Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

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

ECHA/SEAC/RES-O-0000006229-70-03/F

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 8 September 2015) and SEAC's opinion (adopted 4 December 2015)

8 September 2015

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

4 December 2015

ECHA/SEAC/RES-O-0000006229-70-03/F

Opinion of the Committee for Risk Assessment

And

Opinion of the Committee for Socio-economic Analysis

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

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis has adopted an opinion in accordance with Article 71 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 opinions adopted by RAC and SEAC. 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***.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: ***Johanna KIISKI***

Co-rapporteur, appointed by SEAC: ***Jean-Marc BRIGNON***

The draft opinion of SEAC

The draft opinion of SEAC on the suggested restriction has been agreed in accordance with Article 71(1) of the REACH Regulation on ***10 September 2015***.

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

The draft opinion was published at ***http://echa.europa.eu/web/guest/restrictions-under-consideration*** on ***16 September 2015***. Interested parties were invited to submit comments on the draft opinion by ***16 November 2015***.

The opinion of SEAC

The opinion of SEAC on the suggested restriction was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on ***4 December 2015***. The opinion takes into account the comments of interested parties provided in accordance with Articles 69(6) and 71(1) of the REACH Regulation.

The opinion of SEAC was adopted ***by consensus.***

OPINION

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.

THE OPINION OF RAC

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 substances in concentrations equal

[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).	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 semiconductor photolithography processes.

[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.

	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.

THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on information related to socio-economic benefits and costs documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the proposed restriction on ***Perfluorooctanoic acid (PFOA), its salts[4] and PFOA-related substances*** is the most appropriate EU wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its socio-economic costs provided that the scope and conditions are modified.

[4] In the rest of the opinion document, when it refers to PFOA it also includes its salts.

The conditions of the restriction proposed by SEAC 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 (C_7F_{15})C- as one of the structural elements[5,6]. 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[2,3]. 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).	1. Shall not be manufactured, used or placed on the market: a) as substances; b) as constituents of other substances in concentrations equal to or greater than 25 ppb of PFOA or its salts or 1000 ppb for any single PFOA-related substance and 1000 ppb for the sum of all PFOA-related substances identified in column 1; c) as components of a mixture in concentrations equal to or greater than 25 ppb of PFOA or its salts or 1000 ppb for any single PFOA-related substance and 1000 ppb for the sum of all 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 (36 months after entry into force) with the exception of: a) latex printing inks, for which the transitional period is 5 years after entry into force; b) textiles for the protection of workers from risks to their health and safety, for which the transitional period is 6 years after entry into force; c) membranes intended for medical textiles, filtration in water

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

[6] These substances are known as PFOA related substances.

	treatment, production processes, and effluent treatment for which the transitional period is 6 years after entry into force; d) non-implantable medical devices (except wheelchairs and dental treatment chairs) for which the transitional period is 15 years; e) pulsed plasma nano-coating produced using conditions that minimise emissions to the environment, for which the transitional period is 6 years 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 semiconductor photolithography processes and etching processes of compound semiconductors; c) the use of firefighting foams already placed on the market on [date of entry into force], even when subsequently mixed with foams placed on the market after [date of entry into force], for a transitional period of 20 years; d) placing on the market and use of firefighting foam concentrates containing PFOA or its salts or one or

	more PFOA-related substances identified in column 1, as constituents of other substances or components of a mixture in an individual concentration of less than or equal to 1000 ppb, for a transitional period of 20 years. 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 manufacture, placing on the market and use of substances and mixtures needed to produce them; d) the placing on the market of spare parts, if the spare parts are already produced at the date of entry into force, and the date of production can be demonstrated; e) implantable medical devices as defined by Council Directive 93/42/EEC; f) the placing on the market of semiconductor manufacturing equipment for a period of 5 years after [date of entry into force]. 7. Fire fighting foams used for training should be used in such a way that emissions to the environment are minimised, and that effluents collected are safely disposed of.

The following technical changes were introduced to the entry proposed by the Dossier Submitters to better reflect the scope of substances covered by the restriction, and to improve its readability:

- The general structure in column 1 was clarified, for example the reference to C_7F_{15} as a structural element should have been to $(C_7F_{15})C$-.

- It is clarified that the reference to PFOA also covers its salts and that PFOA-related substances cover polymers.

- The derogation for substances covered by the Perfluorooctane sulfonic acid (PFOS) and its derivatives entry in Regulation (EC) No 850/2004 on POPs is moved to column 2.

- It is clarified with a footnote that if a substance contains constituents both in and out of the scope, then it is considered to be in the scope. This could cover fluoropolymers which are out of scope unless they contain an impurity which is within scope above the relevant threshold. It could also cover a situation where a complex substance contains structural elements that were both in and outside of scope.

- In addition to PFNA (C_8F_{17}-C(=O)OH), the related substances C_8F_{17}-C(=O)O-X' should be exempted as these will not degrade to PFOA.

The justifications for the changed concentration limits, the additional derogations and change in the transitional period are explained below in the Justification for the opinion of RAC and SEAC.

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

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'[7], 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[8] 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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7 '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.

8 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[9])*

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

[9] 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[10]) 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

[10] 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	100-1000	5-50	10% if use of FTOH assumed	0.5-5
Use of side-chain fluorinated polymers (imported articles)	20% eventually available for biodegradation [11](the remaining part is assumed to be incinerated)	1000-10 000 (copolymers used in textiles)	200-2000	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	1000-10 000, 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

[11] 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[12], 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.

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[12] 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 characterisation (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

Justification for the opinion of RAC

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 for the opinion of SEAC

The restriction proposal is based on concerns caused by the PBT properties of PFOA. It is also highlighted in the dossier that PFOA is ubiquitous in the environment and in humans, and that PFOA has the potential for environmental long-range transport.

Uses of PFOA and PFOA-related substances are reported to be wide-dispersive. Consumer articles and mixtures containing these substances are placed on the market in all EU Member States.

The Dossier Submitter further justifies the need for EU wide regulation by the need to avoid market distortions caused by action on national level, such as competitive disadvantage to enterprises concerned compared to competitors inside and outside the EU.

SEAC considers that taking into account the potential for long-range transport and also the persistence of PFOA, global action would be more effective in reducing environmental concentrations in the EU. However, possible future global action on PFOA is uncertain and not considered further in this opinion.

SEAC supports the conclusion of the Dossier Submitter that action is required on an EU wide basis.

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

Justification for the opinion of RAC

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.

Justification for the opinion of SEAC

As PFOA is a PBT substance it is not possible to establish a safe level of exposure. Therefore emissions of PFOA are to be minimised (REACH recital 70/ Annex I, para 6.5). A risk management option (RMO) covering all emission sources of PFOA and substances that degrade to PFOA (PFOA related substances), including those from imports, is therefore considered appropriate.

The Dossier Submitter notes that emission sources are diverse and the number of substances contributing to emissions is high. Taking into account the objective to minimise emissions, measures targeting individual emission sources or substances were not considered appropriate. The REACH authorisation process was not considered to be appropriate because it would not cover PFOA or PFOA-related substances in imported articles, which are an important contribution to total EU emissions. The Dossier Submitter also discusses various EU measures as possible RMOs, but none was found to be effective when considering the wide scope of emission sources. However, two alternative RMOs deserve some further discussion: The Stockholm convention and Voluntary industry agreement. They were assessed by the Dossier Submitter but were disregarded on the following grounds:

- The Stockholm convention was considered not to be a sufficient measure on its own due to the long time frames for its implementation, and the uncertainty of the process.

- Voluntary industry agreement was considered difficult to implement as regards imported articles, and very difficult to monitor. There are many sectors involved, and several comments received in the Public Consultation of the Annex XV dossier underline the high complexity of the corresponding supply chains.

  Several manufacturers, under the US EPA Stewardship Program, have voluntarily phased out PFOA. SEAC notes that many but not all of the relevant chemicals manufacturing companies are signatories to this voluntary agreement, and this agreement does not cover imported articles.

  SEAC also took note that very few existing labels for articles covered by the proposed restriction have been initiated by industry. For textiles however, the BlueSign® system has set targets for PFOA (of 0.05 mg/kg) but this does not seem to be effective enough at whole EU market level, since there are still high contents observed in articles surveyed in the textile sector in the EU. The Bluesign® label has only attracted a fraction of textile supply chains producing or importing textiles in the EU so far.

A restriction covering all emission sources was considered in the dossier to be the most appropriate EU wide measure to effectively reduce the emissions.

SEAC considers there is no other foreseeable option than a restriction under REACH to bring significant emission reductions in an acceptable time horizon. Therefore SEAC agrees that a restriction is the most appropriate EU wide measure to address the concern caused by PFOA releases in the environment.

In the original restriction proposal, the Dossier Submitter proposed derogations for recycled materials and second-hand articles. Further information has been received during the Public Consultations on certain uses of PFOA and PFOA-related substances supporting their possible derogation. RAC and SEAC have evaluated this information. Considering the risks, RAC supports only some of the potential derogations. SEAC further evaluates the proposed scope and potential derogations below from the SEAC point of view.

Discussions regarding the scope and possible derogations

Substances covered: inclusion of PFOA-related substances

In addition to PFOA, the proposed restriction intends to cover "PFOA-related" substances because they have the potential to degrade to PFOA. RAC considers that any PFOA-related substance that degrades / transforms in the environment at a rate greater than 0.1% w/w per year should be included in the scope of the restriction. This criterion had previously been applied by the ECHA Member State Committee (MSC) when considering the PBT status of decaBDE, which has potential to transform in the environment to substances with PBT properties, but which does not fulfil the Annex XIII PBT/vPvB criteria itself. After reviewing the available information on the degradation / transformation of PFOA-related substances, RAC concluded that all substances as defined in the Dossier Submitter's proposal should be included in the scope.

According to RAC, no additional information was submitted during the Public Consultation of the Annex XV dossier that shows that substances included in the scope of the restriction

would not degrade to PFOA, despite the question being specifically asked in the Public Consultation. Furthermore, although highly uncertain, calculations by RAC based on their best knowledge of uses and degradation rates indicate that PFOA-related substances are more important than the direct use of PFOA as potential sources of environmental releases of PFOA.

SEAC notes that the scope of the restriction should include PFOA and PFOA-related substances, recognising the need to reduce emissions even if occurring over a very long timeframe.

Uses covered: Contributions of the different uses to total emissions

Before discussing possible derogations for some sectors, an overview of their respective contributions to the total emissions of PFOA and PFOA-related emissions in the EU is provided below. This overview has been developed by RAC based on limited information, and therefore provides comparative information only.

Table 5. Overall potential emissions of PFOA by use, ordered by size (grey rows indicate direct use of PFOA, the others concern PFOA-related substances). Note that "volume" refers to the substance actually used (PFOA or a PFOA-related substance) whereas "overall potential emissions of PFOA" refer to the amount of PFOA itself potentially emitted to / formed in the environment through degradation.

Use	Volume (tonnes/ year) (PFOA or PFOA-related substances)	Overall potential emissions of PFOA (tonnes/year)
Use of side-chain fluorinated polymers (imported articles)	1 000 - 10 000	2-20
Service-life of imported textiles	1 000 - 10 000 (not bound to polymer ≤200)	2-20
Use of fire-fighting foams	<95.5	<9.5
Fluoropolymer production	20	7
Use of paints and inks	50 – 100	<5.1
Manufacture of PFOA-related substances	100 - 1 000	0.5-5
Processing of fluoropolymer dispersions	10	3.8
Textile treatment in the EU	20 (not bound to polymer; 2% of total amount)	>1
Formulation of fire-fighting foams	50 – 100	<0.45
Production of paints and inks	50 – 100	<0.45
Paper-coating and service-life of paper	300 – 400	0.3-0.4
Manufacture and use of photographic material (PFOA and PFOA-related substances)	>0.3	<0.01
Use of PFOA in semiconductor industry and service-life of semi-conductors	≤0.1	≤0.01

SEAC highlights that the figures indeed refer to "potential" emissions (estimates derived without comprehensive standardised data based on estimates of emission factors, volumes used and degradation rates) and not to actual emissions taking place during any limited period of time. SEAC considers that the figures can only be used to get a qualitative picture of the relative importance of different uses as emission sources.

This overview suggests that photographic materials and the semiconductors industry are a marginal source of emissions compared to the other sectors. For these two uses RAC proposes derogations based on their low potential for emissions (uses within the semiconductor industry are reported to be subject to strictly controlled conditions). A discussion from the SEAC point of view can be found later in this opinion.

The medical devices sector is not represented in Table 5 as such (the volume is included in figures for fluoropolymers) but information was received in the Public Consultation on the Annex XV dossier from one company and a trade organisation that they use extremely small amounts of PFOA and therefore should also be considered as a marginal source of emissions. RAC proposes derogation for implantable medical devices based on their low potential for emissions. Discussion from the SEAC point of view can be found later in this opinion.

Uses covered: Compliance costs of the different activity sectors

The Dossier Submitter assessed compliance costs of the proposed restriction, and SEAC evaluates the assessment further in this opinion. In terms of information for sector-specific situations arising from the Public Consultation on the Annex XV dossier, many comments claimed high or unbearable costs for their sectors (e.g. firefighting foams, electronics industry and medical devices). Some stakeholders provided a SEA to justify their claims. After reviewing the comments and the SEAs provided, SEAC found that these responses were mostly based on assumption that C6-based alternatives would not be available (due to the originally proposed 2 ppb threshold), and are related to the costs of being unable to continue an industrial activity or to provide a service. C6 refers to substances containing perfluorinated carbon chains of 6 carbon atoms. This group of substances is considered to include the most important substitutes for PFOA and PFOA-related substances, and the substitution cost calculation carried out by the Dossier Submitter is based on the assumption that using C6-based alternatives will be possible.

Overall, the information provided on costs relates to the proposed 2 ppb threshold and is intended to assess this particular threshold's economic consequences. Since new thresholds, allowing the use of the C6 alternative, are now proposed, SEAC used the information from the Public Consultations to qualitatively assess the need for derogations, but not to assess the overall costs of the restriction and its cost-effectiveness.

Concentration limits applied to PFOA and PFOA-related substances

Many of the comments submitted during the Public Consultations have claimed that the concentration limit originally proposed by the Dossier Submitter of 2 ppb in substances, mixtures and articles is too low, for the following reasons:

- PFOA or PFOA-related substances may be present as impurities in the ppb range in C6-based fluorinated substances, which are the main alternatives available. Implementing the 2 ppb concentration limit would therefore prevent the use of the C6 alternative to PFOA and PFOA-related substances.

- The possibility of unintentional cross-contamination in the ppb range in the long and complex supply chains, since PFOA is widespread in the environment (for instance in water used in industrial processes). Implementing the 2 ppb concentration limit would prevent many articles made from fluoropolymers from being placed on the market.

- Thorough and expensive cleaning and decontamination of production, storage and transportation equipment used in the processing of materials containing PFOA or PFOA-related substances would be needed to prevent

contamination of materials processed after the transition to alternatives, because of the adherence of PFOA and PFOA-related substances within such equipment.

- Lack of reliable and standardised analytical and extraction methods at such low concentrations, potentially leading to serious concerns for enforcing and implementing the restriction.

The information on actual levels of PFOA and PFOA-related substances measured in various matrices relevant for the restriction is scarce and is not helpful to derive threshold levels.

RAC reviewed the Dossiers Submitter's proposals for the concentration limit, incorporating the additional information from the Public Consultation on the Annex XV dossier, and proposed alternative concentration limits for PFOA and PFOA-related substances of 25 ppb and 1000 ppb, respectively, in all mixtures and articles.

Given the above considerations, SEAC agrees with RAC that the threshold proposed by the Dossier Submitter in the original restriction proposal (2 ppb) should be raised significantly. SEAC finds that the alternative approach suggested by the Dossier Submitter after the Public Consultation on the Annex XV dossier for multiple (six) different thresholds for PFOA and PFOA-related substances still raise, even if to a lesser extent, the same concerns as the original proposal, as the limits are still quite low for final articles in particular. SEAC considers that implementing these thresholds could undermine the practicality of the proposed restriction.

SEAC notes that setting a high threshold limit value could put the EU industry under a competitive disadvantage in relation to non-EU manufacturers. This would be the case where the substances and mixtures used in the manufacture of an article contain PFOA, its salts or PFOA-related substances in concentrations exceeding the concentration limits, but the finished article does not. In these cases imports of articles manufactured with intentional use of the restricted substances would be allowed, whereas manufacturing such articles inside the EU would not be possible. This affects the risk reduction capacity of the proposed restriction and is considered by SEAC with the information on C8 impurities in the C6 alternatives, background concentrations and analytical challenges in testing when evaluating the proposed thresholds.

Further discussion on the rationale behind the choice of the limit values can be found in the RAC opinion justification. SEAC agrees with the RAC conclusions.

RAC does not support sector or mixture/article specific thresholds, in order to avoid complexity in the restriction entry. While recognising this, SEAC also considered the need to avoid disproportionate burdens and discusses below some sector-specific situations regarding thresholds.

Discussions on possible derogations

The following discussion is based on the concentration limits proposed by RAC and only comments briefly on issues related to the 2 ppb concentration limit. A general observation shared with RAC is that the thresholds are set on limited information, and uncertainties remain as to whether they will achieve the necessary demarcation between restricting intended use and allowing use of the C6 alternative in every sector and situation.

Substantial efforts were made during the preparation of the restriction report and the opinion forming to ensure all the relevant stakeholders were consulted. However the

possibility that some niche uses or applications may not have responded remains. As a consequence, while SEAC has made substantial effort to take into account all submitted information when considering derogations, it cannot exclude the possibility that additional derogations may be justified.

Fluoropolymers

The main fluoropolymer is PTFE (60% of the market). Other polymers (e.g. PVFD, PFA, FEP) represent 40% of the fluoropolymer market but no information is available in the Background Document nor from the Public Consultations on their applications (except for PVDF in coil coatings and portable batteries)[13]. Fluoropolymers can contain low concentrations of PFOA or PFOA-related substances as impurities, even when PFOA is not used in their manufacture (but levels are of course much greater when PFOA is used in the process). Members of the FluoroCouncil have agreed under the US EPA Stewardship program to manufacture fluoropolymers without using PFOA (as processing aid) by the end of 2015.

The objective of the proposal is to restrict the placing on the market, import, and use of fluoropolymers manufactured with PFOA, while allowing the use of the same fluoropolymers when they are not manufactured with PFOA. This substitution is being carried out by around 70% of the global market for fluoropolymers, and is thought to happen at a moderate price increase while achieving significant emission reduction. The initial concentration limit of 2 ppb was not able to discriminate between the two types of fluoropolymer manufacturing processes, and there is currently limited information available to derive a concentration limit that would differentiate between the two. The fluorine chemical industry (FluoroCouncil) therefore requested an exemption for "fluoropolymers manufactured without PFOA". They suggest that a certification scheme could be established by industry to guarantee along the supply chain that they use such fluoropolymers.

However, given the lack of information available, SEAC cannot assess whether a certification scheme would work and how it could be verified. If the certification would be verified through analytical monitoring of PFOA and PFOA-related substances in fluoropolymers, the question of the appropriate concentration limit would need to be solved. Then it is unclear why this concentration limit could not be introduced in the restriction proposal itself, instead of the mention "without PFOA" and reference to a certification scheme. RAC considers a certification requirement for fluoropolymers produced without PFOA not justified from a risk perspective. Given RAC's conclusion and low confidence in the certification scheme, SEAC does not agree to derogate fluoropolymers manufactured without PFOA. SEAC also regards that such derogation should be not necessary with the concentration limits suggested by RAC.

13 Some further and specific information was provided during the PC: PTFE waxes are also used in other printing inks and varnishes, that are applied for instance in food can coating. PVFD resins are used in coil coating applications in several sectors (construction, white goods). Other uses of PTFE and PVDF, especially in membranes used for filtration in process industries, in water and air treatment, are not documented by the Dossier Submitter and were not addressed during the PC (except the use of PVDF in portable batteries by one comment).

Manufacture of C6 alternatives

It is a key prerequisite for the practicality and proportionality of the restriction that the possibility to manufacture and use C6 alternatives to C8 chemistry will not be jeopardised. It was confirmed during the Public Consultation on the Annex XV dossier that under the scope originally proposed by the Dossier Submitter this condition would not be fulfilled. For that reason, the Dossier Submitter and RAC proposed a derogation for C6 fluorochemicals as transported isolated intermediates for further processing, provided that they are transported and used under strictly controlled conditions as mandated by Article 18(4). SEAC agrees with this derogation which will allow that C6 alternatives are available and therefore ensure the risk reduction capacity of the proposed restriction.

On-site isolated intermediates are exempted from the restriction process according to REACH Article 68(1), therefore no specific derogation is needed in this case.

Nano-coatings

A company applying coating for smartphone manufacturers requested during the Public Consultation on the Annex XV dossier a derogation for 3 years for pulsed plasma nano-coating in order to be able to move to an alternative C6 chemical. During the Public Consultation on the SEAC draft opinion this stakeholder announced that the transition would take longer than initially foreseen, and an extension of the transitional period to 6 years was requested. The company provided a confidential SEA that suggests significant economic impacts in case sufficient time is not allowed to switch to alternatives.

SEAC considers that the annual emissions related to this use are probably low compared to other uses, and agrees that 6 years is an acceptable length for the transition to alternatives.

Spare parts

During the Public Consultation on the SEAC draft opinion, industry stakeholders requested extending the exemption for spare parts for automobiles included in the SEAC draft opinion to other kinds of spare parts (aviation, telecommunication, semiconductors, ICT industry). The concern relates to the possibility to place on the market and use in the EU spare parts already manufactured at the date of entry into force. According to their comments, in the absence of derogation, those spare parts would have to be destroyed, which would represent an economic loss for EU manufacturers.

SEAC finds derogation for spare parts in stock before the entry into force of the restriction justified for all applications, including the cases mentioned above as well as other cases), given the costs of their elimination and low emissions associated with their prolonged life.

Cookware

The concerns raised during the Public Consultation of the Annex XV dossier by the cookware sector relate to the low concentration limit, and are expected to be solved with the higher concentration limits proposed by RAC.

Firefighting foams

SEAC proposes to derogate **firefighting foams already placed on the market** before the entry into force of the restriction, because replacement of all foams containing PFOA or PFOA-related substances will incur high costs over a relatively short period. SEAC does not have quantitative information on the costs expected partly because cost information submitted during the Public Consultations was based on the assumption that the limit value will be 2 ppb. However, an indicative estimate could be derived based on a comment stating that the incineration of one litre of water or foam agent "requires a corresponding minimal amount of fuel (reportedly 1.5-2 times the volume)". This is however only one component of destruction costs. And apart from the destruction, costs would also be incurred from cleaning the equipment, and the purchase of alternative foam. It is also noted that the actors in question have recently replaced PFOS-containing foams. SEAC notes that emissions from these foams are partly theoretical since most of the foams will probably not be used before the expiry date and will then be disposed of (incinerated).

As communicated by industrial stakeholders during the Public Consultations, significant and defined volume of firefighting foams is kept **stored on industrial sites** to supply mandatorily required fixed installed fire protection systems or as an emergency stock in moveable large volume containments (trailers, skids, etc.). Any consumption of that stored volume must be restored to the required minimum storage volume (in Europe typically defined by EN-Standards). Storage containments must be refilled with fresh foam agent in any case of partial consumption of the stored (old) foam agent. After entry into force of the proposed restriction, this would lead to mixtures of restricted new foams with existing foams (exempted from the proposal).

In order to be consistent with the exemption for foams already in use, and in order to avoid the need for early replacement of exempted foams, SEAC proposes to derogate these mixtures from the proposed restriction for 20 years. This is the normal lifetime for firefighting foams, and this time period is supported by comments from the Public Consultations.

Regarding the **placing on the market of new firefighting foams**, SEAC notes that during the Public Consultations, some stakeholders (firefighting services, foams manufacturers) requested higher concentration limits for PFOA-related substances and PFOA, or total exemption of firefighting foams (German Association of Firefighting Services). A request for 10 000 ppb (German Association of Firefighting Services) does not clearly specify whether it is related to PFOA or PFOA-related substances, nor for a single substance or all substances. Comments by an EU foam manufacturer, a US and an EU organisation of foam manufacturers (FFFC and EUROFEU), and another stakeholders suggest a limit value of 1 000 ppb per substance, including PFOA and all PFOA-related substances, for firefighting foam concentrates. Furthermore, another manufacturer (Dynax, also a member of the FFFC) informed in the Public Consultation on the Annex XV dossier that impurities in fluoropolymers used for aqueous film forming foams (AFFF) are present below the ppm range, and are further diluted in the production of firefighting foams. Several comments, especially from organisations of firefighting services (including the EU organisations) rejected the 2 ppb concentration limit as impeding the use of any AFFF that they state are necessary for several situations, but did not propose another threshold.

Some of the requests seem to be related to special scenarios (like large hydrocarbons/chemicals tanks fires) but the information from the Public Consultations is not sufficient to propose a targeted derogation for very specific uses of the foams. It is also unclear whether a derogation for foams used in very specific fires would be practicable for all firefighting services, as some of them may have a limited variety of foams, adapted equipment and know-how at their disposal. Furthermore, the concerns raised by the stakeholders seem to be a general problem related to impurities, or contamination of

production lines and storage facilities by the current foams.

According to FFFC[14] the replacement of C8 by C6-based alternatives is still ongoing and will still require some fire safety certification. A particular concern noted in the Public Consultations is the ability to fight fires at airports. The Dossier Submitter has highlighted some comments showing that fluorine-free alternatives are used at some airports in the EU, and that it could be a response to concerns expressed in the Public Consultations. Uses have been reported in EU also in refineries and nuclear sites. The fluorine free foams seem to perform as well as fluorinated foams already for many applications. Some fluorine free foams have fully met the requirements set by technical standards (e.g. EN 1568 part 1, 2, 3 and 4 for both hydrocarbon and polar solvents for chemical industry, ICAO for airports, Lastfire for petrochemical industry). However, it is unsure that fluorine-free foam can be used in all situations and are compatible with all practice and strategies to combat fires across all firefighting services in the EU. Moreover, availability and costs issues could arise. SEAC considers that fluorine-free foams can be taken into account on a medium to long-term basis. SEAC notes also that the Dossier Submitter did not provide any cost assessment of substituting fluorine-containing firefighting foams with fluorine-free alternatives.

SEAC recognises that use of firefighting foams containing PFOA or PFOA-related substances results in direct emissions to the environment, leading to negative impacts on the environment and possibly human health. Furthermore, it may impose e.g. additional treatment on drinking water when causing underground contamination. SEAC notes that RAC considered that a derogation cannot be justified in terms of reduction of the risks related to PFOA. However SEAC takes into consideration the balance between the need to reduce long-term risks related to PFOA emissions, and the direct and immediate human health, environmental, and socio-economic impacts related to fires. SEAC also notes that fires have long term and indirect negative consequences, since they cause high emissions to air and the environment of hazardous chemicals, some of them being PBTs, with delayed environmental impacts and indirect human health impacts. Therefore SEAC adopts a cautious and balanced approach in order to have enough confidence that the restriction and concentration limits still ensure the availability of suitable firefighting foams for every situation.

Overall, given the information provided, SEAC proposes to adopt the higher concentration limit of 1 000 ppb per substance, **for both PFOA or for each PFOA-related substance when used in firefighting foam concentrates**, and to reconsider this concentration limit with an aim to lower it in the proposed review of the restriction 5 years after entry into force. SEAC underlines that this derogation is merely intended to allow the currently used firefighting foams based on C6 technology.

An overall limit value on the combined concentration of these substances in firefighting foams would be preferable taking RACs advice into account, however, the composition of these foams is unknown and so this approach has not been taken at this time. To inform any future review it would be advisable to gather more information on the composition of firefighting foams and the technical feasibility of using non-fluorine foams in all situations.

This SEAC proposal (including the higher concentration limit of 1 000 ppb for PFOA) will also apply to **firefighting foams used for training**. RAC considers that the use of the existing stocks of firefighting foams for training should be avoided when possible. Given the reported cases in the EU of underground water contamination associated with the use of firefighting foams for training, SEAC shares this view with RAC. Representative stakeholders stated in the Public Consultations that best practice is generally used during training, including use of

[14] "Fact sheet on AFFF fighting foams agents" dated 2014.

non-fluorinated alternatives and minimisation of effluents reaching the environment through safe disposal of runoff etc. SEAC underlines that continuing this practice is extremely important.

Electrical monitoring and control instruments used in industry (ROHS Category 9)

During the public consultation on the SEAC draft opinion, a transitional period of 15 years for electrical monitoring and control instruments used in industry was requested. The concern was that since there is such a large number of different parts needed and since the supply chains are complex, it would be time-consuming to find out in which parts these substances will be found. SEAC notes that the comment does not mention specific processes, chemicals or materials that give rise to the concern expressed. This request was made by a non-EU actor, and since the EU actors did not bring this up, it could be assumed that the EU actors expect to be able to find equipment complying with the restriction. One European actor expressed concern on the possibility of PFOA being found in electronic products in concentrations exceeding the threshold concentration due to use of PFOA in the manufacture of fluoropolymers, but this concern was linked to the threshold value of 2 ppb. In the absence of more information (for example on emissions and costs) SEAC does not support derogation.

Lithium ion battery technologies

According to a stakeholder, fluoropolymers (Polyvinylidene Fluoride) are used in lithium ion battery technologies, and they may contain PFOA in concentrations higher than 25 pbb and there are no viable alternatives available. It is not clear to SEAC why fluoropolymers complying with the restriction or other materials are not suitable for this use even after the transitional period of 36 months. In the absence of more information, SEAC does not support derogation.

Photolithography and etching processes in the semi-conductor industries

RAC proposed a derogation for this sector.

This sector is responsible for a very low share of total emission of PFOA and PFOA-related substances. The volume used in the sector is a very minor part of the total volume used in the EU (see Table 1 for an indicative picture) and the substance is reported to be used under strictly controlled conditions. Information submitted by the sector tends to demonstrate that substitution is at present not possible, and that timeframes for substitution are long (10 years). Comments from the Public Consultations confirmed that the costs incurred would be high if this use was not derogated. SEAC agrees with RAC on a derogation without an end date, on a cost-effectiveness basis.

Requests for derogating production equipment used in the manufacture of semiconductors (in which parts are made with fluoropolymers) were also received during the Public Consultation. Given the complexity of supply chains for this equipment, the low PFOA content (around 10 kg for the whole industry sector according to industry), and high potential costs for early equipment adaptation or replacement, SEAC agrees on a derogation of 5 years, that should be reviewed with the whole restriction.

SEAC notes that the exemption of second hand articles covers imports of used machinery.

Photographic coatings applied to films, papers, or printing plates

RAC proposed a derogation for this sector.

This sector is responsible for a very low share of total emission of PFOA and PFOA-related substance. Information submitted by the sector tends to demonstrate that substitution is not technically feasible and there is a decline in the amounts used. On a cost-effectiveness basis, and also because some uses are related to important sectors in the society (use for medical imaging in hospitals and by doctors), SEAC agrees with a derogation for this sector.

Textiles and clothing products

Since textiles are a major emission source of PFOA and PFOA-related substances as recognised in the RAC opinion, SEAC considers that strict lines need to be kept in allowing exemptions.

Furthermore, information exists that also fluorine free chemistry (already developed by many companies) can provide the fabrics with good water repellency for many applications, when only water repellency is required. Research is currently ongoing at industrial level to achieve good levels of oil repellency with fluorine free chemistry too.

However for some technical textiles derogations are proposed by SEAC.

- *Technical textiles for the protection of workers from risks to their health and safety*

  During the Public Consultations, some stakeholders claimed that for some specifications requiring very strong water, oil and/or chemical repellence, alternatives are not technically feasible. The applications concern critical protections, e.g. firefighters, the military, policemen, workers exposed to risks from oil and chemicals needing specific PPE (Personal Protective Equipment) and workers in the healthcare sector. This would also cover textile filters etc that are used to protect health and safety of workers (not just clothing).

  One company further specifies using nano-coating for textile in military applications, and that the possibilities to adopt an alternative still need investigation.

  The main issue seem to be that not all manufacturers can provide coatings with C6 technology resisting high temperature washing, and reapplication of C6 coatings after washing is often necessary. This would entail less effectiveness (possibly 10-fold higher emissions of C6 chemicals than C8) and substantial additional costs. The net benefits of replacing emissions of C8 chemicals by much higher emissions of C6 chemicals at a substantial cost are doubtful. Even if C6 chemicals seem to have a better hazard profile, they still pose some concerns (according to RAC they are less (eco)toxic and bioaccumulate less but are likely to be equally persistent as PFOA). A goal is replacement of C8 chemistry by less hazardous chemicals (fluorine free alternatives are said to be available by one stakeholder), or reformulation of C6 chemicals to resist heavy duty washing. Available information suggests that C6 alternatives that can resist washing and outdoor exposure are increasingly available.

  Overall, given the critical human health / life protecting functions of the C8 chemicals, and the above consideration on cost and effectiveness of substitution by C6 chemicals, SEAC proposes an extended transitional period of 6 years after entry into force for textiles for the protection of workers from risks to their health and safety. This means that for example rain jackets (since they have no safety purposes) are not covered by this extended transitional period. Voluntary workers in fields requiring protection from

risks to their health and safety should be covered. This extension is not supported by a detailed assessment but is thought to give the time for the development and adoption by the sector of cost-effective alternatives in all applications. It would also allow coordination with the proposed review of the restriction 5 years after entry into force.

- *Other technical textiles (than textiles for the protection of workers)*

  Some stakeholders requested a derogation for different kinds of technical textiles (other than textiles for the protection of workers health and safety), such as textiles used for breathable membrane systems, medical textiles, special fibres for exhaust air filters/exhaust gas cleaning, etc. In this wide category are also included certain technical textiles used in articles for consumers use, such as tents, automotive textiles (car capotes), awnings, tarpaulins, pergolas, sails, and canopies.

  The stakeholders claim that C6 alternatives do not provide the adequate durability or same level of performances as C8 products for all the potential applications, whereas there are some comments conveying the opposite information. The Dossier Submitter and RAC proposed to include technical textiles in the restriction (i.e. not to derogate them), especially considering that outdoors textiles can contribute to direct emissions to the environment.

  This group includes very different article types with varying social value. SEAC considers that different approaches need to be taken with regard to the different article types. SEAC does not have in-depth information per article type but prefers to allow a longer implementation period for certain article types where uses could be critical for the protection of human health and the environment, or for the safety of industrial processes.

  Therefore, SEAC supports an extended transitional period of 6 years for membranes intended for medical textiles, filtration in water treatment, production processes, and effluent treatment and to reconsider this in light of technological development in the context of the review after 5 years of the entry into force. Regarding the other types of articles, the social value of C8 is less clear.

Medical devices

Information submitted during the Public Consultation on the Annex XV dossier indicates that amounts of PFOA and PFOA-related substances related to this use are extremely low. The exact amount for all devices in the EU is not known but available information suggests that it would be not greater than one kg. In the case of implantable devices, a manufacturer estimates that the total amount of PFOA involved in all devices put on the market in the EU during the period 2018 – 2025 without the restriction would amount to 20 g (it is however unclear if this amount includes only PFOA or also PFOA-related substances). Annual emissions to the environment are expected to be much lower.

Stakeholders indicate that substitution is ongoing but is a lengthy process given the complexity of supply chains and the certification processes. They request for a general transitional period of a minimum of 5 years, but warn that for some devices this transitional period could be too short.

In the specific case of implantable medical devices, a manufacturer requests a transitional period of 15 years. This request is supported by an SEA comparing the costs of non-using

the devices with the avoided emissions. SEAC finds that even if all costs are not clearly justified and might include some overestimation, this SEA demonstrates that a shorter transitional period than requested would not be cost-effective.

Based on the information from the Public Consultation on the Annex XV dossier, the Dossier Submitter proposed derogation for medical devices until 2020, and for implantable cardiovascular devices until 2030. RAC proposes derogation for implantable medical devices.

SEAC agrees to the derogation for implantable medical devices given the very low amounts of PFOA and PFOA-related substances involved and high costs reported. SEAC further considers that an extended transitional period of 15 years seems to be necessary for non-implantable medical devices in order to avoid the situation that some critical applications might not remain available to the healthcare sector. This excludes wheelchairs and dental treatment chairs identified by SEAC as potential applications in which uses of PFOA and PFOA-related substance are not related to the safety of the patient or a caregiver.

Latex printing inks

Comments submitted during the Public Consultation on the Annex XV dossier indicate that C8 perfluorinated chemicals are present in latex inks used in professional printers. This use only continues in printers that are no longer manufactured, and therefore a phase-out is already underway. There seems to be a clear decreasing trend in the amounts used and related emissions. The company manufacturing the printers and inks in question claims that in absence of a transitional period of 5 years, there would be a need for premature replacement of the printers in use, and the costs would be high because there would be a loss in image quality. SEAC thinks it is doubtful every printer would be replaced, but acknowledges there would still be an impact in terms of possible market loss when a printer is not replaced. It was also brought forward in the Public Consultation that the companies using the printers in question are typically SMEs and therefore less able to absorb the costs of the earlier replacement of a printer. SEAC concludes it is justified to accept a longer transitional period of 5 years for this use.

Ski waxes

High-performance ski waxes may contain PFOA or PFOA-related chemicals. The availability of alternatives with the same performance is unclear, especially for professional users and competitions. According to a major European producer of ski waxes, no alternatives with same performance exist.

The related annual emissions of PFOA to the environment may be significant (order of magnitude of 1 tonnes per year (t/y) of PFOA-related substances), however, there is insufficient information available on substitution or non-use costs. There is no information in the Background Document or from the Public Consultations whether PFOA-related waxes are only used with the objectives to improve speed in relation to their alternatives, or if other functions are sought (e.g. durability of the treatment, of skis, safety for skiers). There are some indications that the function is improving speed for competition purpose, and that there could be alternatives based on PTFE (manufactured without PFOA)[15].

[15] "DuPont™ TechnologyBank™" page "Teflon® Paraffin Low Friction Wax for All Snow Conditions".

The socio-economic consequences of the proposed restriction if alternatives with the same performance are not available could be loss of profit for the EU manufacturer of waxes, and inequities during some international competitions (equity in EU-level competition would not be affected). This has to be weighed against the relatively high (direct) emissions to the environment of the manufacture and use of ski waxes. The transitional period of 36 months is seen as allowing stakeholders to seek agreements for international competitions if needed. Based on the limited information available SEAC overall considers that a derogation would not be justified.

Paper industry (papers other than those coated with photographic film)

The issues raised during the Public Consultations are linked to the possibility to continue using C6 alternatives, and the new thresholds are intended to allow a continued use (with some uncertainty since no information on the suitability of adapted thresholds for this sector was received in the Public Consultations[16]). SEAC proposes to extend the general transitional period of the restriction to 36 months, which should allow to the materials already in the supply chain to be used up. This period could also be used to find alternatives for possible specialty applications where there might not be suitable alternatives available yet. SEAC notes that a major application of water and oil repellents in paper is for food-contact papers, and that the Dossier Submitter and RAC consider that derogations are not justified for food contact applications (direct human exposure and potentially high emissions to the environment). Based on the limited information available SEAC overall considers that no derogation is justified for this sector.

Exported articles

Some stakeholders raised concerns on the competitiveness of the European textile industry, especially technical textiles. According to the stakeholders, many European textile companies compete in a global market with Asian and South-American producers that would not need to comply with the proposed restriction.

SEAC notes the concern, but available information does not allow assessing the potential impacts on the industry exporting articles from the EU. Furthermore, for uses where substitution is considered more challenging at the moment, derogations are proposed covering also the production for exports.

Second hand articles and recycled materials

Second hand articles and recycled materials were excluded from the scope by the Dossier Submitter. This was done in order to facilitate the sustainable management of resources. Inclusion in the scope was also considered not proportionate due to anticipated difficulties for enforcement.

The Dossier Submitter could not assess the restriction option where second hand articles and recycled materials were included within the scope. Neither was such an assessment submitted through the Public Consultation of the Annex XV dossier.

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16 In one comment, a paper manufacturer seems to use the Norwegian threshold for PFOA as a reference for paper articles, which is expressed in µg/m² and not in w/w, so not easily comparable with the proposed threshold in this restriction proposal.

SEAC agrees that the derogation for recycling and second-hand articles is justified, given that:

- A restriction on recycling could create costs and difficulties in managing waste flows to separate contaminated and non-contaminated waste, for instance for paper and textile.

- Information available is not sufficient to determine a suitable concentration limit for recycled materials.

- For several sectors it is expected that the inclusion of second-hand and recycling in the restriction would not be effective in reducing emissions, since fluorochemicals are progressively washed-off during the use phase (textiles especially).

- Articles with higher content of PFOA or PFOA-related substances are probably generally not recycled and the second-hand market is probably marginal or inexistent (e.g. professional protection equipment and professional textiles), and

- The amount of eventual environmental emissions is considered to be determined rather by the final destination of the article (incineration or landfill); in case of landfill, the main effect caused by recycling or second-hand use would be a shift in time or relocation of the emissions.

SEAC notes that once PFOA and PFOA-related substances will be eliminated from primary production, the volumes contained in second hand articles and recycled materials will also gradually decline.

Review of the restriction

SEAC recommends that the Commission will review the restriction 5 years after the entry into force, for the following purposes:

- To monitor the actual progress in the introduction of alternatives (especially as regards textiles for the protection of workers from risks to their health and safety and other technical textiles), which is currently uncertain.

- To re-assess the derogations and make the eventually justified revisions.

- To check the relevance of the concentration limits (especially as regards firefighting foams and PFOA-related substances in articles).

- To review the progress in the development of analytical methods, and the relevance and practicality of the lead substances approach.

- To check the appropriateness of the scope as regards substances covered with regard to any relevant new information.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

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[17]. 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[18], photographic[19] and semi-conductor applications (photoresist or photolithography processes)[20]. Whilst the use of some polymers might also result in low

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17 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).

18 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.

19 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.

20 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.

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[21], 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[22]. 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).

Justification for the opinion of SEAC

Proportionality to the risks

Cost assessment

The cost assessment presented in the dossier is focussed on **substitution costs**. The alternatives identified have higher prices compared to PFOA or PFOA-related substances, or higher quantities have to be used to achieve a similar technical performance. It was assumed by the Dossier Submitter for the calculations that C6 alternatives will be applicable and applied for all uses. Many other (non-fluorinated) alternatives are mentioned in the Background Document but not assessed in terms of substitution costs. The Public Consultations confirmed that C6 alternatives are by far the most used alternatives.

The substitution costs were calculated based on 1) volumes of PFOA and PFOA-related substances used annually, 2) price information on PFOA and PFOA-related substances, 3) coefficients to account for higher volumes of C6 fluorinated alternatives needed, and 4) coefficients to account for the higher prices of the C6 fluorinated alternatives. Assumptions made by the Dossier Submitter regarding the magnitude of the price difference and higher quantities that are needed to perform the same function were confirmed by some stakeholders during the Public Consultation on the Annex XV dossier. No information challenging the general approach for cost assessment was provided in the Public Consultation.

The Dossier Submitter estimates the total substitution costs at €9.3 million per year for PFOA and €25.4 million per year for PFOA-related substances post 2015. Cost information for all the specific uses of PFOA and PFOA-related substances, such as in semiconductors and in photographic applications, was not available to the Dossier Submitter and costs relating to these applications are not included in their cost assessment. This is not

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

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

considered problematic since SEAC proposes derogations for these uses.

The Dossier Submitter noted that uncertainties surrounding their analysis are high and reported that the uncertainties mainly originate from diverging information received from industry on substitution cost but also related to the estimated volumes of PFOA and PFOA-related substances to be substituted. The Dossier Submitter has analysed the sensitivity of the cost estimates to changes in volumes, price differences and necessary loadings by making separate upper bound and lower bound cost estimations.

SEAC notes that there are several sources of uncertainty underlying the substitution cost calculations:

- Uncertainties on estimated amounts of substances that need to be substituted annually.

- Uncertainties in the price differences, additional loading of alternatives needed, and durability of the treatment (mainly due to scarcity of information). For example, during the Public Consultation on the Annex XV dossier, several stakeholders noted that for some professional textiles, C6 alternatives might need to be re-applied after each or a certain number of washings.

- The high number of uses and sectors covered, and the likelihood that the data is not representative for all the uses covered.

SEAC considers that the sensitivity analysis carried out by the Dossier Submitter gives more confidence to the conclusions drawn.

SEAC agrees that the substitution costs form a major cost element for this restriction proposal. SEAC however notes that other possibly significant cost sources have not been assessed:

- Investment costs (typically reformulation costs) might be high. Some comments in the Public Consultations by manufacturers of alternatives suggest that reformulation and adaptation costs of downstream users might be higher than the adaptation costs of the manufacturers, and are therefore significant. However, SEAC proposes derogations for sectors that are thought to incur the highest investment costs.

- Monitoring costs will encompass one-time costs to set up standards, learn and adopt new monitoring techniques (for PFOA and the relevant lead substances on which the analytics would rest on), and there will also be the annual cost of carrying out the analysis to take into account.

- Certification costs are expected especially for the medical devices, firefighting foams, and professional textiles and protection equipment.

- Enforcement costs would be incurred to authorities.

Stakeholders have given the following information during the public consultations on the costs already occurred due to voluntary action:

"The six FluoroCouncil member companies have invested over €500 million of R&D and capital expenditures into the development of alternative polymerization aids and short-chain products, as well as emissions control technology. This figure does not include the transition and qualification costs for downstream users to replace PFOA and its related substances, which vary significantly up to over €1,000,000 per use per downstream user, depending on the application. While the FluoroCouncil cannot provide

specific costs per use, we believe the total costs to European downstream customers for testing, recalibration, etc. are many times greater than the investment made by FluoroCouncil member companies."

SEAC notes that this statement by industry is not supported by corroborating evidence, but agrees with the Dossier Submitter that investments needed by EU industry have already been made to some extent, triggered by the US-EPA stewardship program. SEAC however lacks information to assess to what extent this reduces investment costs related to this proposed restriction. SEAC also notes that the same remark can be made regarding certification costs.

The longer transitional periods proposed by SEAC (36 months with longer transitional times for some sectors) should lower at least the *annual* investment and certification costs, compared to the 18 months period proposed by the Dossier Submitter.

From the information gathered in the Background Document and through the Public Consultations, SEAC also finds that given the amendments proposed to the scope, no significant loss of performance in articles put on the market is expected.

Overall SEAC considers that the costs of the proposed restriction are underestimated, but agrees that the results correctly estimate the order of magnitude of the actual costs.

Changes to the original scope have an impact on substitution costs. However, in its evaluation, SEAC focuses on possible consequences on the cost-effectiveness of the proposal, which will be discussed in the following section.

Cost-effectiveness

As the actual impact on human health and the environment of reduced PFOA exposure cannot be described in quantitative terms, it was not possible for the Dossier Submitter to quantify the overall benefit of the restriction. Reduced emissions were therefore used as a proxy of the benefits of the proposed restriction in line with the approach to evaluate restriction dossiers for PBT/vPvB substances in SEAC (SEAC/24/2014/04). Following the agreed approach, cost-effectiveness estimation was carried out as part of the proportionality assessment by the Dossier Submitter. Potential risks to human health caused by exposure to PFOA have been used to further justify the proposed restriction.

The **emission reductions** in the restriction proposal were estimated based on 1) the volumes of PFOA and PFOA-related substances used or imported into EU as such, in mixtures or in articles, and 2) emission factors for different uses.

The total emission reduction was estimated to be >5.7 tonnes per year for PFOA and 35.2 tonnes per year for PFOA-related substances post 2015. The Dossier Submitter has analysed the sensitivity of the emission estimates to changes in volumes of PFOA-related substances used or imported by making separate upper bound and lower bound emission estimations.

SEAC notes that there are uncertainties surrounding the analysis of emissions both relating to volume estimates and relating to emission factor estimates. SEAC also notes that emissions relating to production of imported articles taking place outside Europe were only marginally reflected for PFOA in fluoropolymers and were not further taken into account in the analysis by the Dossier Submitter. SEAC considers that these emissions are also relevant taking into account the potential for long range transport and high volumes used.

SEAC notes that RAC supports the emission estimates. Overall SEAC considers that the estimates are acceptable to be used to derive cost-effectiveness estimates of an indicative nature.

The transformation rates of PFOA-related substances to yield PFOA are considered to have a significant influence on the overall amounts of PFOA in the environment. SEAC recognizes that actual transformation rates are mostly unknown and not considered in the cost-effectiveness estimates, even if they clearly affect the risk reduction capacity of the proposed restriction. However, taking into account that this effect cannot be reliably quantified and that RAC considers also the emissions of PFOA-related substances a suitable proxy for the risk, SEAC supports to use the total emissions of PFOA and PFOA-related substances reduced as a basis for the cost-effectiveness analysis. SEAC however underlines that this has to be recognized when making conclusions as regards PFOA-related substances.

Based on the cost and emission estimates derived, the cost-effectiveness of the proposal to reduce emissions was assessed by the Dossier Submitter with central estimates of <1 649 €/kg for PFOA (range 0 – 6 551 €/kg) and 734 €/kg (range 4 – 3 533 €/kg) for PFOA-related substances based on emissions reduced.

The Dossier Submitter underlined that given the uncertainties mentioned previously regarding costs and emissions, the cost-effectiveness estimates have to be considered as indicative values only. SEAC shares this view with the Dossier Submitter.

Changes made to the original scope (derogations) affect both costs and emission reduction estimates. Exclusion from the scope of the semiconductor and photographic sectors does not affect emission reductions since emissions from these sectors are negligible. They do not affect the costs either, since these sectors were not included in the calculations by the Dossier Submitter because of the lack of information. Overall, due to the relatively low tonnages involved in the derogated uses and the time-limited nature of some derogations, SEAC did not find it necessary to carry out new calculations. Since SEAC proposes derogations for sectors with demonstrated high compliance costs, changes in the scope are considered to improve the cost-effectiveness of the proposed restriction.

Changes in transitional periods are not expected to affect significantly the estimated annual substitution costs or emission reductions after the end of the transitional period. Extending the transitional period will give more flexibility to move to alternatives and reduce the economic impact of the proposed restriction on supply chains, and is expected to improve its proportionality.

Changes in concentration limit values are not expected to have an effect on the cost-effectiveness estimates because the numerical value of the concentration limit was not used in the derivation of the substitution cost estimates by the Dossier Submitter.

Overall, SEAC considers that the changes proposed to the scope by RAC and SEAC do not require new calculations but notes that they improve the cost-effectiveness of the proposed restriction.

Costs relating to the purification of drinking water in polluted areas

Information on costs relating to the mitigation of PFOA pollution in groundwater after contamination was submitted during the Public Consultation of the SEAC draft opinion. The information is related to an EU plant having produced PFOA. Discharges from the plant led to a continuous and severe pollution of the groundwater in an area wider than 150 km^2. Due

to the pollution, the PFOA average concentration in the groundwater is 360 ng/L, and the maximum concentrations in many sites are >1000 ng/L. The cost of removal of PFOA was estimated to be more than €10 million with major share of these costs already occurred. It is estimated in the submission that the time needed to recover the ground water can be roughly estimated to many decades.

Overall Proportionality assessment

The Dossier Submitter positively concludes on the proportionality of their proposal based on the cost-effectiveness of the proposed restriction, as well as other qualitative arguments.

In line with the general approach to evaluating PBT/vPvB substances in SEAC (see SEAC/24/2014/04), emission reduction is considered as the proxy for benefits. Therefore, cost-effectiveness is used as one element to assess proportionality. The cost-effectiveness of the proposed restriction is in a similar order of magnitude as past restriction decisions taken on PBT/vPvB chemicals. In particular, the cost-effectiveness of this restriction is close to the restriction proposal on DecaBDE[23]. SEAC notes that the cost-effectiveness of the proposed restriction is within the range of the cost-effectiveness estimates of a broader set of past risk management on PBT/vPvB like substances[24], as reported by the Dossier Submitter.

SEAC highlights that the cost-effectiveness estimates *per se* do not give any indication on the proportionality of the proposed restriction. To conclude on proportionality, the cost-effectiveness has to be considered in relation to the benefits of the proposed restriction. So far, SEAC has not been able to establish a benchmark (range) of proportionate costs to reduce emissions of PBT/vPvB substances.

SEAC consider that the following factors support the conclusion that the proposed restriction is proportionate, as it could be expected to reduce:

- The need to remediate environmental compartments in the future and the high costs associated with this. The widespread exposure and the persistence of PFOA and PFOA-related substances in the environment and the observation that PFOA is particularly resistant to degradation compared to other PBTs. PFOA and PFOA-related substances have contaminated a number of soils and underground water resources and have also been discovered in drinking water; high remediation costs have been incurred in several cases.

- Further bioaccumulation of the substance in humans and the environment. Human exposure has been demonstrated and whilst risks have not been identified considering the exposure information currently available[25], there are still concerns considering the long elimination half-life of PFOA in human blood. Indeed, RAC reported a concern for effects on the mammary gland, and that there is epidemiological information suggesting an association between PFOA-exposure and decreased birth weights and hypercholesterolemia. This is specific to PFOA and not common to all PBTs. SEAC recognises that quantitative human health impact assessment of the restriction is not possible, and is not needed to reach a conclusion on proportionality.

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23 (€125 and €4000 per kg DecaBDE emitted).
24 (Oosterhuis and Brouwer, 2015; to be published).
25 RAC stated 'Risks have not been identified for other human populations due to direct toxic effects of PFOA on the basis of existing data.'

Further factors that support the conclusion that the proposal is proportional include:

- The availability of alternatives and the current trend to substitute PFOA and PFOA-related substances in the EU triggered by voluntary action taken by industry. SEAC considers that the voluntary action is a clear indication of feasibility, and may indicate willingness of society to substitute PFOA and PFOA-related substances in many applications, and
- The fact that changes in scope and transitional periods proposed by RAC and SEAC will improve the proportionality of the initial restriction proposal by the Dossier Submitter.

SEAC also took into account that, even if RAC concludes that overall the alternatives seem to have a better environmental profile (lower (eco)toxicity and bioaccumulation, but comparable persistence), they do not present a negligible concern, and that this may affect the validity of using emission reduction as a proxy for benefits. However, this is not seen as compromising the SEAC conclusion on the proportionality of the proposed restriction.

The transition to fluorinated alternatives is seen as a step forward for potential progress in the direction of fluorine-free and less hazardous alternatives. Full transition to fluorine-free alternatives is not yet feasible given that fluorine-free alternatives are not available for all uses. SEAC recommends that, especially when the Commission reviews the restriction, particular attention is given to possibilities of substitution by fluorine-free alternatives.

Taking into account the estimated cost-effectiveness and qualitative arguments provided, SEAC concludes that the proposed restriction, with the recommended changes in concentration limits, scope (derogations) and transitional periods, is proportionate.

Practicality, incl. enforceability

Justification for the opinion of RAC

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[26].

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.

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[26] 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.

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 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 historically 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[27].

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

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

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.**

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[28];

- 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

[28] 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).

proposed by the Dossier Submitter are likely to be too ambitious at the present time.

On balance, RAC would therefore favour a higher limit of 25 ppb for PFOA[29] 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[30]. 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[31]. 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[32].

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29 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).

30 10 ppm PFOA in liquid mixtures, 1000 ppm PFOA in solid products and 1 $\mu g/m^2$ 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.

31 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.

32 Some respondents to the public consultation also advocated a 1 ppm limit per lead substance (e.g. for fire-

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.

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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.

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.

Justification for the opinion of SEAC

Transitional period

It is concluded in the Background Document that the proposed restriction being in line with the US-EPA stewardship program and industry having already taken actions to phase out PFOA and PFOA-related substances, it is practicable, and it is implementable within 18 months. However, SEAC also notes that the transition to alternatives was a much longer process than 18 months in the USA. Even though the transition has already started also in the EU due to stewardship program, SEAC notes that many EU downstream and end users would benefit from more time to switch to alternatives. This is demonstrated by the many comments received during the Public Consultations suggesting that 18 months could be too short.

SEAC proposes a longer transition of 36 months that would have the following merits:

- allow diffusion of information in numerous and complex (often at global scale) supply chains, making the restriction more effective when the transitional period ends;
- allow more time for R&D, as this seems to be needed for some stakeholders;
- allow progress in various monitoring related challenges (definition of reference chemicals, standardisation of analytical methods, definition and standardisation of extraction methods and associated reference matrices);
- avoid potential need for sector specific time-limited derogations (e.g. nano-coatings and paper) and therefore simplify the scope and improve enforceability.

For several sectors, extended transitional periods have been proposed and these are discussed in the part of the opinion dealing with sector-specific discussions on possible derogations.

Clarity of the scope

SEAC finds it critical that what is actually covered by the scope of the restriction is clear to all parties. The scope as defined in the entry in the Annex XV dossier may be difficult to understand for many SMEs. Guidelines or similar accompanying tools would be useful in this context.

Burden of proof for second-hand market

The original proposal by the Dossier Submitter to derogate second-hand market relied on the proof of using second-hand material relying on public authorities. After the Forum advice, the Dossier Submitter proposed to place the burden of proof on concerned economic

actors. Those actors include charity associations and very small businesses that play a socially useful role of providing textile at low or no costs, or of recycling textiles at low cost for society. SEAC cautions against placing too much burden on these actors and hampering their viability with disproportionate administrative compliance costs. SEAC recognises that this issue is not chemicals specific and the burden of proof is a more general issue for this type of activity.

Lead substance approach

SEAC notes that RAC has stated that the benefits of a lead substance approach from an enforcement point of view, at least initially, seem greater than the potential for confusion but has raised several concerns as the focus could be directed towards only a small number of substances whereas many more substances will contribute to the eventual emissions of PFOA. SEAC shares this view but stresses the need so select a sufficient number of lead substances, to reflect the many uses of PFOA, its salts and PFOA related substances and that, for example in textiles, it does not underestimate the content of the substances in the relevant articles.

SEAC sees a possibility that the lead substances approach could be an incentive to substitute lead substances by other PFOA-related substances by some actors. SEAC considers that the selection of lead substances should be flexible and there should be a possibility to add new lead substances after the review, in light of better information of PFOA-related substances used in textiles specifically.

Monitorability

Justification for the opinion of RAC

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.

Justification for the opinion of SEAC

Monitoring of the proposed restriction will be conducted through regular enforcement activities. It is suggested in the dossier that time trend monitoring could be performed with samples from the environment, from animals or from humans. Long range transport, persistence of the chemicals restricted would however complicate such monitoring. Monitoring based on verification of emission reductions should also be considered.

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.

Basis for the opinion of SEAC

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 and Norway are the change in concentration limit; a longer general transitional period, specific longer transitional periods for some sectors (e.g. medical devices, textiles for the protection of workers from risks to their health and safety along with some other types of technical textiles, firefighting foams in stock), and the addition of derogations for semiconductor photolithography processes, photographic coatings applied to films, papers or printing plates, implantable medical devices, , the use of substances as transported isolated intermediates (to allow the production of C6-based alternatives), and the placing on the market of spare parts, if the spare parts are already produced at the date of entry into force. The basis for these changes is information received in the Public Consultations that has been reflected in the justification to the opinion and the revised Background Document.

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