Committee for Risk Assessment (RAC)

Opinion

on an Annex XV dossier proposing restrictions on

Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances

ECHA/RAC/RES-O-0000006229-70-02/F

Adopted

8 September 2015

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Opinion of the Committee for Risk Assessment

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

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation on the proposal for restriction of

Chemical names:	**Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances**
EC No.:	**206-397-9**
CAS No.:	**335-67-1**

This document presents the opinion adopted by RAC. The Background Document (BD) provides support to both RAC and SEAC opinions, giving the detailed ground for the opinions.

PROCESS FOR ADOPTION OF THE OPINIONS

Germany and Norway have submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at: http://echa.europa.eu/web/guest/restrictions-under-consideration on ***17 December 2014***. Interested parties were invited to submit comments and contributions by ***17 June 2015***.

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: ***Bert-Ove LUND***

Co-rapporteurs, appointed by RAC: ***Frank JENSEN and Stephen DUNGEY***

The RAC opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment has been reached in accordance with Article 70 of the REACH Regulation on ***8 September 2015***.

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

The RAC opinion was adopted ***by consensus***.

THE OPINION OF RAC

Original proposal by the Dossier Submitter:

Perfluorooctanoic acid (PFOA, CAS 335-67-1, EC 206-397-9), including its salts and any other substance having linear or branched perfluoroheptyl derivatives with the formula C_7F_{15}- as a structural element, including its salts except those derivatives with the formula C_7F_{15}-X, where X= F, Cl, Br and any other substance having linear or branched perfluorooctyl derivatives with the formula C_8F_{17}- as a structural element, including its salts, except those derivatives with the formula C_8F_{17}-X, where X= F, Cl, Br or, C_8F_{17}-SO_2X', C_8F_{17}-C(=O)OH or C_8F_{17}-CF_2-X' (where X'=any group, including salts)	1. Shall not be manufactured, used or placed on the market - as substances, - as constituents of other substances in concentrations equal or above 2 ppb of a single substance, - in a mixture in concentrations equal or above 2 ppb of a single substance 2. Articles or any parts thereof containing one of the substances in concentrations equal to or greater than 2 ppb of a single substance shall not be placed on the market. 3. Paragraph 1 and 2 shall apply from (18 months after entry into force). 4. By way of derogation, paragraph 2 shall not apply to the placing on the market of second-hand articles which were in end-use in the European Union when the restriction becomes effective.

RAC has formulated its opinion on the proposed restriction based on information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction on ***perfluorooctanoic acid (PFOA), its salts[1] and PFOA-related substances*** is the most appropriate EU wide measure to address the identified risks in terms of the effectiveness in reducing the risks provided that the scope and conditions are modified.

The conditions of the restriction proposed by RAC are:

Perfluorooctanoic acid (PFOA, CAS 335-67-1, EC 206-397-9) and its salts. Any substance (including salts and polymers) having a linear or branched perfluoroheptyl group with the formula	1. Shall not be manufactured, used or placed on the market: - as substances, - as constituents of other

[1] In the rest of the opinion document, when referring to PFOA this also includes it salts.

$(C_7F_{15})C-$ as one of the structural elements[2,3]. Any substance (including salts and polymers) having a linear or branched perfluorooctyl group with the formula $C_8F_{17}-$ as one of the structural elements[3]. The following substances are exempted from the above two paragraphs: $C_8F_{17}-X$, where X= F, Cl, Br. $C_8F_{17}-C(=O)O-X'$ or $C_8F_{17}-CF_2-X'$ (where X'=any group, including salts).	substances in concentrations equal to or greater than 25 ppb of PFOA or its salts or 1000 ppb of one or a combination of PFOA-related substances identified in column 1, - as components of a mixture in concentrations equal to or greater than 25 ppb of PFOA or its salts or 1000 ppb of one or a combination of PFOA-related substances identified in column 1. 2. Articles or any parts thereof containing one of the substances identified in column 1 in concentrations equal to or greater than 25 ppb of PFOA or its salts or 1000 ppb of one or a combination of PFOA-related substances shall not be placed on the market. 3. Paragraphs 1 and 2 shall apply from (18 months after entry into force). 4. By way of derogation, paragraphs 1 and 2 shall not apply to Perfluorooctane sulfonic acid and its derivatives (PFOS) covered by the Regulation (EC) No 850/2004. 5. By way of derogation, paragraph 1 shall not apply to: a) the use of substances containing one or more constituents identified in column 1, as transported isolated intermediates where the conditions in Article 18(4) are met. b) the production, placing on the market and use of substances and mixtures containing one or more substances identified in column 1 for mixtures used in

[2] In the case where a substance contains structural elements both inside and out of scope, then the substance is still within the scope.

[3] These substances are known as PFOA-related substances.

	semiconductor photolithography processes. 6. By way of derogation, paragraph 2 shall not apply to: a) the placing on the market of second-hand articles for which an end-use in the European Union before the restriction becomes effective can be demonstrated. b) the placing on the market of articles produced from recycled articles. c) photographic coatings applied to films, papers or printing plates nor to the substances and mixtures needed to produce them. d) implantable medical devices as defined by Council Directive 93/42/EEC.

JUSTIFICATION FOR THE OPINION OF RAC

IDENTIFIED HAZARD AND RISK

Description of and justification for targeting of the information on hazard and exposure (scope)

In addition to PFOA, the restriction proposal includes 'PFOA-related substances'[4], i.e. substances that, based on their molecular structure, are considered to have the potential to degrade or be transformed to PFOA. They are more precisely defined as substances with linear or branched perfluoroheptyl- or perfluorooctyl- chains (in general terms, they may be referred to as C-8 fluorochemicals). There are some exceptions to the definition (detailed in the proposed restriction entry) where the molecular structure is expected to prevent transformation to PFOA.

RAC supports this proposal for substance identification, since it effectively captures the substances considered to be of concern, but excludes those that are not. For example, the proposal includes side-chain fluorinated polymers (as they are consistent with the definition of a PFOA-related substance). The substance identification, however, does not include fluoropolymers (i.e. polymers with a fluorinated carbon backbone), unless they contain PFOA or PFOA-related substances as an impurity greater than the prescribed threshold[5] or side-chains with a structure that is consistent with the definition above of a PFOA-related substance. RAC notes that the EU restriction of PFOS uses a similar type of wording for a similarly broad scope, and that an industry stakeholder has also recommended an 'open list' approach during the public consultation.

Description of the risk to be addressed by the proposed restriction

The restriction proposal is based on the PBT properties of PFOA. No relevant quantitative environmental risk assessment can as such be conducted for PBT substances (REACH Guidance R.11.1 page 10, version 2.0, 2014), so the overall intention is to minimise emissions. Any environmental exposure has the potential to give rise to risks (including indirect risks to the general public because of potential long-term effects on the food chain). Information on environmental emissions (supported by environmental monitoring data) for PFOA and PFOA-related substances are therefore used as a proxy for potential risk. Hhuman biomonitoring data can to some extent be used as a proxy for emissions, as indirect exposure via food and drinking water is an important source of PFOA for humans (beside direct exposure via specific articles or uses).

The restriction proposal also contains a quantitative risk assessment for human health as supporting information. This is limited to specific uses and is presented separately from the environmental assessment.

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[4] 'PFOA-related substances' are also referred to as 'PFOA-precursors' in the scientific literature, and Commission Regulation (EU) No. 757/2010 uses the term 'PFOS and its derivatives' to include PFOS-related substances/PFOS-precursors.

[5] As specified in the proposal from RAC: greater than 25 ppb of PFOA or its salts or 1000 ppb of one or a combination of PFOA-related substances.

Assessment of environmental risks

Information on hazard(s)

The PBT properties of PFOA are not discussed further in this opinion as there is already an EU agreement on PFOA fulfilling the PBT criteria, that is, that PFOA is persistent, bioaccumulative and toxic (see Section B.4.3 of the restriction proposal and the Member State Committee (MSC) opinion for identification of PFOA as an SVHC, June 2013). There is no indication of new data challenging the 2013 opinion from MSC.

RAC notes that decabromodiphenyl ether (decaBDE) was added to the Candidate List because of its ability to degrade or transform to lower molecular weight polybromodiphenyl ethers (PBDEs) that have PBT/vPvB properties. The Member State Committee opinion for that substance states that "*there is a high probability that decaBDE is transformed in the environment to form substances which themselves have PBT/vPvB properties, or act as precursors to such substances, in individual amounts greater than 0.1% w/w over timescales of a year*." Whilst the MSC did not explicity consider whether PFOA-related substances meet the PBT criteria in its opinion on PFOA, RAC considers that it is scientifically consistent to apply the logic of the decaBDE opinion to PFOA-related substances (including side-chain polymers).

Information on emissions and exposures

Scope of substances

The REACH Regulation does not distinguish between different PBT or vPvB substances once they are identified. However, the rate and extent of transformation of substances to form PBT or vPvB substances under different environmental conditions are relevant considerations during risk assessment, at least on a scientific basis, and subsequently for assessing the proportionality of the risk reduction that would be achieved by any risk management.

It is estimated that in total 40 tonnes of PFOA are imported into the EU annually, partly as pure substance (20 tonnes), partly as a component in mixtures and in articles (10 tonnes each). The use of PFOA has been observed to progressively decrease over time and reasonable estimates of environmental emissions are currently in the order of a few tonnes per year. PFOA-related substances however, are used in quantities which are orders of magnitude greater than PFOA itself and are therefore of considerable interest. An assessment of the significance of PFOA-related substances to the overall environmental load of PFOA requires an understanding of both the proportion of parent substance that is likely to transform to PFOA in the environment (yield as % or mol %) and information on how rapidly this could occur (for example, over a period of months, years or decades).

Following the approach used previously by the MSC in its opinion on decaBDE, RAC has used the criterion of 0.1% w/w minimum transformation or degradation per year as a threshold for considering which PFOA-related substances should be within the scope of this proposal.

The available information on the transformation or degradation of PFOA-related substances is described in the sub-sections below. There is a great diversity in the available data, both in terms of the type of study (e.g. the substance considered, the environmental compartment, duration and the experimental conditions).

A range of transformation or degradation rates has therefore been estimated for individual substances (where there is sufficient data, such as for 8:2 fluorotelomer alcohol) or for

groups of similar PFOA-related substances (i.e. 8:2 fluorotelomer derivatives, polyfluoroalkyl phosphates [PAPs] and side-chain fluorinated polymers).

In addition, a typical degradation or transformation rate has been chosen for each substance or group of substances for use in further calculations of potential emissions. Although comprehensive standardised data for all relevant media, over an appropriate time frame, are not available for any substance or group of substances, these estimates should be interpreted as reliable; ranges are given to indicate the level of variability of the data. In addition, in some of the pathways described below there is potential for the identified degradation product(s) to further degrade to PFOA over time, so that the reported degradation rates might underestimate the total amount of PFOA formed over the relevant time period. Thus, the typical values are not worst-case estimates.

8:2 fluorotelomer alcohol *(8:2 FTOH[6])*

The degradation of 8:2 FTOH has been extensively studied in many different matrices. The half-life of 8:2 FTOH is generally rather short, but metabolites are more stable and may be degraded to PFOA over time (reviewed by Butt et al, 2014). Wang et al (2009) showed that on average 25% of the radiolabelled 8:2 FTOH had been transformed into PFOA (range 10-40%) in three types of aerobic soil after 7 months. Dinglasan et al (2004) showed that at least 3% of (non-labelled) 8:2 FTOH had been transformed into PFOA in a shorter experiment using aerobic sediment (81 days). When incubating radiolabelled 8:2 FTOH in aerobic activated sewage sludge, Wang et al (2005a) recovered 2.1% as PFOA after 28 days, and when using a combination of sludge and a mixed bacterial culture 6% of the radiolabel was recovered as PFOA after 90 days (Wang et al, 2005b). In anaerobic sludge, less PFOA is formed (0.3 mol% in 181 days) (Zhang et al, 2013).

Aqueous photolysis (at 765 W/m^2) has also been studied, with dependence on water chemistry indicated. Using Lake Ontario water, 18% of the 8:2 FTOH was transformed into PFOA after 6 days (Gauthier et al, 2005).

Atmospheric degradation of 8:2 FTOH in a smog chamber results in $\geq$1.5% being transformed into PFOA following 15 minutes of UV irradiation (Ellis et al 2004). Global atmospheric modelling has suggested a transformation of 1-10% of 8:2 FTOH to PFOA (Wallington et al, 2006).

RAC concludes that there is clear evidence for the transformation of 8:2 FTOH into PFOA across environmental compartments.

The available studies indicate that emitted 8:2 FTOH will be degraded, with at least 1-40% transformed to PFOA within 12 months of initial release. For the purpose of estimating emissions, RAC assumes that following initial release, at least 10% of 8:2 FTOH will be transformed into PFOA within 12 months.

Other 8:2 fluorotelomer derivatives

The biodegradation of 8:2 fluorotelomer stearate monoester in aerobic (grass turf) soil was studied by Dasu et al (2012). They found 1.7 mol % being transformed into PFOA after 80 days, but a low mass balance (38 mol %, likely caused by strong sorption to surfaces) raises the possibility that the transformation to PFOA might be underestimated. A similar study by Dasu et al (2013) on biodegradation of 8:2 fluorotelomer stearate monoester and 8:2 fluorotelomer citrate triester in forest soil showed that 4 mol % had been transformed

[6] 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluordecan-1-ol

into PFOA over 3 and 7 months, respectively (with good mass balance and parent substance still remaining). Royer et al (2014) studied the degradation of 8:2 fluorotelomer acrylate and 8:2 fluorotelomer methacrylate in aerobic soils for up to 105 days. Both substances degraded with half-lives ⩽15 d. Up to 10.3 mol% of PFOA was found after 105 days.

Based on QSAR modelling (SPARC software program, validated for carboxylic acids by Hilal et al 2003), Rayne et al (2010) have predicted marine hydrolytic half-lives in the order of a few years for 8:2 fluorotelomer acrylate, 8:2 fluorotelomer metacrylate, and 8:2 fluorotelomer iodide, yielding FTOH that subsequently can be transformed into PFOA. Under other optimal conditions the half-lives could be much shorter (weeks to months) according to the modelling.

RAC concludes that the available information on a limited variety of 8:2 fluorotelomer derivatives (arcylates, methacrylates, fatty acid esters) indicates that they can be transformed into PFOA in sufficient amounts to be relevant PFOA-precursors in the context of this restriction proposal. Critically, there is no information, including from the public consultation, to indicate that there are 8:2 fluorotelomer derivatives that cannot be transformed into PFOA.

The available studies indicate that emitted 8:2 fluorotelomer derivatives will be degraded by at least 1-15% to PFOA within 12 months of release. For the purpose of estimating emissions, RAC assumes that following initial release, at least 5% of the 8:2 fluorotelomer derivatives will be transformed into PFOA within 12 months.

Polyfluoroalkyl phosphates *(PAPs)*

Lee et al (2010) studied the aerobic degradation of different mono-PAPs (including 6:2 and 8:2) and polyfluoro alkyl phosphate esters (6:2 di-PAP) in mixed sewage sludge and raw wastewater over 90 days. There was some limited degradation of 8:2 fluorotelomer alcohol mono-phosphate (8:2 mono-PAP) to 8:2 FTOH, with no PFOA observed during the 90 days. The authors speculate that the limited degradation is caused by strong absorption of 8:2 mono-PAP to surfaces of the experimental system. 6:2 mono-PAP and 6:2 di-PAP were both degraded via FTOH to the corresponding C-6 carboxylic acid (PFHxA). The formation of PFHxA is estimated by the authors to be in the order of a few % of the parent 6:2 PAP-substances.

D'Eon et al (2007) showed that PFOA could be measured in blood and tissues of rats dosed with 8:2 mono-PAP or 8:2 fluorotelomer alcohol di-phosphate (8:2 di-PAP). The study shows that 8:2 PAPs are bioavailable and metabolised to PFOA. A subsequent study has proposed that ~1% of a given oral dose of 8:2 di-PAP is transformed within weeks into PFOA in rats (D'Eon et al, 2011).

RAC concludes that PAPs can be degraded to PFOA, but that the extent is less certain than for FTOH.

Nevertheless, for the further emission estimation RAC has assumed that around 1% of PAP substances released per year will be transformed into PFOA.

Other potential PFOA-related substances

It has not yet been shown that all members of this group of 'other potential PFOA-related substances' such as N-methyl perfluorooctane sulfonamidoethanol, N-ethyl perfluorooctane sulfonamide, and polyfluorinated sulfonamides degrade to PFOA, although their C4 analogues are known to do so (D'Eon et al 2006 and Jackson 2013). RAC concludes that an estimate of the the formation of PFOA from such C8 derivatives is not currently possible. However, it is noted that these substances can be degraded to PFOS and that they are

therefore already covered by the PFOS regulation.

In contrast, no reliable evidence of degradation of a fluorotelomer ethoxylate (polyethoxylated 2-perfluoroalkylethanol; mix of C-4 to C-12 perfluorinated chains and degree of ethoxylation between 0 and 13) to carboxylic acids in unfiltered effluent water from a municipal waste water treatment plant were seen in a 50-day study (Frömel and Knepper 2010), but the short duration of the study is noted. Some PFOA was indeed found (0.3%) but could have been formed from residual amounts of 8:2 FTOH rather than from the fluorotelomer ethoxylates.

Side-chain fluorinated polymers

Side-chain fluorinated polymers are generally rather persistent, but they may over time release perfluorinated side-chains via breakage of the ester bonds. By analogy with the designation of decaBDE as a PBT substance, RAC has used the assumption that if 0.1% of a persistent polymer is degraded into PFOA per year, the polymer is therefore a relevant PFOA-related substance in the context of this restriction proposal.

Four studies have investigated the degradation of fluortelomer-based acrylate polymers in soil. Russel et al (2008) found formation of PFOA, but believed that this PFOA was formed from residual unreacted raw material and impurities. The modelled half-life of the polymer was ≥95 years. It is noted that subsequent studies have indicated that the extraction method used may not have been optimal, and thus may have underestimated the degradation of the polymer. Washington et al (2009) found formation of PFOA in soil, and calculated a half-life of 870-1400 years for a coarse-grained test polymer. The modelled half-life of finely grained polymers was 10-17 years. Washington (2015) studied the degradation of polymers in four types of (saturated) soil and found formation of many transformation products including 8:2 FTOH and PFOA. They estimated a half-life of ≥33 years for the polymer, but state that more aerobic conditions (i.e. not saturated soil) could decrease the half-life.

Washington (2015) also studied hydrolysis in water at different pH levels. The limited data indicate base-mediated hydrolysis, raising a possibility of shorter half-lives in more basic soils. Rankin et al (2014) studied the biodegradation of a specifically synthesised 8:2 FTOH-based acrylate polymer (in an aqueous dispersion) in a soil-plant microcosm with or without addition of wastewater treatment plant biosolids. Degradation products were indicated both in the soil and in the plants, with PFOA identified as a major constituents. Degradation was increased in the presence of both plant and biosolids. Based on the figures presented in the publication it could be estimated that >1% of the added side-chains were degraded to PFOA during the 5.5 month period, considering likely loss of volatile FTOH to air and loss of metabolites via leaching during watering. Also breakdown of the carbon backbone was indicated, but commercial polymers are longer and therefore probably less susceptible to backbone breakage. The authors calculated a half-life in the range of 8-18 years for the polymer, which would correspond to 4-8% degradation per year if assuming linear kinetics.

One study has investigated the degradation of a fluorotelomer-based urethane polymer (Russel et al 2010). An aqueous dispersion of the polymer, where 31% of the telomers were 8:2 FTOH, was incubated for 2 years in 4 types of aerobic soils. Degradation occurred, with 0.6-1.7% of the fluorotelomer side chains in the polymer being transformed into PFOA. Even if considering that only part of the telomers were 8:2 telomers and that the experiment continued for 2 years, it seems possible that >0.1% of the available 8:2 telomers will degrade to PFOA per year.

Based on the available studies on two different types of fluorotelomer-based polymers (out of many on the market), RAC concludes that they may lead to emissions of PFOA by degradation of the polymer side-chains. It is noted that the available studies only concern

the soil compartment, and nothing is known about the potential degradation in sediment, which is considered to be an important information gap. In addition, there may be degradation of monomeric PFOA-related residues and impurities. The amount of PFOA released will depend on environmental conditions, such as pH and microbial activity in the soil, as well as on composition of the polymer (including concentration of residues and impurities). The available information may indicate degradation rates in the order of 0.1-5% per year, although there are significant uncertainties involved in extrapolating this information to the wide range of polymers on the market.

For the purpose of emission estimation RAC has assumed an overall environmental transformation of 1% per year of the fluorotelomer-based polymers into PFOA (recognising that this might be an over-estimate for some types).

Substances out of the scope

Exclusions are necessary for substances that cannot degrade to PFOA (e.g. PFNA) and are therefore not PFOA-related substances, and those that are already restricted by Commission Regulation (EC) No 850/2004.

The exemption for derivatives with the formula C_8F_{17}-X, where X= F, Cl, Br, is proposed as these substances are considered unlikely to degrade to PFOA (fully fluorinated substances are unlikely to degrade at all). RAC notes that there is a theoretical possibility of degradation of C_8F_{17}-Br via an alcohol to PFOA. However, this metabolic pathway is not confirmed. RAC therefore supports the exemption of C_8F_{17}-X, where X= F, Cl, Br.

RAC also agrees with the Dossier Submitter that PFNA (C_8F_{17}-C(=O)OH) and related substances C_8F_{17}-C(=O)O-X', and other longer chain PFASs (C_8F_{17}-CF_2-X') should be exempted as these wil not degrade to PFOA.

Summary regarding the scope of substances

RAC concludes that based on the available information on transformation, all PFOA-related substances seem to degrade to PFOA in amounts >0.1% per year, and therefore are relevant to include in the proposed restriction. Importantly, there was no information provided in the public consultation showing that there are substances with linear or branched perfluoroheptyl- or perfluorooctyl-derivatives (beside the exceptions already defined in the proposal[7]) that cannot degrade or be transformed into PFOA.

RAC therefore recommends that the proposed restriction should encompass an open-ended list of PFOA-related substances, similar to the current EU restriction of PFOS.

Estimates of emissions and the formation of PFOA in the environment from the release of PFOA-related substances

There is sufficient information available to allow the calculation of rough relative estimates of potential emissions of PFOA to the environment on both a substance (Table 1) and use

[7] N.B. PFOS (C_8F_{17}-SO_2X'), PFNA (C_8F_{17}-C(=O)OH) and other longer chain Perfluorocarboxylic acids are subject to other regulatory activities.

(Tables 2, 3 and 4) basis. Emission factors for individual uses come from either the scientific literature or, in a few cases, REACH guidance documents. It is acknowledged by RAC that these estimates are uncertain (i.e. could be over- or underestimations). Worst-case estimates, where relevant, are highlighted in the tables. The purpose is to explore if any prioritisation among the substances or uses is possible with regards to the potential risk reduction capacity of the proposed restriction.

The list of example substances (Table B1-3 in the Background Document) has been complemented with information on the volumes used and extent of potential transformation to PFOA in the environment (as described in the previous sections). As the actual volumes used are confidential, only ranges have been used. No emission factors are available for specific substances (as they have many different uses with varying emissions potential) so Table 1 (highly conservatively) assumes that the entire annually used amount is released into the environment, and is available for degradation. Based on this highly theoretical exercise one may conclude that the 8:2 telomer alcohol is the most important group, but that it is difficult to exclude any specific group of substances as not contributing to PFOA emissions.

Table 1. Potential formation of PFOA in the environment from the use of PFOA-related substances

PFOA-related substance / substance group	**Estimated volumes (tonnes/year)**	**Typical degradation rate** (% of emitted substance transformed into PFOA per year)	**Amount of PFOA *potentially* formed in the environment[a] (tonnes/year)**
Fluorotelomer alcohols (FTOH)	100-1000	10%	10-100
Fluorotelomer derivatives	100-1000	5%	5-50
diPAP and monoPAP	?	1%	?
Polyfluorinated silanes	?	No data	?
Per- and polyfluorinated phosphonic acids	?	No data	?
Polyfluorinated iodides	100-1000	5%	5-50
Perfluorinated iodides	< 10	100% assumed	10
Polymers	100-1000	1%	10

Note: a – assuming 100% of the used amount is released to the environment as a very worst case

Several scientific studies have attempted to assess emission factors for different uses/sectors, and they are described further in the Background Document. Using this information, incombination with estimated volumes used and degradation rates, RAC has attempted to estimate potential emissions of PFOA from the different uses of PFOA or PFOA-related substances (Tables 2-4).

Table 2. Potential releases of PFOA from intentional uses of PFOA (N.B. does not consider releases from imported articles)

Use	**Emission Factor (%)[a]**	**Volume (tonnes/year)**	**Total PFOA release (tonnes/year)**
Fluoropolymer production	35 (lower bound estimate)	20	7
Processing of fluoropolymer dispersions	38 (PFOA residues)	10 (imported dispersions)	3.8 seems as an overall reasonable estimate
	Another estimate is 15% x (0.03-0.85)		

Production of photographic materials	0.02 (best guess)	0.1[b]	<0.0001
Service-life of photographic materials	0.01 (worst case estimate)	0.1[b]	<0.0001
Production of semiconductors	8 (Industry estimate)	<0.05	<0.004
Service-life of semiconductors	0 (Industry estimate)	<0.05	0

Note: a – The Dossier Submitter does not always give a thorough justification for the choice of emission factors, so RAC cannot assess their reliability for the EU.
b – Public consultation suggests that the volume is declining, and will be about 88 kg by 2016.

Table 3. Potential releases of PFOA from uses of PFOA-related substances (N.B. the figures are very uncertain, but give a rough indication of potential relative emissions)

Use	Emission Factor (%)	Volume (tonnes/ year)	Total release of PFOA-related substances (tonnes/ year)	Typical degradation rate (% of emitted substance transformed into PFOA per year)	Overall emissions of PFOA (tonnes/year or tonnes per emitted amount[a])
Manufacture of PFOA-related substances	0.05	100-1,000	5-50	10% if use of FTOH assumed	0.5-5
Use of side-chain fluorinated polymers (imported articles)	20% eventually available for biodegradation [8](the remaining part is assumed to be incinerated)	1,000-10,000 (copolymers used in textiles)	200-2,000	1%	2-20
Formulation of firefighting foams (direct use of PFOA-related substances)	4.5 worst case estimate	50-100	<4.5	10% if use of FTOH assumed	<0.45
Use of firefighting foam	100 direct environmental release		<95.5	10% if use of FTOH assumed	<9.5
Textile treatment in the EU	50 % for fraction monomer not bound to polymer	20 not bound to polymer (2% of total amount)	10	10% if use of FTOH assumed	1 (there is potentially a similar release during service life)
Service-life of imported textiles	100 % for fraction monomer not bound to polymer	1000-10000, 2% not bound to polymer = ≤200	20-200	10% if use of FTOH assumed	2-20
Production of photographic material	<50 worst case estimate	>0.1 FTOH	<0.05	10%	<0.005
Paper-coating	50 % for fraction monomer not	150-200	1.5-2	1% if use of PAPs assumed	0.15-0.2

[8] The Dossier Submitter assumes an emission factor of 50-100%, but as many articles are incinerated or put in landfills RAC believes 20% is a more realistic estimate (Russel et al 2010).

Use	Emission Factor (%)	Volume (tonnes/ year)	Total release of PFOA-related substances (tonnes/ year)	Typical degradation rate (% of emitted substance transformed into PFOA per year)	Overall emissions of PFOA (tonnes/year or tonnes per emitted amount[a])
	bound to polymer (2%)				
Service-life of paper	50 % for fraction monomer not bound to polymer (2%)	150-200	1.5-2	1% if use of PAPs assumed	0.15-0.2
Production of paints and inks	4.5	50-100	2.2-4.5	10% if use of FTOH assumed	≤0.45
Use of paints and inks (presumably including service life)	50-100 for surfactants	25-50	≤50	10% if use of FTOH assumed	≤5
	100 for fraction not bound to polymer (2%)	25-50	0.5-1	10% if use of FTOH assumed	≤0.1

Note: a – Polymers may degrade over a long time frame.

Table 4. Overall potential emissions of PFOA by use, ordered by size (grey rows indicate direct use of PFOA, the others concern PFOA-related substances)

Use	Overall potential emissions of PFOA (tonnes/year)
Use of side-chain fluorinated polymers (imported articles)	2-20
Service-life of imported textiles	2-20
Use of firefighting foams	<9.5
Fluoropolymer production	7
Use of paints and inks	<5.1
Manufacture of PFOA-related substances	0.5-5
Processing of fluoropolymer dispersions	3.8
Textile treatment in the EU	>1
Formulation of firefighting foams	<0.45
Production of paints and inks	<0.45
Paper-coating and service-life of paper	0.3-0.4
Manufacture and use of photographic material (PFOA and PFOA-related substances)	<0.01
Use of PFOA in semiconductor industry and service-life of semi-conductors	≤0.01

Recognising the aforementioned uncertainties, Table 4 suggests that the PFOA-related substances are more important than direct use of PFOA as potential sources to environmental releases of PFOA. Comments in the public consultation from producers suggest lower concentrations of PFOA/PFOA-related substances in firefighting foams currently on the market compared to withdrawn PFOS-based foams, but as the composition of firefighting foams are more or less confidential, there is no possibility for RAC to assess

this information. RAC notes that emissions from firefighting foams are only potential, since they might be stored without being used before their expiry date. However, they can be stored for a very long time (increasing the chance of use), and where foams are used, the level of environmental contamination can be high, as demonstrated by environmental monitoring data at airport and fire drill sites. RAC agrees with the Dossier Submitter that whilst existing stocks should be allowed to be used up[9], the use of such foams for training exercises should be avoided, if possible.

Summary regarding emissions

The use areas of biggest concern when it comes to potential EU emissions of PFOA are (imported) textiles and firefighting foams. The use in semiconductor and photographic applications seems rather marginal, and little is known about the use in paints and inks. However, paints could potentially be an important source of emissions to the environment during their application and service life.

The groups of PFOA-related substances of greatest concern are **fluorotelomers** and **side-chain fluorinated polymers**. RAC concludes that a regulation of only PFOA itself would thus be rather meaningless as a measure to decrease the environmental burden of PFOA. Only the additional regulation of the PFOA-related substances will serve to decrease PFOA concentrations in the environment and humans both in the short and the long-term.

Characterisation of environmental risk(s)

The restriction proposal is based on environmental concerns based on the PBT properties of PFOA. No relevant environmental risk assessment can as such be conducted for PBT substances, so the overall intention is to minimise emissions.

Based on the assessment of the information provided in the restriction proposal, it is concluded that a restriction of only PFOA (and salts) will decrease emissions somewhat, but that a restriction of PFOA-related substances is needed to reduce the (quantitatively) most important sources of PFOA to the environment. Important potential sources of PFOA are considered to be the use of side-chain fluorinated polymers in general, and specifically the use in the textile sector. Other main sources are paints/inks and firefighting foam. Based on the available information, it is not possible to definitively identify specific uses or PFOA-related substances that will not contribute to emissions, but emissions from some generic uses (e.g. photographic and semiconductor (photoresist/photolithography) applications) appear to be less than 100 kg/year for the whole EU (and therefore lower risk in relative terms).

There is a voluntary commitment among some producers to stop using C-8 chemistry (including PFOA and the PFOA-related substances), which most likely will reduce emissions over time. However, this commitment does not cover all producers, and clearly not the importers of treated textiles which are considered to be a major source of PFOA to the environment.

There are no regulatory risk management instruments currently in place. The voluntary actions by some companies will reduce emissions but as import from non-signatory companies continues, a sufficient level of emission reduction will not be reached without further regulatory action.

[9] This could be achieved by exempting this particular use from the proposed restriction.

Assessment of human health risks

Information on hazard(s)

RAC has assessed the hazards decribed in the restriction proposal, and the detailed results for all endpoints can be found in the Background Document.

Animal data - Effects on growth and survival of newborn mice

Lau et al (2006) found increased incidence of full litter loss (and some additional increased neonatal mortality) beginning at doses of 5 mg/kg/day during gestation days 1-17. Birth weights were only affected at doses ≥20 mg/kg/day, but a decreased pup growth rate in the order of 25-30% during post natal days 13-23 was observed at doses of 3 mg/kg/day and higher, resulting in a no-observed-adverse-effect-level (NOAEL) of 1 mg/kg/day and a calculated benchmark dose lower limit ($BMDL_5$) of 0.86 mg/kg/day (for reduced pup growth). The pup weights normalized at adulthood. As estimated from figure 3 of the paper, the serum concentration was roughly 20 000 ng/mL in the dams exposed to 1 mg/kg/day at gestation day 18. The serum concentration of PFOA in the dams at the $BMDL_5$ is stated to be 15 700 ng/mL in the restriction proposal, referring to Borg and Håkansson (2012), but this particular concentration is not cited in the original study. RAC can in principle agree with a NOAEL/$BMDL_5$ of 1/0.86 mg/kg/day, but as there is some uncertainty concerning the serum concentration of PFOA in the dams at the $BMDL_5$, RAC would prefer to use the NOAEL of 1 mg/kg/day. Thus, the corresponding serum concentration as estimated from the publication, gives a NOAEL of approximately 20 000 ng/mL.

The restriction proposal uses assessment factors of 2.5 for remaining differences, 5 for worker intraspecies differences (or 10 for the general population), but an assessment factor for kinetic differences is not needed as the starting point is a serum concentration. A 'combined' factor of 3 for sub-chronic to chronic extrapolation (2) and accumulation potential (1.5; long half-life in humans) is also used. RAC notes that extrapolation for duration is not usually used when the starting point is a developmental toxicity study. The kinetic differences should have been covered by using serum concentrations of PFOA, and an additional factor for accumulation potential should normally not be used. However, having said that, RAC acknowledges the extreme difference in half-lifes between mice and humans (perhaps 3 weeks vs several years), which introduces uncertainty in the assessment that will therefore be handled in a qualitative manner in the risk characterisation.

RAC would rather use a total assessment factor of 12.5 (2.5 x 5), resulting in a worker derived no effect level (DNEL) of 1600 ng/mL, roughly 4-fold higher than the DNEL of 419 ng/mL proposed by the Dossier Submitter. The corresponding DNEL for the general population is then 800 ng/mL, using an intraspecies assessment factor of 10.

Abbot et al (2007) performed a similar developmental toxicity study in mice (wildtype and PPARα knockout mice) with exposure of the dams during gestation days 1-17. Similarly to Lau et al (2006), they observed increased incidences of full litter loss beginning at doses of 5 mg/kg/day. Abbot et al also found a dose-dependent decrease in neonatal survival at doses of 0.6 mg/kg/day and higher (NOAEL 0.3 mg/kg/day), which was not seen at such low levels in the Lau et al 2006 study. Serum PFOA concentrations were only measured in the dams at postnatal day 22 at weaning. A 4-fold higher concentration was found in females without pups than in females with pups, indicating quite extensive clearance via the breast milk. The serum concentration of 10 400 ng/mL in females without pups at PND 22 was extrapolated (using a PFOA half-life of approximately 3 weeks in mice) in the restriction proposal to a 2-fold higher concentration at the end of the exposure period (at delivery), i.e 20 800 ng/mL. Using the same assessment factors as RAC has suggested for the Lau study

above, a worker DNEL of 1665 ng/mL was obtained. RAC notes the uncertain serum concentration also in this study, but similar DNELs from both studies provide some reassurance of reliability.

In support for the NOAEL discussed above (1 mg/kg/day), it is noted that the EFSA TDI from 2008 is based on a $BMDL_{10}$ of 0.3 mg/kg/day for liver effects in rodents (similar to a NOAEL). EFSA uses a total uncertainty factor of 200, resulting in a TDI of 1500 ng/kg/day. The TDI is expressed as external exposure (mg/kg/day), in contrast to the DNEL which is expressed as a serum concentration, making comparisons between the TDI and the DNEL difficult. As to the assessment/uncertainty factors, RAC proposes to use a factor of 25 for the general population, leaving out the AF (of 7) otherwise used according to the REACH guidance for kinetic differences between mice and humans as the kinetic differences are reflected in the resulting serum concentrations. Although difficult to compare, is seems that the EFSA TDI and the DNEL proposed by RAC are in the same order of magnitude.

RAC supports the use of a modified DNEL of 1600 ng/mL based on the Lau et al (2006) study for the worker risk characterisation.

Animal data – Mammary gland effects

RAC is concerned for the effects on the mammary gland, but believes that it is currently not possible to set a robust NOAEL as basis for a DNEL and for risk characterisation.

Human data – developmental toxicity

Similar to animal data, there are some epidemiological studies suggesting an association between PFOA-exposure and decreased birth weights. RAC acknowledges these studies but also notes the relatively small magnitude of the effect over a 10-fold PFOA serum-range. Due to unclear adversity and uncertainties in dose-response, RAC is of the opinion that this does not allow for the use of these epidemiology data in a quantitative way for risk characterisation.

Human data - Cholesterolemia

RAC acknowledges the epidemiological studies suggesting an association between PFOA-exposure and cholesterolemia. RAC notes that the increase is more evident at low than at high PFOA serum levels. It is of a relatively small magnitude, and although not within a range directly associated with adverse health effects, it might increase the need for medication in people having already rather high cholesterol levels. Due to unclear adversity and uncertainties in dose-response, RAC is of the opinion that this does not allow the use of these epidemiology data in a quantitative way for risk characterisation.

Epidemiology studies on other endpoints (e.g. immunotoxicity) were submitted in the public consultation but these were also not considered robust enough to include in a quantitative assessment.

Information on emissions and exposures

Exposure to PFOA may be both direct at the manufacturing and use stage, and indirect via the environment because of the PBT-properties of PFOA. Thus, in the environment PFOA may bioaccumulate, and it is persistent both in the environment and in biota (e.g. the human food chain), leading to exposure of the general public both via food and via contaminated drinking water (via e.g. fire fighting foam).

Fluoropolymer production

The exposure assessment for fluoropolymer production workers is based on the study of Fromme et al (2009). This describes measured PFOA serum concentrations from four fluoropolymer production factories (three in the US and one in Belgium), representing in the order of 2500 samples taken between 1995 and 2004 in 20 sampling campaigns. Minimum, maximum and mean values are given for each campaign. The risk characterization in the restriction proposal is based on the median (1750 ng/mL) of the mean values measured in the 20 campaigns. The REACH guidance advises against using medians of measured data, and instead recommends the use of 90th percentile data (R14.4.5, page 15, version 2.1, 2012).

In the most recent EU study (2003), 30 Belgian serum samples varied between 920 and 5690 ng/mL, with a mean value of 2630 ng/mL. It is noted that such high levels are at odds with suggestions from the public consultation that polymer production is carried out under strictly controlled conditions. However, no further information on the distribution of the data is available in either the restriction proposal or the original publication. It is noted that the US data is in the same order of magnitude, although slightly lower.

The data from the most recent EU study is rather old and only represents one site and the production of one polymer. In the absence of other information, it is not known whether this reflects the current situation in the EU. For illustrative purposes only, RAC will therefore use the mean of 2630 ng/mL as a 'typical' value and the maximum of 5690 ng/mL as a reasonable worst case value for use in risk characterization (noting that the latter value is a worst case value and would change if the 90th percentile value were available).

Ski waxers

Two sampling campaigns have been performed, one in Norway and the other in Sweden (with very few samples). The restriction proposal gives mean values and the ranges of the two campaigns, and the risk characterisation is based on the mean of the mean values (137 ng/mL serum). As the REACH guidance recommends the use of 90th percentile data, RAC has analysed the studies in more detail.

The study by Nilsson et al (2010) involved eight ski wax technicians, and found concentrations of 40, 44, 46, 212, 262, 306, 552, 1070 ng PFOA/mL serum in 2007/8 (the values are transformed from whole blood concentration into serum concentrations by multiplication with a factor of 2). The Norwegian study found concentrations of 20-174 ng PFOA/mL serum in thirteen ski wax technicians (Freberg et al, 2010). When combining these two studies, sample number 19 (306 ng/mL) represents the 90th percentile.

RAC concludes that the risk characterisation should use 137 ng/mL as the typical value and 306 ng/mL as a reasonable worst case for ski waxers, noting that this is based on a very small sample.

General population

PFOA might migrate from consumer products into house dust as well as to both indoor and outdoor air. Ingestion of house dust contributes, especially for small children, to the indirect exposure of humans via the environment, including exposure from food (major source), beverages and drinking water. Food, such as meat, might be contaminated with perfluoroalkyl substances (PFASs) present in the environment or through animal feed. For babies, breast milk can be a considerable source. The exposure assessment uses plasma levels of PFOA, being a measure of combined exposure to all sources.

The exposure assessment generally uses both mean of median serum concentrations (3.5 and 6.4 ng/mL for adults and children, respectively) and mean of the reported maximum values (21 and 108 ng/mL for adults and children, respectively). Neither is directly in line with the REACH guidance. RAC agrees to use these data sets, but more attention should be given to the mean of maximum values as reasonable worst case estimates.

RAC notes that the exposure of the general population includes both background sites and a few sites with known heavily contaminated drinking water.

RAC concludes that the risk characterisation should use 3.5 and 21 ng/mL as typical and reasonable worst case values for adults, and 6.4 and 108 ng/mL as typical and reasonable worst case values for children, respectively.

Characterisation of human health risks

The RCRs in the table below are based on the DNELs based on decreased pup growth in mice (Lau et al, 2006), supported by a similar DNEL for decreased pup survival in mice (Abbot et al, 2007).

Population	**Exposure (ng/mL serum)**		**DNEL (ng/mL serum)**	**RCR**	
	Typical	**Reasonable worst case (RWC)**		**Typical**	**RWC**
Workers; polymer manufacturing†	2630	5690	1600	**1.6**	**3.6**
Workers; ski waxers	137	306	1600	0.09	0.19
General population; adults	3.5	21	800	0.004	0.03
General population; children	6.4	108	*	*	*

† This information is provided for illustrative purposes only.
*The DNEL for effects on decreased pup growth (and pup survival) is based on serum concentrations in mothers, and is not relevant for children.

Due to the limited information in the dossier on the relevance of the available monitoring data for the current exposure of polymer manufacturing workers in the EU, and the lack of any supporting exposure modelling, RAC concludes that the level of risk to fluoropolymer workers in the EU is uncertain and a concern for reproductive effects in fluoropolymer workers (due to effects on growth/survival of newborn offspring) is indicated under worst case conditions of the illustrative calculations based on the 2003 data.

For ski waxers, the 90th percentile value of 306 ng/mL results in an RCR of 0.19. The RCR is uncertain because of large variation in the exposure levels (and small sample size). However, blood samples were also taken from the technicians once in March in at least one additional year (2009-2011), suggesting lower blood levels.

For the general population, there is no concern based on the current level of knowledge and the risk characterisation above.

RAC acknowledges the extreme difference in half-lifes between mice and humans (perhaps 3 weeks versus several years), and that these kinetic differences are considered when basing the DNEL on blood levels rather than the external dose. Still, this significant

difference in half-lives introduces uncertainty in the assessment which cannot easily be quantified.

Overall RAC conclusion on environmental and direct human health risks

Environmental emissions (and hence risks, due to the PBT properties) of PFOA can arise from direct uses, but also from the presence of PFOA as an unintentional impurity in a wide variety of other substances (including polymers that are made with PFOA as a processing aid). Emissions can also arise from the degradation of PFOA-related substances (which might also be present as monomers/impurities in some substances, including polymers). It is difficult to predict confidently which specific uses contribute most to the risk, especially as there is such a diverse range of potential sources, and detailed information about most of them is lacking. Important potential sources of PFOA are considered to be the use of side-chain fluorinated polymers in general, and specifically their use in the textile sector. Other important sources appear to be coatings and firefighting foam. Based on the available information, it is not possible to definitively identify specific uses or PFOA-related substances that will not contribute to PFOA emissions, but PFOA emissions from photographic applications and from the semiconductor industry appear to be less than 100 kg/year for the whole EU (and therefore lower risk in relative terms). In addition, an indirect risk to the general public exists because of potential long-term effects on the food chain arising from the PBT properties of the substance.

There is a potential concern for workers at fluoropolymer production sites based on limited monitoring data and animal studies that indicate adverse developmental effects. There is no information about whether the monitoring data represent current worker exposures at such sites. Risks have not been identified for other human populations due to direct toxic effects of PFOA on the basis of existing data. A DNEL cannot be reliably derived for some effects (e.g. on the mammary gland) that may be more sensitive than the animal data currently used in the risk characterisation.

ASSESSMENT OF ALTERNATIVES

The dossier identifies many potential alternatives and states that alternatives exist for most uses. Among all members of the Fluorocouncil, representing a large share of the global manufacturing capacity (which includes Archroma Management LLC, Arkema France, Asahi Glass Co., Ltd., Daikin Industries, Ltd., Solvay Specialty Polymers, The Chemours Company LLC), there is a voluntary agreement to phase out the use of C-8 fluorochemicals as there are alternatives available.

The main alternatives are shorter-chain length fluorinated substances (with less than seven fully fluorinated carbon atoms, i.e C-4 or C-6 fluorochemicals). Non-fluorine containing substances are available for some applications, but they may be less efficient in some situations. Generally speaking, RAC agrees with the Dossier Submitter that the alternatives (including the shorter-chain length fluorinated substances) would currently appear to have hazard profiles of lesser concern than PFOA, with a lower potential for bioaccumulation and lower (eco)toxicity. However, RAC notes that comparable data are not available for all potential alternative substances and that this conclusion is therefore subject to revision should additional reliable information to the contrary become available. RAC notes that some short-chain fluorochemicals outside the scope of this restriction proposal are already subject to further regulatory attention under REACH as either potential SVHC (PACT listing)

or under substance evaluation (listed on the CoRAP). Equally, RAC notes that the fluorine-containing alternatives (or their breakdown products) are likely to be as persistent as PFOA. RAC supports that further work is undertaken on the risks of alternatives.

The use of PFOA as a polymerisation aid in polymer production has been substituted with C3 Dimer salt (CAS no. 62037-80-3), ADONA (CAS no. 919005-14-4) or EEA-NH4 (CAS no. 908020-52-0), which contain ether linkages between short fluorinated chains. These linkages will theoretically result in degradation to very short (≤C-3) fluorinated compounds. These degradation products are likely to be persistent, but are likely to be less bioaccumulative and less toxic than PFOA. RAC notes the lack of comprehensive studies on the 'PBT'-properties of the shorter chain length fluorinated substances and the alternative substances (including their degradation products).

Overall, RAC considers that, based on the available information, the identified substitutes seem to be of lower environmental concern than PFOA. The suitability of specific substitutes for any particular application is a matter for SEAC, but RAC notes the comments made during public consultation that the use of shorter-chain length fluorinated substances in some applications (such as for some types of textile) may result in higher emissions than C-8 fluorochemicals because they have to be applied in higher amounts, and are more easily washed off. The balance of risk in this case has not been assessed by the Dossier Submitter or RAC.

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

PFOA is a highly persistent PBT substance with a potential for environmental long-range transport, which makes emission of PFOA and PFOA-related substances a transboundary pollution problem. Evidence from contaminated sites such as airports (where fire-fighting foams containing PFOA or PFOA-related substances have been used) shows that it is very difficult to reduce the level of pollution once it has occurred.

The uses of PFOA and PFOA-related substances are widespread and consumer articles and mixtures containing these substances are placed on the market in all EU Member States. In addition, emissions could potentially occur at every stage in the life cycle, i.e. during production, service life and disposal. EU wide action is therefore necessary to eliminate emissions of PFOA and PFOA-related substances.

Therefore, any national regulatory action cannot adequately minimise emissions of PFOA and PFOA-related substances. As a consequence, risk management action is needed on an EU wide basis.

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

Emissions (and therefore risks) of PFOA and PFOA-related substances could potentially arise during all life cycle stages. PFOA-related substances can contribute to human and environmental exposure of PFOA since they might contain PFOA as an impurity or degrade to PFOA in the environment. Imported mixtures and articles constitute relevant emission sources of PFOA and PFOA-related substances during use and at disposal within the EU. They cannot be targeted by other risk management measures than restriction.

Voluntary agreements might contribute to emissions reduction, but not all producers have committed to such an approach, and a commitment of all importers (e.g. of treated textiles) into the EU is not likely. Effective enforcement of voluntary agreements can also be a challenge.

A restriction covering all emission sources is considered to be the most appropriate EU wide measure that can effectively reduce emissions of PFOA and PFOA-related substances.

RAC cannot assess to what extent non-EU use of PFOA and PFOA-related substances contributes to pollution in the EU, but recognises that global efforts may be required to reduce the long-range transport of PFOA to Europe.

Effectiveness in reducing the identified risks

The aim of the proposed restriction is to stop all intentional use of PFOA and PFOA-related substances, with the only remaining sources being due to the presence of PFOA and PFOA-related impurities below the threshold(s) set in the proposal as well as products still in use (and existing uses for which substitution is not technically feasible). The lower the threshold, the greater the risk reduction capacity will be.

Short-chain (C-6 or shorter) PFASs are alternatives that are available on the market and already used as substitutes of PFOA and PFOA-related substances. Overall, the use of short-chain PFASs is increasing, which illustrates a general shift of some parts of the market away from the use of PFOA and PFOA-related substances and a general technical feasibility to substitute PFOA and PFOA-related substances in the main uses. The restriction will therefore be very effective, provided that the selected threshold limit is sufficiently low to prevent intentional use but still allows the use of alternatives (which may contain PFOA/PFOA-related substances as unintentional impurities). The proposed restriction is similar to the previous restriction on PFOS, which has been shown to be very effective, but the PFOA proposal has much lower concentration limits.

There have been many requests for derogations (including longer transitional periods) in the public consultation[10]. In response the Dossier Submitter (and subsequently RAC) has revised the proposed threshold limit(s) (see "Practicality" below), and it is not clear to what extent derogations are still needed. The analysis of potential emissions suggests that many different uses contribute to the environmental levels of PFOA. Since detailed information on emissions has been provided for only a very few specific uses during the public consultation, RAC has not supported the derogation of any use on the basis of low tonnage equating to low environmental risk, with the exception of generic uses for which supplied information demonstrates that EU emissions are negligible in relative terms (i.e. in this context, use under strictly controlled conditions and/or emissions less than 100 kg/year), specifically implantable medical devices[11], photographic[12] and semi-conductor applications (photoresist

[10] Uses for which derogations have been requested during the public consultation include manufacturing of C-6 substances, fluoropolymers made without the intentional use of PFOA or PFOA-related substances (and the articles made from them), outdoor and personal protection fabrics, food contact materials and articles, paper, firefighting foam, printing inks, nano-coatings, ski waxes, medical devices, spare parts, photographic applications and semiconductor manufacture. In general, these involve the use of substances that are unintentionally contaminated with PFOA/PFOA-related substances, and therefore reflect concerns about being able to meet the 2 ppb threshold, but in some cases it is based on claims that C-8 fluorochemicals are still necessary (i.e. the existing alternatives are not technically suitable).

[11] Implantable medical devices are intended to remain in the body for at least 30 days, and represent around 18% of all medical devices on the EU market. Information received after the public consultation suggests that the total amount of PFOA in such implantable devices is around 20 g/year, which is not necessarily all available for release.

[12] Niche technical uses are expected to account for 88 kg PFOA in the EU by 2016. Use is in decline, and process wastes are (in general) incinerated. Whether any derogation is open-ended or time-limited will depend on the desire of the Commission to provide continued pressure to seek alternatives (otherwise C-8 fluorochemicals might continue to be made for this purpose). The Dossier Submitter supports derogation until 2030.

or photolithography processes)[13]. Whilst the use of some polymers might also result in low emissions for a particular application, RAC does not have comprehensive information on all polymer applications, so there is no basis to evaluate the relative contribution of different polymer sources to the overall risk (e.g. vehicles spare parts, medical applications[14], etc.). Decisions about requests for derogation in these other sectors (including firefighting foam, non-implantable medical devices and personal protective equipment (PPE) that are required to meet certain safety standards, and applications already subject to existing regulatory requirements (such as food contact materials)) are therefore related to socio-economic factors, especially as some of these uses appear to be (potentially) significant sources of emission (and so derogation cannot be supported from a risk perspective). In principle, RAC can support longer transitional periods for safety critical applications (such as PPE for professionals), which could be subject to a review[15]. In addition, it is important to allow the continued production and use of the main fluorinated alternatives, which may contain a high concentration of PFOA/PFOA-related substances until final processing is completed, and this is a key issue for the setting of thresholds (see "Practicality" below).

Given the widespread uses of fluorochemicals, RAC also notes that information may be missing for some uses that would be affected by the proposal, especially if the final user has no knowledge about the levels of PFOA/PFOA-related substances in their product (examples might possibly include hydraulic fluids and mist suppressants for chrome plating baths).

Practicality, incl. enforceability

The most effective way to enforce this restriction is to target articles and mixtures. Since the proposed restriction is in line with the US-EPA stewardship program, some companies have already taken action to phase out PFOA and related substances by 2015, indicating that the restriction in general is practicle. However, RAC notes that the limit value in the original proposal (2 ppb for individual substances, i.e. 0.0000002% w/w or 0.002 mg/kg) is remarkably low in the context of a REACH restriction[16].

The information provided during the public consultation on levels of PFOA/PFOA-related substances in mixtures and articles is patchy. Apart from many specific complaints that 2 ppb is impractical (with numerous requests for higher limits), some sectors (e.g. textiles) appear to have little reliable information on levels of PFOA-related substances in finished articles. In the absence of comprehensive information on the amounts of specific products on the EU market and the distribution of PFOA/PFOA-related substance levels they contain, RAC cannot provide any quantitative analysis of the level of risk reduction capacity offered by any particular threshold limit.

Practical considerations include the availability of reliable analytical methods. The Dossier Submitter is of the opinion that reliable analytical methods with very low limits of quantification should become available in the next few years. However, a number of serious

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[13] Public consultation resulted in an estimated ("very") worst case release to waste water of 4 kg PFOA/year for the entire sector. Whether any derogation is open-ended or time-limited will depend on the desire of the Commission to provide continued pressure to seek alternatives (otherwise C-8 fluorochemicals might continue to be made for this purpose). The Dossier Submitter supports derogation until 2025.

[14] Public comments suggest that many suppliers will not be aware if their products contain less than 1000 ppm of PFOA.

[15] RAC and SEAC recommend that the Commission will review the restriction by 5 years after the entry into force.

[16] For comparison, the PFOS restriction has a concentration limit of ≤ 0.001 % by weight (10 mg/kg [ppm]) for substances and preparations, and <0.1 % by weight (1000 mg/kg [ppm]) for semi-finished products and articles (or parts thereof). PFOS is also a PBT substance, like PFOA.

reservations have been expressed during the public consultation about the availability and costs of such methods and inter-laboratory variation. In addition, several respondents indicated that contamination of samples is a real possibility due to, for example:

- Unavoidable unintentional contamination of fluorochemicals due to the production process and via thermal decomposition during downstream processing;
- The historical widespread use of PFOA (and related substances) and its high persistence resulting in trace background concentrations in the environment (e.g. in water) that may be high enough to contaminate finished products;
- Releases from historically contaminated equipment in production and storage facilities into "clean" products, due to surface adsorption/desorption; and
- Trace contamination of laboratory testing equipment and the laboratory environment (e.g. through textiles and coatings).

RAC therefore believes that a very low threshold limit (such as 2 ppb) is likely to give rise to significant problems in implementation (potentially leading to false positive tests).

Current detection limits for various analytical methods are reported in Appendix E of the Background Document. Quantification limits (LoQ) vary with the method, and are influenced by the amount of solvent used to extract a specific amount of sample and further concentration steps, as well as by blank contamination. Reported LoQs for PFOA range from 1 ppb to 2000 ppb. Standardised methods exist for the analysis of PFOA in water samples at concentrations much lower than 1 ppb, but perhaps more relevant is a standardised method for more complex environmental samples with detection limits of 0.01 ppb for sediment and 0.144 ppb for blood (ICES, International Council for the Exploration of the Sea). However, matrix effects of manufactured formulations and articles could present greater challenges. A liquid chromatography-tandem mass spectrometry method for textiles and carpets reports an LoQ of 2.5 ppb (Mawn et al., 2005), whereas a GC-MS method for personal care products reports an LoQ of 131 ppb (Fujii et al., 2013). A standardised analytical method is available for the determination of PFOS in coated and impregnated solid articles, liquids and fire-fighting foams (CEN/TS 15968:2010), which most likely could be adjusted to also include PFOA with a similar detection limit[17].

PFOA-related substances (e.g. FTOH) have been analysed in research laboratories during the last 10 years, and detection/quantification limits are gradually decreasing. However, considering difficulties with extraction from articles and mixtures, varying detection limits are also reported in the Background Document (range: 2 – 2000 ppb).

It seems reasonable to assume that PFOA and some PFOA-related substances can be analysed with detection limits in the low ppb range in research laboratories, but it is acknowledged that there are at present no standard methods available for extraction and chemical analysis of PFOA-related substances. The Forum has remarked that the broad scope of the restriction may be difficult to enforce due to the absence of such methods. However, RAC notes that the current PFOS restriction has a similar very broad scope, and it has still worked, although it is not clear to RAC to what extent, if any, the PFOS-related substances have been analysed for the purposes of enforcement (and the concentration limit is also much higher than 2 ppb). RAC concludes that the lack of standard analytical methods is a significant drawback for enforcement at the proposed limit, but it is not a sufficient reason for decreasing the scope.

[17] N.B. the concentration limit in the PFOS restriction is higher than the proposed limit for PFOA.

In response to public consultation comments, the Dossier Submitter has revised the proposed thresholds as follows:

	PFOA	PFOA-related substances
Manufacturing (transported isolated intermediate) and import of C-6 raw material for further processing	20 ppb	10 000 ppb
Formulations and mixtures	5 ppb	1 000 ppb
Final articles	2 ppb	100 ppb

Their rationale is to:

- allow the manufacture in the EU, and the import, of C-6 mixtures used as alternative substances, which might otherwise be prohibited based on the unavoidable PFOA (and related substance) content reported by the only EU manufacturer (RAC notes that the limit for PFOA-related substances is only half the concentration of such substances in emulsions in which C-8 fluorochemicals are intentionally used). As some of the manufacturing steps require transport of the isolated intermediates this should be exempted under certain conditions[18];

- allow the use of C-6 mixtures, including firefighting foam concentrate (the majority of comments submitted in relation to to firefighting foams supported a threshold of 1000 ppb for PFOA-related substances); and

- ensure that fluoropolymers (such as PTFE) used in treated articles are not intentionally manufactured using PFOA (the Dossier Submitter believes that a higher limit would probably allow the use of imported fluoropolymers that are made with PFOA).

RAC is not in favour of multiple limits or numerous derogations for different sectors, since this may create complexities and uncertainties in the supply chain, and create difficulties for enforcers. RAC also notes that the aim of the legislation is to minimise emissions of PBT/vPvB substances. RAC is of the opinion that the threshold needs to strike a balance between a value that is sufficiently low to promote the transition away from C-8 fluorochemicals (i.e. make intentional use very difficult), but also realistically achievable for industry stakeholders and measurable in a reliable way to provide legal certainty.

These principles received wide support from industrial stakeholders during the public consultation, but the large number of comments submitted suggests that the low thresholds proposed by the Dossier Submitter are likely to be too ambitious at the present time.

[18] Uses for which derogations have been requested during the public consultation include manufacturing of C-6 substances, fluoropolymers made without the intentional use of PFOA or PFOA-related substances (and the articles made from them), outdoor and personal protection fabrics, food contact materials and articles, paper, firefighting foam, printing inks, nano-coatings, ski waxes, medical devices, spare parts, photographic applications and semiconductor manufacture. In general, these involve the use of substances that are unintentionally contaminated with PFOA/PFOA-related substances, and therefore reflect concerns about being able to meet the 2 ppb threshold, but in some cases it is based on claims that C-8 fluorochemicals are still necessary (i.e. the existing alternatives are not technically suitable).

On balance, RAC would therefore favour a higher limit of 25 ppb for PFOA[19] and 1000 ppb [1 ppm] for PFOA-related substances, including side-chain polymers, in all mixtures and articles, with a derogation for C-6 fluorochemicals as transported isolated intermediates for further processing, provided that they are transported and used under strictly controlled conditions. Additionally, RAC can support derogations for implantable medical devices, photographic and semi-conductor (photoresist or photolithography) applications based on seemingly negligible emission potentials from these uses.

A higher limit than originally proposed will presumably result in a less effective measure in terms of risk reduction potential (although as noted above, RAC is unable to comment on the magnitude of the difference). However, several respondents to the public consultation stated that they would be able to meet a threshold of level of 25 ppb, and they are also closer to the limits in the existing national restriction in Norway[20]. In qualitative terms, this should achieve a significant reduction in PFOA/PFOA-related substance residues in numerous products, whilst minimising the number of compliance failures (mainly caused by analytical problems with a too low threshold).

RAC recommends that these limits should be subject to confirmation that appropriate analytical methodology is available. Whilst there might still be a need for derogation on socio-economic grounds for some products that will not meet these limits (e.g. some types of firefighting foam and textile), there is conflicting information about a) their actual PFOA (and related substance) content and b) the availability of suitable alternatives. RAC recommends that this issue is explored further during the public consultation on the SEAC draft opinion.

It should then be possible to tighten the thresholds as limits of quantification decrease with improved analytical methods (provided this remains proportional to the remaining risk). The possible review signal an intention to assess whether the limits should be lowered after a suitable time period has elapsed (e.g. 5 years, or if a specific timescale is not necessary, then when new technology is available). This could also take into account updated information on concentrations in products. Similarly, the derogations and the resulting emissions from these uses should be reviewed. Incrementally phased-in concentration limits were also favoured by several stakeholders during the public consultation.

The Dossier Submitter proposes to use a lead (or indicator) substance approach, and thus to focus enforcement on PFOA, perfluorooctyl iodide (PFOI) and 8:2 FTOH[21]. The threshold for PFOA-related substances would apply to the **sum of concentrations of these lead substances**. Some respondents to the public consultation were in favour of this approach and proposed that the substances should be explicitly mentioned in the legal text[22].

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19 To limit the number of derogations required, the PFOA limit could even be raised further (e.g. to 100 ppb [0.1 ppm]), but this would then for example allow the use of C-8 fluorochemicals for applications such as paper and textile coatings (for which PFOA concentrations in treated articles have been reported to be in the range <10 to 100 ppb).

20 10 ppm PFOA in liquid mixtures, 1000 ppm PFOA in solid products and 1 µg/m^2 PFOA in textiles. N.B. Industry stakeholders have recommended avoiding using a limit based on weight per unit area of fabric because of claimed difficulties in implementation of the PFOS restriction.

21 The FluoroCouncil has proposed to add C8 methacrylate monomer and C8 acrylate monomer as indicator substances because of their importance in the production of PFOA-related substances. RAC has not been able to assess the usefulness of this proposal due to the lack of relevant supporting data.

22 Some respondents to the public consultation also advocated a 1 ppm limit per lead substance (e.g. for fire-fighting foams). Clearly, if the limit were applied to each substance, an article or mixture could potentially contain much higher concentrations than the Dossier Submitter intended. RAC has insufficient information to judge how this would affect risk reduction capacity in practise.

However, the Forum has noted that the concept of lead substances is closely related to the availability of appropriate analytical methods, and may lead to excessive analytical expenditure.

It is likely that the present CEN standard method for PFOS could be updated to cover these substances within a number of years, aiding enforcement. In particular, comments made during the public consultation indicate that a standard method for long chain per- and polyfluorinated substances in textile products is being considered by CEN (TC248/WG26) (it is not known whether this method would be applicable to other types of matrix). However, there is a risk that broadening the method will lead to higher detection limits than methods focusing on individual substances. Still, RAC supports the development of standard methods for these substances, which could be particularly helpful for textiles (which seems to be (one of) the most important sectors when it comes to potential for emissions of PFOA from PFOA-related substances (e.g. 8:2 FTOH)).

RAC notes that there might be a risk that the concept of lead (indicator) substances in the restriction text might lead to confusion as to the broad scope of the restriction, as most focus would be directed towards only a small number of substances whereas many more substances will contribute to the emissions of PFOA. However, the benefits of a lead substance approach from an enforcement point of view, at least initially, seem greater than the potential for confusion. The approach to enforcement could be included in the review proposed by RAC and SEAC.

RAC has no information to indicate whether the development of a suitable analytical method will be possible within the proposed transitional period of 18 months, but recommends that the transitional period is sufficiently long to ensure that this is achievable. A longer transitional period would also allow more time for users to communicate the requirements of the restriction along their supply chain outside Europe, and to seek further substitution possibilities. However, it would also delay risk reduction, so RAC is not in favour of extending the transitional period to more than 36 months (a doubling of the existing proposal by the Dossier Submitter), especially as the global industry should already be making efforts to find replacements to comply with the US EPA initiative.

In the future, a method might be available where all PFOA-related substances are converted into PFOA by oxidation prior to analysis of only PFOA (and this is favoured by the Forum), but RAC notes that such methods are still in the development at the research level and not ready for regulatory application.

Whatever the scope will be with regard to substances to analyse, it is clear that further development of standardised methods will be needed. RAC recommends that the Commission should consider this need when a restriction is adopted.

RAC notes that some respondents to the public consultation have suggested the use of certification to identify fluoropolymers made without the intentional use of PFOA (or possibly PFOA-related substances), mainly to avoid chemical analysis, which could be costly given the wide range of polymers that are made (depending on the threshold limit selected). The Dossier Submitter has pointed out that certification is not a REACH instrument, and it is unclear which actor(s) would be responsible for the certification procedure. Certificates could, however, be a good additional voluntary measure to help demonstrate compliance and promote the use of fluoropolymers made without PFOA.

Stakeholders have requested clarity during the public consultation about whether the restriction will apply to the total concentration in the finished article or to specific components of the article. RAC refers to the existing restriction of PFOS, which uses the terminology "semi-finished products and articles (or parts thereof)", i.e. not just the entire finished article but to any part of the article tested.

Regarding the derogation for second-hand articles placed on the market, the Forum indicates that this may create significant workload on national enforcement agencies if they have to prove that inspected articles are not second-hand. This burden might be avoided by putting the burden of proof for any article benefitting from the second-hand exemption on the duty holders.

Monitorability

Monitoring of the proposed restriction will be conducted through regular enforcement activities for substances, mixtures and articles on the market. Ongoing environmental monitoring as well as biomonitoring might also illustrate the effectiveness of the restriction. However, given the ubiquity and high persistence of PFOA, it could take a very long time for environmental monitoring to demonstrate significant declines in levels in some matrices (as observed with polychlorobiphenyls, for example). This may be exacerbated if uses with significant emissions are given a long transitional period.

BASIS FOR THE OPINION

The Background Document, provided as a supportive document, gives the detailed grounds for the opinions.

Basis for the opinion of RAC

The main changes introduced in the restriction as suggested in this opinion compared to the restrictions proposed in the Annex XV restriction dossier submitted by Germany with Norway are:

- An increase in the proposed threshold limit for PFOA and PFOA-related substances in mixtures and articles.
- A specific derogation for substances (covering C-6 fluorochemicals) used as transported isolated intermediates for further processing, provided that they are transported and used under strictly controlled conditions.
- A specific derogation for use in implantable medical devices, photographic and semi-conductor (photoresist/photolithography processes) applications.

The basis for these changes is to ensure that the restriction is practically implementable and enforceable, while allowing the continued use of shorter chain fluorochemicals (which act as important alternatives) and generic applications carried out under strictly controlled conditions and/or with relatively low environmental emissions (and therefore risk). It takes account of the extensive comments submitted during the public consultation, particularly about the analytical challenges that a very low threshold of 2 ppb would bring in terms of demonstrating compliance.

Other derogations (and changes to the proposed transitional period) may be warranted on the basis of socio-economic considerations (e.g. relating to safety critical applications), but RAC cannot comment on the level of risk involved due to the lack of information on emissions at EU level.

RAC also recommends that the Commission takes advice about the length of time needed to develop suitable analytical methods that can be applied to all matrices, since this might affect the length of the transitional period.

References:

- RAC opinion on PFOA/APFO December 2011 (ECHA/RAC/DOC No CLH-O-0000002225-82-01/F; http://echa.europa.eu/documents/10162/4d9637d4-a066-4bdb-a014-9ee5fcb0b676)

- MSC opinion (a) and support document (b) for identification of PFOA as a substance of very high concern, June 2013:

a) http://echa.europa.eu/documents/10162/14598347/agreement_pfoa_20130614_en.pdf

b) http://echa.europa.eu/documents/10162/14598345/support_document_pfoa_20130614_en.pdf