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

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, CF₄, CHF₃, C₂F₆) and for inorganic fluorine. The LOQs for C1-C3 fluorocarbons in gaseous samples were up to 40 µg/m³ (corresponding to an RF in the order of 0.05%), for trifluoroacetic acid 30-90 ng/m³ and for the rest mostly in the low ng/m³ 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/m³ 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 Al₂O₃ and SiO₂).

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 C₂F₆, 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 CF₄ and C₂F₆ 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 CF₄. CF₄, measured with reporting limits in the order of units of µg/m³, was detected at highest levels in the runs with fire-fighting foam and nine spiked PFAS, up to 16 µg/m³ by FTIR or 6 µg/m³ by GC-MS. It can be estimated (based on data in Appendix A, tables A-1-2 and A-2-6) that these CF₄ concentrations correspond a release factor in the order of 0.01% to 0.02%. C₂F₆ was detected by FTIR in one C₂F₆-spiking run at 7 µg/m³. Other substances in the exhaust gas were mostly below the reporting limits or below 1 µg/m³.

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

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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 Gehrman 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 Gehrman 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 Gehrman 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

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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 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 CO₂), 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

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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%

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(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

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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 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.

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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 of microplastics, 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

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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

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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

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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

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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

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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

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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

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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 ($>1\,000\text{ }^{\circ}\text{C}$) 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

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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 PFSAAs 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 matrixes such as drinking water, WWTP effluents, waters close to point-sources, and precipitation (Aro et al., 2021; Björnsdóttir 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.

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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 TOPA¹³ 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

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.

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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 dashboard¹⁴ 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

¹⁴ <https://www.hbm4eu.eu/>

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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

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70 000 t/year¹⁵ (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.

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.

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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

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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

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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 model¹⁶ 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

¹⁶ <https://publikationen.dguv.de/widgets/pdf/download/article/3737>

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"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

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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).

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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-

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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

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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 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

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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:

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- 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,

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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 installations, 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 packaging 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

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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):

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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 RO3b¹⁷ 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

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

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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):

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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.

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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	
PFAS manufacturing	50 532	51 736	48 795	49 961 (97%)	45 324	44 950 (89%)
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%)

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	Effectiveness					
Manufacturing and use sectors	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	
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%)

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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	
<i>(14 sectors + PFAS manufacturing)</i>						Total PFAS emission reduction as calculated by RAC***
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

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Effectiveness						
Manufacturing and use sectors	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***
	9 618	Not evaluated in detail	9 228	Not evaluated in detail	6 556	Not evaluated in detail
	250 544	Not evaluated in detail	238 670	Not evaluated in detail	187 331	Not evaluated in detail
	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 batteries.

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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).

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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

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

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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

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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

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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

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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 in 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

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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

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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

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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/EC¹⁹, 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

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

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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 PPORD²⁰ states that examples of SR&D may include any experimental research or analytical activities at a laboratory scale such as synthesis and testing of

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

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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

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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/EU and 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.

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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 ($\mu\text{g}/\text{kg}$) 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 ($\mu\text{g}/\text{kg}$), 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

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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

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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.

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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):

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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

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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 ($\mu\text{g}/\text{kg}$) 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 ($\mu\text{g}/\text{kg}$), 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.

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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

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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.

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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