the Food contact materials and packaging sector)
10. Transport	The assessment of the Transport sector covers the uses of PFAS in transport vehicles, mobile machinery, and associated infrastructure. Examples are automotive vehicles, aerospace vehicles, watercraft vehicles, rail vehicles, agricultural and forestry vehicles, construction and industrial vehicles, and transport-related infrastructure. PFAS uses related to Transport but NOT considered as part of this sector: • Sealing applications e.g., gaskets, O-rings, pipe/tank linings (considered as part of the Sealing applications sector, except for hoses in combustion engines and hose linings in aerospace applications which are considered part of the Transport sector) • Machinery and equipment e.g., robotic arms, presses (considered as part of the Machinery applications sector) • Lubricants e.g., lubricants in engines and self-lubricating parts (considered as part of the Lubricants and Machinery applications sectors) • Metal plating e.g., mist suppressants (considered as part of the Metal plating and manufacture of metal products sector) • Electronical and electronic equipment in transport vehicles, excluding cable linings and coatings in transport vehicles (considered as part of the Electronics and semiconductors sector) • Batteries and fuel cells (considered as part of the Energy sector) • Immersion cooling (considered as part of the Electronics and semiconductors sector)

	• Optical fibres (considered as part of the Electronics and semiconductors sector) • Membrane textiles for mould-injection (considered as part of the Technical textiles sector) • Textiles in engine bays (considered as part of the Technical textiles sector) • Textile cover sheets e.g., convertible tops, vehicle protection covers (considered as part of the Technical textiles sector) • Filters e.g., for air conditioning systems (considered as part of the Technical textiles sector) • Interior textile treatments e.g., seats, carpets, roof linings (considered as part of the TULAC sector) • Anti-drip additives/flame-retardant additives in plastics (considered as part of the Electronics and semiconductors sector) • Acrylic foam tape (considered as part of the Sealing applications sector) • Fire extinguishers for aircraft e.g., 2-BTP (considered as part of the Applications of fluorinated gases sector) • Propellants for spray biocides in aircraft (considered as part of the Applications of fluorinated gases sector)
11. Electronics and semiconductors (Electronics)	The assessment of electronics covers the uses of PFAS uses in electronic components and assemblies including wires and cables, circuit boards, connectors, sensors, insulation of electrical components, coatings of electrical components, photonics, etc. Plastic additives (e.g., flame retardancy and anti-drip performance), heat transfer fluids for immersion cooling, cold plate cooling and vapor phase soldering in relation to electronics are also in scope. PFAS uses related to electronics but NOT considered as part of this sector: • Sealing applications e.g., gaskets, O-rings, pipe lining (considered as part of the Sealing applications sector) • Machinery applications e.g., conveyor systems, robotic arms (considered as part of the Machinery applications sector) • Technical textiles e.g., membranes, vents and filters (considered as part of the Technical textiles sector) • Lubricants e.g., for use in magnetic recording media (considered as part of the Lubricants sector) • Non-electronic industrial automation monitoring and control (IAMC) parts (considered as part of the Sealing applications or Machinery applications sectors) • All electrical parts (including wires) which are part of an implantable or invasive medical device (considered as part of the Medical devices sector) • Refrigerants (chillers) for cooling in electronics and semiconductor sector (considered as part of the Applications for fluorinated gases sector) • Electrical insulation gases (considered as part of the Applications for fluorinated gases sector) • Industrial precision cleaning other than specific uses related to chemical vapor deposition and etch cleaning in electronics and semiconductors (considered as part of the Broader industrial uses sector) • Non-electronic parts of sensors e.g. liners, filters, membranes and gaskets (considered as part of the Sealing applications, Machinery applications and Technical textiles sectors)
11. Electronics and semiconductors (Semiconductors)	The assessment of semiconductors covers the uses of PFAS in semiconductor manufacturing processes, including etching, chamber cleaning, wafer processing, photolithography and micro-electromechanical systems (MEMS). PFAS in semiconductor inspection equipment and semiconductor packaging are also in scope.

	PFAS uses related to semiconductors but NOT considered as part of this sector: • Sealing applications e.g., gaskets, O-rings, pipe linings (considered as part of the Sealing applications sector) • Machinery applications e.g., conveyor systems, robotic arms (considered as part of the Machinery applications sector) • Technical textiles e.g., membranes, vents and filters (considered as part of the Technical textiles sector) • Lubricants e.g., for use in magnetic recording media (considered as part of the Lubricants sector) • Non-electronic industrial automation monitoring and control (IAMC) parts (considered as part of the Sealing applications or Machinery applications sectors) • All electrical parts (including wires) which are part of an implantable or invasive medical device (considered as part of the Medical devices sector) • Refrigerants (chillers) for cooling in electronics and semiconductor sector (considered as part of the Applications for fluorinated gases sector) • Electrical insulation gases (considered as part of the Applications for fluorinated gases sector) • Industrial precision cleaning other than specific uses related to chemical vapor deposition and etch cleaning in electronics and semiconductors (considered as part of the Broader industrial uses sector) • Non-electronic parts of sensors e.g. liners, filters, membranes and gaskets (considered as part of the Sealing applications, Machinery applications and Technical textiles sectors)
12. Energy	The assessment of the Energy sector covers the uses of PFAS in renewable energy generation, hydrogen technology, manufacturing of chemicals via electrolysis, batteries and electrical grids. PFAS uses related to Energy but NOT considered as part of this sector: • Sealing applications e.g., pipe linings, tubing, tanks, O-rings, gaskets etc. (considered as part of the Sealing applications sector. Note that, in relation to sealing applications, PFAS used in the 'core' of membrane electrode assemblies (MEA) in fuel cells and electrolysers in energy applications are assessed in the Energy sector as part of hydrogen technology and manufacture of chemicals via electrolysis) • Machinery applications and equipment e.g., robotic arms, production and assembly line equipment (considered as part of the Machinery applications sector) • Lubricants in relation to energy applications (considered as part of the Lubricants sector) • Hydropower applications (considered as part of the Sealing applications and Machinery applications sectors) • Anti-drip additives in polymers (considered as part of the Electronics and semiconductors sector) • Power plants, including fossil fuel power plants, nuclear power plants, waste-to-energy plants and engine power plants (considered cross-sectorally as part of sectors such as Sealing applications, Machinery applications, and Electronics and semiconductors) • Oil and gas applications (considered cross-sectorally as part of sectors such as the Sealing applications, Machinery applications, Electronics and semiconductors, and Lubricants sectors) • Membranes e.g., HEPA-filter, H2 and zinc-air battery membranes, excluding membranes for fuel cells and electrolysers (considered as part of the Technical textiles sector)

	• Solid oxide electrolyser cell (SOEC) and Solid oxide fuel cell (SOFC) (considered as part of the Sealing applications sector) • Storage, refuelling and transport of hydrogen (considered as part of the Sealing applications and Machinery applications sectors) • Solvents for cleaning (considered as part of the Electronics and semiconductors, Broader industrial uses, or Metal plating and manufacture of metal products sectors) • Electrical grids, excluding PFAS uses in switchgear and circuit breakers, such as PTFE nozzles for arc quenching (considered as part of the Sealing applications, Machinery applications, Electronics and semiconductors, and Applications of fluorinated gases sectors) • Electronics e.g., wires and cables (considered as part of the Electronics and semiconductors sector) • Industrial automation monitoring and control (IAMC) (considered as part of the Sealing applications, Machinery applications and Electronics and semiconductors sectors) • Spare parts are assessed as an overarching issue (please see Annex E, Section 3.3)
13. Construction products	The assessment of the Construction products sector covers the uses of PFAS in building materials and construction products. Examples include roofing materials, paints and coatings, polymer additives for fire-safety purposes, impregnations, sealants, and adhesives. PFAS uses related to Construction products but NOT considered as part of the Construction products sector: • Architectural membranes and weatherproofing membranes, including vapour barriers, coated fabric and fiberglass coating (considered as part of the Technical textiles sector) • Sealings, PTFE thread sealing tape, valves and pipes (considered as part of the Sealing applications sector) • Flexible solar panels, renewable energy systems and film/coating of wind turbines/solar panels (considered as part of the Energy sector) • Foam blowing agents in roofing and fluorinated gases in foam insulation (considered as part of the Applications of fluorinated gases) • Wires and cables (incl. insulation) and electrochromic functionalities in e.g. glazing (considered as part of the Electronics and semiconductors sector) • Coil coating of metal products (considered as part of the Metal plating and manufacture of metal products sector) • Lubricants in manufacturing PEX-pipes and compression sleeves for underfloor heating (considered as part of the Lubricants sector) • Plain bearings for non-building applications (e.g. energy systems, cranes, lifts or elevators) in machinery/equipment, pumps, valves, gas installations and coil coating in manufacturing process (considered as part of the Machinery applications sector) • Anti-drip agents and flame retardants for electronics (considered as part of the Electronics and Semiconductors sector) • Explosives used in the construction applications (considered as part of the Explosives sector)
14. Lubricants	The assessment of the Lubricants sector covers the uses of PFAS in liquid or semi-fluid lubricant mixtures designed to remain viscous throughout their lifecycle, as well as PFAS additives in coatings that provide low-friction properties once cured or solidified. Examples include low-viscosity lubricants (base oils, mineral or synthetic, sometimes with additives), greases (base oil combined with a thickening agent and additives), solid/dry films (lubricant mixed with alcohol, water, or other volatile solvents), release agents (such as dry films used in manufacturing thermoplastics and elastomers) and carrier solvents for lubricants. PFAS uses related to Lubricants but NOT considered as part of this sector: • Lubricants for piano keys or the strings of musical instruments e.g., guitars, harps, ukuleles, violins, violas, lutes, and other old stringed

	instruments (considered as part of the Consumer mixtures and miscellaneous consumer articles sector) • Articles and complex objects e.g., bearings, bearing liners, pumps (considered as part of the Machinery applications sector) • Low friction sealings (considered as part of the Sealing applications sector) • Solvents e.g., for cleaning and dissolving purposes (considered as part of the Electronics and semiconductors and Metal plating and manufacture of metal products sectors) • General industrial precision cleaning fluids (considered as part of the Broader Industrial Uses sector) • EEE (electrical and electronic equipment) specialist equipment (considered as part of the Electronics and semiconductors sector) • Hydraulic oils (considered as part of the Transport or Broader industrial uses sectors)
15. Petroleum and mining	The assessment of the Petroleum and mining sector covers the uses of PFAS in petroleum extraction, mining operations, and downstream industries such as refineries, petrochemical plants, carbon capture and storage, and geothermal applications. Note that only non-polymeric PFAS are in the scope of this sector, while polymeric PFAS used in these industries are addressed cross-sectorial. PFAS uses related to Petroleum and mining, but NOT considered as part of this sector: • Piping, tubing, tanks etc. used in the production and transportation of oil and gas (considered as part of the Sealing applications sector) • Sealing devices in petroleum and mining applications e.g., sealants in O-rings, V-rings, gaskets, fittings, and seals (considered as part of the Sealing applications sector) • Anti-corrosive coatings of equipment and infrastructure (considered as part of the Construction products sector and the Machinery applications sector) • Cables, specialised uses in petroleum and mining (considered as part of the Electronics and semiconductors sector) • Membranes, diaphragms, filters etc. in petroleum and mining applications (considered as part of the Technical textiles sector) • Machinery, valves, pumps etc. in petroleum and mining applications (considered as part of the Sealing applications and Machinery applications sectors) • Bearings, skidways etc. in petroleum and mining applications (considered as part of the Machinery applications sector) • Lubrication of equipment (considered as part of the Lubricants sector) • Personal protective equipment (PPE) (considered as part of the TULAC sector) • Explosives in mining (considered as part of the Explosives sector)
16. Printing applications	The assessment of the Printing applications sector covers the uses of PFAS in various specific applications within printing, which are further organised in two use categories: consumables (e.g. toners, latex printing inks, PTFE wax, pigments and colourants, PTFE powders, photosensitive materials, surfactants used in printing equipment) and permanent parts (e.g. electrophotographic press units, kinetic printing components, printing plates (offset and letterpress printing), rollers). It should be noted that 'permanent parts' refer to components that are not consumed during use. However, while they are not used at the rate of consumables, they may still require replacement multiple times throughout the printer's lifespan - in some cases several times per year. PFAS uses related to Printing applications but NOT considered as part of this sector: • PFAS in printing inks, lacquers and coatings that are used for food contact materials (considered as part of the Food contact materials and

	packaging sector) • Solvents for 3D-printing (considered as part of the Broader industrial uses sector) • Lubricants (considered as part of the Lubricants sector) • Printed circuit boards and sensors (considered as part of the Electronics and semiconductors sector) • Components that are used in printing machinery, but are not directly associated with the actual printing process (considered as part of other sectors, e.g. sealing applications are considered in the Sealing applications sector)
17. Sealing applications	The assessment of the Sealing applications sector covers the uses of fluoropolymers (FPs) and perfluoropolyethers (PFPEs) in applications designed to (i) prevent unintended substance migration, (ii) contain pressure, and (iii) avoid contamination. Sealing applications are used across multiple sectors and may entail the use of FPs and PFPEs as substances/mixtures, in the manufacturing of FP/PFPE-containing sealing articles and during their service life as components in complex objects. Examples of sealing applications include seals, gaskets, piping, linings, valve parts, and packing. PFAS uses related to Sealing applications but NOT considered as part of this sector: • Hoses in combustion engines and hose linings in aerospace applications (considered as part of the Transport sector) • Cable linings (considered as part of the Electronics and semiconductors sector) • Vents for electronic components (considered as part of the Technical textiles sector) • PFAS used in the ‘core’ of fuel cells and electrolysers i.e., membrane electrode assemblies (MEA) or similar assemblies (considered as part of the Energy sector) • Sealants and adhesive products for specific construction purposes (considered as part of the Construction Products sector) • Lubrication of dynamic seals related to use cases where PFAS-based lubricants are applied, not the seals themselves (considered as part of the Lubricants sector) • Spare Parts (considered as an overarching issue in Annex E.3.3.)
18. Machinery applications	The assessment of the Machinery applications sector covers uses of fluoropolymers (FPs) and perfluoropolyethers (PFPEs) in industrial process equipment across various sectors, as well as in machinery applied for both professional and consumer uses, when such uses are not covered elsewhere in the Background Document. It includes the use of FPs and PFPEs as substances/mixtures, in the manufacture of FP/PFPE-containing machinery parts, and during their service life as components in complex objects. Examples include self-lubricating/low-friction elements, structural parts, machinery components and parts (e.g. bearings, belts, rollers, etc.) and protective/durable coatings in stationary and portable machinery not covered in the Transport sector. PFAS uses related to Machinery applications but NOT considered as part of this sector: • FP/PFPE coatings e.g., on needles, surgical equipment, tubes (such as implantable probes and stents), endoscopes and medical devices (considered as part of the Medical devices sector) • Wind turbine-blade protection coatings and PTFE nozzles for the quenching of electrical arcs in switchgear (considered as part of the Energy sector) • FP/PFPE used in bridge and building bearings, coatings for metal components, skidways for specific construction purposes (considered as part of the Construction products sector) • PFAS-based lubricant mixtures used for specialised ‘external’ coatings of the contact surfaces of articles where the primary function is to provide low-friction (considered as part of the Lubricants sector)

	• FP/PFPE used in diaphragms and membranes (considered as part of the Technical textiles sector) • Spare Parts (considered as an overarching issue in Annex E.3.3.)
19. Other medical applications	The assessment of the Other medical applications sector covers the uses of PFAS in excipients, immediate packaging and drug delivery devices. Examples include propellants in pressurized metered dose inhalers (pMDIs), excipients in medicinal products for ophthalmic and dermatological therapies, coatings in release liners and backing films for transdermal patches, PFOB as a processing aid in the manufacture of porous particles (excipients in pMDIs), blisters for solid oral dose formulations, coated rubber stoppers for vials/flasks for injectable medicinal products, coated packaging for transdermal patches, fluorinated HDPE packaging (FHDPE) used for some veterinary medicinal products, coated canisters in pMDIs, coated plungers in prefilled syringes, and pre-filled injection pens, and autoinjectors. PFAS uses related to Other medical applications but NOT considered as part of this sector: • Fluoropolymer-coated electronics in pre-filled on-body delivery systems (considered as part of the Electronic and semiconductors sector) • Lubricants in drug delivery devices (considered as part of the Lubricants sector) • Process chemicals (considered as part of the Broader industrial uses sector)
20. Military applications	The assessment of the Military applications sector covers the uses of PFAS (including fluoropolymers and fluorinated gases) in articles intended for military personnel. Examples include fluorinated gases used as refrigerants in military applications, fluorinated gases used in fire extinguishing systems for military vessels, vehicles, and aircraft, as well as other military uses. PFAS uses related to Military applications but NOT considered as part of this sector: • Military electrical systems e.g. coatings and cabling of electronics (considered as part of the Electronic and semiconductors sector) • Military applications of sealing materials (considered as part of the Sealing applications sector) • Military explosives e.g. munitions, flares and explosive charges (considered as part of the Explosives sector) • Military textiles e.g. tents, parachutes, filtration and separation media, medical textiles and textiles used in military vehicles (considered as part of the Technical textiles sector) • Military protective garments, uniforms and personal protective equipment (PPE) (considered as part of the TULAC sector)
21. Explosives	The assessment of the Explosives sector covers the uses of PFAS in products or compositions designed to provide a useful liberation of energy, typically causing a release of heat, light, gas/smoke or a combination of the above. Civil products with uses of explosives include professional/consumer uses (e.g. ammunition for hunting and sport shooting, fireworks, flares) and transport (e.g. safety pyro mechanisms). Additionally, explosives can be used independently in industrial processes such as mining and blasting or in military applications (e.g. large calibre ammunition). PFAS uses related to Explosives but NOT considered as part of this sector: • Related uses of PFAS in petroleum and mining applications (considered as part of the Petroleum and mining sector) • Related uses of PFAS in military applications (considered as part of the Military applications sector) • Related uses of PFAS in transport applications (considered as part of the Transport sector)
22. Technical textiles	The assessment of the Technical textiles sector covers the uses of PFAS in textile materials (such as woven fabrics, knitted fabrics, non-wovens and felts) and textile manufactured products that are used primarily for their technical and functional properties and not for their aesthetic and decorative character. The assessment covers the uses of PFAS in outdoor technical textiles, architectural membranes, other tensile fabrics and other construction applications, filtration and separation media (e.g. virus and contaminant removal membranes and filters in water treatment and water,

	gas/air and other media filtration applications, purification applications), removable covers for industrial process equipment, technical textiles in medical applications (e.g., blood filtration textiles, transducer membranes, sterile ventilation membranes in medical devices, sound-permeable vent filters), and technical textiles for transport vehicles. PFAS uses related to Technical textiles but NOT considered as part of this sector: • Home textiles, including comparable uses in vehicles (such as carpets and seat covers) and public settings, e.g. hospital settings and public transport (considered as part of the TULAC sector) • Consumer apparel (considered as part of the TULAC sector) • Professional apparel and personal protective equipment (PPE) (considered as part of the TULAC sector) • Leather (considered as part of the TULAC sector) • Home fabric treatments (considered as part of the TULAC sector) • Packaging (considered as part of the Food contact materials and packaging sector) • Optical fibre weaving solutions for lighting applications in health, costumes, automotive, safety, environment, communication, architecture and industrial applications (considered as part of the Electronics and semiconductors sector) • Latex printing inks, including applications for printing on textiles (considered as part of the Printing applications sector) • Solvents for dry-cleaning of textiles (considered as part of the Applications of fluorinated gases sector) • Uses of PFAS in electrical components, sealing applications or machinery applications related to the manufacture of textiles or textile products (considered as part of the Electronics and semiconductors, Sealing applications and Machinery applications sectors respectively) • Conveyor belts (considered as part of the Machinery applications sector) • PTFE fibres/yarns used for the manufacture of braided packings for sealing applications (considered as part of the Sealing applications sector) • Use of PTFE in chemically inert fabrics used by the chemical and petrochemical industry for flange protection (considered as part of the Sealing applications sector) • Coating of fabric expansion joints (considered as part of the Sealing applications sector) • Uses of PFAS in relation to textiles used for self-lubricating /low-friction purposes (considered as part of the Machinery applications sector) • Uses of PFAS for textiles used for anti-adhesive/release purposes (considered as part of the Machinery applications sector) • Fuel-cell membranes and ion-exchange membranes for the manufacture of chemicals via electrolysis (considered as part of the Energy sector)
23. Broader industrial uses	The assessment of the Broader industrial uses sector covers the uses of PFAS in hydraulic fluids (if not covered under the Transport sector), solvents (solvents and reaction media for precision cleaning, extraction solvents and 3D printing), and catalysts and processing aids (catalytic reaction media and processing aids, including ionic liquids). These uses apply across different use sectors involving different actors (producers and users) along the supply/value chain. PFAS uses related to Broader industrial uses but NOT considered as part of this sector: • Precision cleaning in electronics and semiconductor manufacturing (considered as part of the Electronics and semiconductors sector)

	• Hydraulic fluids in transport (considered as part of the Transport sector, mainly for aviation) • Analytical and laboratory applications (considered as an overarching issue, please see the explanatory notes of the main report of the Background Document and in particular the sub-heading '*Scientific research and development*') • Engineered fluids: Fluids used for lubrication (considered as part of the Lubricants sector), cooling applications (considered as part of the Electronics and semiconductors sector), or precision cleaning agents (partly considered as part of the Broader industrial uses sector, partly considered as part of the Electronics and semiconductors sector) • Heat transfer fluids for immersion cooling and cold plate cooling (considered as part of the Electronics and semiconductors sector) • Engineered fluids for diagnostic laboratory applications (considered as an overarching issue, please see the explanatory notes of the main report of the Background Document and in particular the sub-heading '*Scientific research and development*') • Coatings for metals (considered as part of several different sectors, e.g. anti-acid coatings for metals are considered as part of the Metal plating and manufacture of metal products sector) • Solvents e.g., for cleaning and dissolving purposes (considered as part of the Electronics and semiconductors and Metal plating and manufacture of metal products sectors) • Solvents for dry-cleaning of textiles (considered as part of the Applications of fluorinated gases sector) • Carrier solvents for lubricants (considered as part of the Lubricants sector)

ANNEX II

Detailed analysis of degradability of PFAS proposed to be excluded from the scope

The Dossier Submitter indicates that specific PFAS types (i.e. trifluoromethanol, trifluoromethylamine and difluoromethanediol) are inherently unstable and therefore more complex molecules containing these moieties will also degrade. It supports this initial claim with various publications (e.g.: (Christe et al., 2007; Redwood and Willis, 1965; Seppelt, 1977; Taniguchi et al., 2003, Klöter and Seppelt, 1979, Francisco, 1993) on the fate of CF_3OH, CF_3NH_2 and $CF_3(OH)_2$. Later the Dossier Submitter provides experimental data with more complex substances containing these moieties to prove their hypothesis.

It is to be noted that the Dossier Submitters have not concluded that all substances in these PFAS subgroups are non-persistent, as they might contain non-perfluorinated moieties which could show some persistence themselves, but the persistence in such cases would not follow from the PFAS-fragments and the PFAS chemistry. This is explained to be different from the PFAS subgroups included in scope, that are either highly persistent themselves, or contain PFAS elements that warrant persistent arrowhead substances to be formed.

RAC has evaluated the information provided to justify the exclusion of certain PFAS subgroups looking at both to the degradation potential of trifluoromethanol, trifluoromethylamine and difluoromethanediol and of more complex molecules containing these moieties. RAC evaluations are based on Annex XIII REACH criteria for Persistency Assessment and ECHA Guideline R11.

For the case of trifluoromethanol, RAC notes that different publications have examined via modelling the fate of this substance in the atmosphere (e.g.: Buszek and Francisco 2009, Parandaman et al 2018, Long et al 2010, Nguyen et al 2008). Scientific data shows that trifluoromethanol rapidly transforms into carbonyl difluoride and HF. For instance, Nguyen et al 2008 derived rate constants (k) for different decomposition pathways of CF3OH. For the most likely decomposition pathway a first order k constant of 10^{-2} s^{-1} was determined with a calculated half-life of less than one minute in the gas phase, whereas for another likely decomposition pathway a much smaller first order k constant of merely 10^{-9} s^{-1} was derived. Other authors provide much slower decomposition kinetics (see Parandaman et al 2018 who reports first order k values of 10^{-8} seconds or lower). RAC notes that the different degradation rates found in literature points to the fact that CF_3OH likely disappears fast in the atmosphere, although the rate of degradation can be slow depending on the presence of catalysts. It remains therefore uncertain how fast CF_3OH 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 and therefore photolysis of CF_30H is insignificant (Buszek and Francisco 2009).

Further, although RAC recognizes that carbonyl fluoride [C(O)F2], a degradation product of trifluoromethanol, is not a PFAS compound, this substance is toxic and its half-life in the environment is not clear. Whereas Uchimaru et al. (2004) reports a hydrolysis first order reaction coefficient of 3.3 s-1, in Figure B.41. of the report, the Dossier Submitter indicates that the residence time of carbonyl fluoride can be five years. Further, Wallington et al 1994 indicates that the potential lifetime of this substance in the ocean could be up to two years.

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. Assuming that CF_3OH, CF_3NH_2 and $CF_3(OH)_2$ degrade fast in the atmosphere, this only 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.

The Dossier Submitter also provides data on degradability of Trifluoromethanol derivatives. The hypothesis is that a larger molecule containing a trifluoromethoxy-group attached to a degradable moiety (CF3-X, where X = -OR and where R = methyl (-CH3), methylene (-CH2-), an aromatic group or a carbonyl group (-C(O)-)) is expected to degrade with formation of trifluoromethanol.

The studies presented with trifluoromethanol derivatives show that the substances tested defluorinate and degrade under the test conditions (see Peschka et al 2008, Fromel and Knepper 2015 or (soil degradation study)). However, except for the test performed according to Guideline OECD 307, the inherent test performed by Peschka et al 2008 and hydrolysis data provided by Schiesser et al 2020, experiments provided are of limited relevance for Persistence Assessment according to REACH. They could be used as part of a weight of evidence approach

In **Peschka et al 2008**, 10-(trifluoromethoxy)decane-1-sulfonate was inherent biodegradable in a Zahn-Wellens test with a degradation > 75% in less than 28 days. As the degradation was not ≤20% the results do not suggest that degradation in the environment would be slow (ECHA guidance R.11). Unfortunately, based on the information provided in the Peschka paper, 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 mineralization within 7 days, the length of the log phase, and the percentage removal before degradation starts are not specified in the paper (see ECHA Guideline R-11). General study details were also limited to allow comparison of test conditions and results against guideline requirements. Therefore, RAC considers that it is not possible to make definite conclusions on persistence based on this study.

In the fixed-bed bioreactor tests (FBBR) performed also from Peschka et al 2008, results showed that the substance defluorinated more than 60% by day 70 (less than 60% by day 28). Two degradation pathways were proposed, one of them (minor degradation pathway accounting for ca. 10% of the total amount) lead to the formation of oxo-10-(trifluoromethoxy)decane-1-sulfonate) whose degradation was quite slow. This stands in coherence with the slow release of fluoride at the end of the experiment, i.e. between days 43 and 87.

RAC notes that in terms of standardised test conditions recognised in REACH for persistence determination, it is not possible to benchmark the results of the FBBR studies. It is also relevant to consider that FBBRs favour biodegradation and are an efficient method (hosting a high density of microbes in a small area) for treating waters with medium to high BOD. Yet, under these favorable conditions for degradation the substance degraded into a PFAS metabolite which could be potentially vP due to the C-F bond. Based on the above and given the uncertainties described for the inherent test it is not possible to reach definite conclusions on the non persistence (P/vP) of the proposed substance.

In **Fromel and Knepper 201**5, two substances (6-(trifluoromethoxy)-hexan-1-ol (TFMHxOH) and 3-(trifluoromethoxy)-propan-1-ol (TFMPrOH)) were tested under test conditions that RAC cannot unequivocally relate to any of the guidelines used to evaluate the persistence of chemicals according to Annex XIII of REACH since the level of reporting is not detailed enough. In addition, considering that the experiments were carried out under aerobic conditions with effluent water from a municipal wastewater treatment plant it is not possible to obtain half-lives for directly comparing to Annex XIII criteria from this study.

Results show that 6-(trifluoromethoxy) hexan-1-ol (TFMHxOH) was almost completely mineralized after 37 days as judged from the fluoride release. Two acidic transformation products were detected for TFMHxOH, 6-(trifluoromethoxy)hexanoic acid (TFMHxA) and trifluoromethyl carbonate (TFMC). Both compounds were generated rapidly with TFMC showing a maximum after only four days and no signal after 11 days. TFMHxA showed its maximum concentration after five days and was completely degraded (mineralised) afterwards showing complete degradation also after 11 days.

On the contrary, 3-(Trifluoromethoxy)-1-propanol (TFMPrOH) only mineralised to the extent of 15% and transformed into a metabolite (3-trifluoromethoxy-propanoic acid (TFMPrA)) which did not show any further degradation under these conditions within a 47 days period. This metabolite is a PFAS and could be very persistent in the environment. RAC notes that the study authors indicated that the reason for the dissimilar stability of TFMHxA and TFMPrA could not be entirely explained with the knowledge obtained. *"One possible reason could be a different accessibility of the methylene group in vicinity to the TFM group in the two compounds. In TFMPrA, the methylene group might be shielded by the polar carboxylic acid function, so that it cannot be hydroxylated enzymatically, which in turn could be possible in TFMHxA, where the carboxylic acid group is separated by more methylene groups. However, these suggestions remain speculative unless one or several transient transformation products are detected in other studies."*

The Dossier Submitter indicated that based on the chemical structure of TFMPrA, it should not be regarded as an arrowhead, but rather a relatively stable intermediate that is likely to mineralize under environmentally relevant conditions over time. To support this assertion in the Dossier Submitter utilized EAWAG-BBD pathway prediction. However, RAC's analysis of EAWAG-BBD for TFMPrA flagged a warning, stating, *"The rules used by the PPS do not accurately predict the unique characteristics of these materials. All per- and highly-fluorinated chemicals should not have their biodegradation predicted."* Similar findings were observed with CATALOGIC software, which deemed the substance beyond its applicability domain. Consequently, RAC concluded that these predictions lack reliability to supersede test results.

Overall, RAC notes that test conditions, duration and concentrations do not allow a comparison of this study with any of the accepted test methods used for persistence assessment in accordance with Annex XIII of REACH, making interpretation of the results difficult. Whereas 6-(trifluoromethoxy) hexan-1-ol (TFMHxOH) was almost completely mineralized after 37 days suggesting this substance could degrade in the environment, results show that TFMPrOH only mineralises to the extent of 15% and transforms into a metabolite (3-trifluoromethoxy-propanoic acid) which did not show any further degradation under these conditions within a 47 days period. Based on this, RAC considers this study contradicts the Dossier Submitter Hypothesis that *trifluoromethoxy-derivatives* can be labelled as "fully degradable" PFAS for which very persistence concerns do not exist. this trifluoromethoxy-derivative.

Another study provided by the Dossier Submitter evaluates the metabolism of OSI 390 **(Dihel et al 2009).** RAC notes that mammalian metabolism studies could be informative for environmental persistence evaluation of substances but not conclusive. In the present restriction proposal, the information refers to xenobiotic metabolism of mammals, and no justifications are presented that the same metabolism would occur e.g., by micro-organisms.

During the consultation to the Annex XV report a study according to OECD 307 with a trifluoromethoxy derivative radio-labeled directly at the CF3- group was provided (confidential comment).

Study findings:

The study revealed that the substance mineralised in the three soils tested by day 28. The mass balances were adequate during the 28 days. For the extended sampling lower mass balances were observed together with unusually high radioactivity values in the second NaOH trapping solutions. For each application group, the amount of CO2 at 56/57 DAT was lower than the one at 28 DAT. According to the authors, this indicates that the low mass balances at 56/57 DAT are caused by losses of CO2 due to the insufficient capacity of the NaOH trapping solutions to capture the still evolving ^{14}CO2.

The non-extractable residues peak at 2-6 days and then decreased to some extent after 56/57 days. The study authors explain that this indicates that part of the parent test item was bound to the humic matrix in soil. However, the proceeding defluorination and mineralization (increasing CO2-levels) would show that this does not stop the further degradation of trifluoromethoxy-group but just slows it down to a certain extent.

In the original study, DegT50s were calculated using the parent concentration decline in the test system and considering NER as degraded parent substance using SFO as the best fitting model. This led to DegT50s < 6 at 12 degrees, well below the P criteria according to Annex XIII of REACH. The authors of the study propose as a degradation pathway the release of carbon dioxide and the formation of non-extractable residues which would further degrade to CO2.

In the evaluation of extractable residues, the authors of the study indicate that beside the parent compound, a few unknown metabolites were detected, but all below levels of 0.2% TAR. No further characterization of non-extractable residues was performed.

RAC has evaluated the study results following the advice provided in Guideline R.11: PBT/vPvB assessment (ECHA, 2023b). First, following comments provided by a RAC member, RAC has looked to whether the mineralisation half-life for the whole system is below the respective half-life value of P/vP criteria. In such a case, the substance would be considered not persistent in the tested environmental compartment, although an investigation of degradation pathways/transformation/degradation products would be needed since it cannot be excluded that a second transformation route forms a persistent transformation/degradation product in concentrations relevant for the P assessment. For this RAC has derived mineralisation half-life (based solely on CO2 evolution) for the whole system at days 0-28 and 0-56.

Second, RAC has calculated a DegT50s based on CO2 evolution. In addition, RAC calculated a DegT50 considering NERs as non-degraded parent substance since NERs were not characterised. This aligns with ECHA Guidance R.11 which indicates that "in the context of persistence assessment, the Total NER is considered as a non-degraded parent substance unless further characterisation of the Total NER is performed."

Recalculations were done following FOCUS Kinetic Guideline 2014 and the model CAKE:

Recalculations based on CO2 evolution for 28 days

- In soil 1, the FOMC, DFOP, and Hockey Stick (HS) models exhibited superior visual fits over the Single First Order (SFO) model, with HS displaying the most favourable fit. HS results in a lower chi-square value (4.5) compared to SFO (8.16), FOMC (5.79), and DFOP (5.72). Although DFOP's slow phase yielded a DegT50 of 78.1 days, potentially suggesting persistence, it failed the t-test. Conversely, HS's slow phase yielded a DegT50 of 21.9 days, deemed the most accurate estimation.
- In soil 2, the best visual fit is obtained with FOMC, DFOP and HS. None of the models predict a DT50 higher than the P/vP criteria.
- Similarly, in Soil 3, FOMC, DFOP, and HS models exhibited the best visual fits, with

DFOP and HS outperforming. Modelling results show a bi-phasic CO2 evolution for this soil. DFOP failed the t-test for k2. HS, however, passed the t-test, yielding a k1 DegT50 of 3.72 days, below the P criteria and k2 DegT50 of 87.6 days, which at 12 degrees is 166 days exceeding the P criteria at 12 degrees.

In soil 3, fitting biphasic models to cumulative $^{14}CO_2$ over 0–28 days results in a k1 DT50 below the P criterion and a slow-phase DegT50 (HS) corresponding to 166 days at 12 °C. The CO_2 time course shows that >50% mineralisation is reached early (by approximately day 7–10), followed by a plateau with only limited additional CO_2 formation. RAC notes, however, the slow-phase DegT50 derived from cumulative CO_2 needs to be interpreted with caution. As explained in OECD Guideline 309, *"when the 14C-labelled part of an organic substance is biodegraded, the major part of the 14C is converted to 14CO2, while another part is used for growth of biomass and/or synthesis of extra-cellular metabolites. Therefore, complete "ultimate" biodegradation of a substance does not result in a 100% conversion of its carbon into 14CO2. The 14C built into products formed by biosynthesis is subsequently released slowly as 14CO2 due to "secondary mineralisation". This complicates a kinetic interpretation of the data and for this purpose, only the initial part of the curve (after ended lag phase and before approx. 50% degradation is reached) should normally be used for the estimation of a degradation rate constant."*

Recalculations based on CO2 evolution for 56 days

- In soil 1 SFO resulted in a bad visual fit and a chi square of 15%. The model was discarded. DFOP and HS have the best visual fit and lower chi-square (6.05 and 6.99%) in comparison to FOMC (8.56). DegT50 of FOMC is 9.22. DegT50s for DFOP and HS are above 10000 but they fail the t-test reflecting that from day 28 to day 56 CO2 evolution does not increase but plateaus or even decreases.
- For soil 2 and 3 a similar situation to the one of soil 1 occurs.

RAC notes that the t-test likely fails in the above calculations because CO2 evolution did not increase from day 28 to day 56, and the model accurately represents this lack of variation.

Recalculations with Parent + Ners:

An acceptable single-first order fitting was not possible, the biphasic kinetic models (HS, DFOP) were the best-fit models, based on visual assessment, X^2 values and t-test values Recalculations lead to the following results:

- For soil 1 (Li10) recalculation results in a DegT50 = 74.2 days at 20 degrees = 140 days at 12 degrees, with HS as best model.
- For soil 2 (Lufa 2.2) DegT50 = 90.5 at 20 degrees = 171 days at 12 degrees, with DFOP as best model
- For soil 3, Lufa 2.4, DegT50 = 108 days at 20 degrees = 204 days at 12 degrees, with HS as best model.

RAC interpretation and conclusion

The study shows rapid and extensive mineralisation of the CF3-labelled moiety and the parent can be considered not P/vP in soil based on the mineralization half-lives calculated from 0-28 days (see above explanation on tailing effect). Also, DegT50 values calculated from the decline of parent substance concentration are below the Annex XIII P/vP thresholds.

Further evidence is that the significant mineralization coupled with the limited formation of metabolites suggests that the NERs may lack substantial quantities of the parent compound or transformation products featuring a -CF3 group. In addition, the extraction method used was limited to solvent extraction and did not include exhaustive extraction methods like pressurized liquid extraction. This limitation could have led to an overestimation of NERs.

However, some uncertainties exist mainly due to the substantial NER 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 -CF3 group. Further, when considering the total NERs as non-degradable parent substance the Parent+NER modelling gives a $DegT_{50}$ above the P trigger in one soil.

Therefore, while the parent shows rapid degradation and can be considered not P/vP in soil based on the mineralization 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.

For **trifluoromehylamino derivatives** the Dossier Submitter only presented an experiment **(Schiesser et al 2020)** were the hydrolytic stability of twelve trifluoromethylamino-derivatives and N-Trifluoromethyl azoles in aqueous media was investigated. RAC notes this study shows that N-trifluoromethyl amines are prone to hydrolysis, whereas N-trifluoromethyl azoles have excellent aqueous stability. Data also shows that several trifluormethyl amines transformed into carbamoyl fluoride which is no longer a PFAS. Others, however, such as N-trifluoromethyl piperazine transformed into secondary amine. The identity of the secondary amines formed are unknown to RAC, additionally it is unknown if they still contain a perfluorinated moiety and whether they decomposed fast.

RAC further notes that according to the PBT Guidance R11, concern for P/vP cannot be ruled out by significant and substantial loss of the parent substance by hydrolysis alone. Additional evidence is also needed to examine the persistence of the degradation products, whether the fate properties of the substance would cause attenuation of the hydrolysis rate in sediment or soil, or whether DOC would similarly affect the rate in aquatic media such as river or sea water. There are substances reaching rapid hydrolysis rates which are well known to be persistent or very persistent in soil and/or sediment, e.g. endosulfan and Octamethylcyclotetrasiloxane (D4) (ECHA, 2015). Therefore, rapid hydrolysis rates cannot alone lead to concluding that a substance is not persistent. RAC cannot therefore reach a firm conclusion on the basis of this study alone.

Finally, for confirmation of the degradation of **Difluoromethanediol** derivates, the DS presented a mechanistic study by **(Bygd et al., 2021)**, where the microbial degradation of model compound 2,2-difluoro-1,3-benzodioxole (DFBD) by *Pseudomonas* strains was investigated. In this study, wild-type cells of P. putida F1 were grown on toluene vapors to induce toluene dioxygenase and related enzymes. Bacteria expressing toluene dioxygenase, were able to degrade the substance and a rapid fluoride release was observed that declined within hours. RAC agrees with the authors of the paper that their study demonstrates degradation only under certain conditions and after having induced toluene dioxygenase. RAC further notes that the study does not allow for any comparison with standard degradation test considered for Persistence analysis and is not environmentally relevant and therefore not adequate to conclude that the substance is not very persistent.

The study by **Alexandrino et al. (2020)** reports the degradation of fludioxonil by enriched microbial consortia from estuarine sediment and agricultural soil. After an enrichment period of 6 months, four microbial consortia were able to completely remove and defluorinate the fungicide in co-metabolic conditions. RAC agrees with the authors of the paper and considers it relevant for bioremediation but not to evaluate persistence criteria following the requirements of Annex XIII of REACH. RAC also notes that for the harmonised classification of Fludioxonil the substance was considered hydrolytically stable and not readily biodegradable (ECHA, 2017). Degradation half lives in sediment were considered to be 1326 and 855 days at 12 °C, and 502 days in soil. Further, according to EFSA Journal 2007, "Conclusion regarding the peer review of the pesticide risk assessment of the active substance fludioxonil" fludioxonil is high to very high persistent in soil (DT50 lab 20ºC = 119 – 599 days) (EFSA, 2007). A very limited amount of metabolites was formed. This would lead to the consideration of the substance as vP.

Data pertaining to **Flurprimidol (see EFSA 2011),** an additional pesticide not covered in the initial assessment performed by the Dossier Submitter but that would fall under the exemption, reveals the substance is stable to hydrolysis and is not ready biodegradable. The route of degradation of flurprimidol in soil was investigated at 20 degrees under dark aerobic conditions in two studies with a total of seven soils (pH 6.0 – 8.3; OC 0.9 – 41.9 %; clay 7 – 38.4 %) with flurprimidol ^{14}C labelled at the phenyl ring. In the first study, four metabolites were found. of the metabolites (M1 and M2)9 exceeded 5 % AR in two consecutive data points. These metabolites were not adequately characterized and a data gap was identified for an adequate route of degradation. The rate of degradation of the substance was calculated to range from 98 to 183 days under aerobic conditions at 20 degrees Celsius, or 185 to 347 days at the environmentally relevant temperature of 12 degrees Celsius. As for the case of fludioxonil, this result suggests that vP substances could be regrettably exempted. RAC notes however that in this case, study results did not allow to ascertain whether the associated persistence is related to parent, to a PFAS metabolite or to a non PFAS metabolite.

Overall, RAC acknowledges the weight of evidence presented by the Dossier Submitter, suggesting that some PFAS substances within the exemption group may not exhibit the very persistent properties typically associated with PFAS (at least in some environmental compartments e.g., soil, which is the primary concern for restriction. Moreover, the evidence suggests that there are PFAS substances that may not be persistent (e.g., soil). However, RAC disagrees with the Dossier Submitter that the available evidence leads to the conclusion that all PFAS from the subgroups described above are expected to fully mineralize in the environment and do not have any vP concern warranting a broad exemption.

RAC notes for excluding the P/vP concern and disregard 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. 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. 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 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 persistent or very persistent themselves. Following the above, RAC does not support the group exemption proposed by the Dossier Submitter.