

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

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

Draft

10 September 2015

(Draft)

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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 Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

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

This document presents the opinion adopted by 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 with 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 SEAC

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 proposed restriction is as follows:

Original proposal by the Dossier Submitter:

<p>Perfluorooctanoic acid (PFOA, CAS 335-67-1, EC 206-397-9), including its salts</p> <p>and any other substance having linear or branched perfluoroheptyl derivatives with the formula C_7F_{15}- as a structural element, including its salts</p> <p>except those derivatives with the formula $C_7F_{15}-X$, where $X = F, Cl, Br$</p> <p>and any other substance having linear or branched perfluorooctyl derivatives with the formula C_8F_{17}- as a structural element, including its salts,</p> <p>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)</p>	<ol style="list-style-type: none"> Shall not be manufactured, used or placed on the market <ul style="list-style-type: none"> - 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 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. Paragraph 1 and 2 shall apply from (18 months after entry into force). 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.
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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 salts¹ 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.

The conditions of the restriction proposed by SEAC are:

<p>Perfluorooctanoic acid (PFOA, CAS 335-67-1, EC 206-397-9) and its salts.</p> <p>Any substance (including salts and</p>	<ol style="list-style-type: none"> Shall not be manufactured, used or placed on the market:
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In the rest of the opinion document, when it refers to PFOA it also includes its salts

<p>polymers) having a linear or branched perfluoroheptyl group with the formula $(C_7F_{15})C-$ as one of the structural elements^{2, 3}.</p> <p>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^{1,2}.</p> <p>The following substances are exempted from the above two paragraphs:</p> <p>$C_8F_{17}-X$, where $X = F, Cl, Br$.</p> <p>$C_8F_{17}-C(=O)O-X'$ or $C_8F_{17}-CF_2-X'$ (where X'=any group, including salts).</p>	<p>a) as substances,</p> <p>b) as constituents of other substances in concentrations equal to or greater than 25 ppb of PFOA or its salts or 1000 ppb of one or a combination of PFOA-related substances identified in column 1,</p> <p>c) 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.</p> <p>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.</p> <p>3. Paragraphs 1 and 2 shall apply from (36 months after entry into force) with the exception of:</p> <p>a) latex printing inks, for which the transitional period is 5 years after entry into force;</p> <p>b) protective professional textiles, for which the transitional period is 6 years after entry into force;</p> <p>c) non-implantable medical devices (except wheelchairs and dental treatment chairs) for which the transitional period is 15 years.</p> <p>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.</p> <p>5. By way of derogation, paragraph 1 shall not apply to:</p> <p>a) the use of substances containing one or more constituents identified in</p>
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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.

	<p>column 1, as transported isolated intermediates where the conditions in Article 18(4) are met.</p> <p>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.</p> <p>c) the use of firefighting foams already placed on the market on [date of entry into force].</p> <p>d) placing on the market and use of firefighting foams containing PFOA or its salts or one or a combination of PFOA-related substances identified in column 1, as constituents of other substances or components of a mixture in concentrations less than or equal to 1000 ppb.</p> <p>6. By way of derogation, paragraph 2 shall not apply to:</p> <p>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.</p> <p>b) the placing on the market of articles produced from recycled articles.</p> <p>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.</p> <p>d) the placing on the market of spare parts for automobiles, if the spare parts are already produced at the date of entry into force.</p> <p>e) implantable medical devices as defined by Council Directive 93/42/EEC.</p>
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JUSTIFICATION FOR THE OPINION OF SEAC

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

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

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 Consultation 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 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 1. 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 standardized 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 1 as such (the volume is included in figures for fluoropolymers) but information was received in the Public Consultation 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, many comments claimed high or unbearable costs for their sectors (e.g. fire fighting 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 Consultation 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 Consultation 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 Dossier Submitter's proposals for the concentration limit, incorporating the additional information from the Public Consultation, 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 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. 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.

Sector-specific 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.

Fluoropolymers

The main fluoropolymer is PTFE (60% of the market). Other polymers (e.g. PVDF, PFA, FEP) represent 40% of the fluoropolymer market but no information is available in the Background Document nor from the Public Consultation on their applications (except for PVDF in coil coatings and portable batteries)⁴. 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

⁴ 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. PVDF 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)

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.

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 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

Regarding nano-coatings, a company applying coating for smartphone manufacturers, requested during the Public Consultation a derogation for 3 years in order to be able to move to an alternative C6 chemical. SEAC considers that the annual emissions related to this use are probably low compared to other uses, and agrees that 3 years is an acceptable length for the transition to alternatives. Since SEAC is proposing a general transitional period of 36 months for the proposed restriction (see section on Practicality), there is no need for a specific derogation.

SEAC considers that the difficulties expected with complying with the concentration limit due to presence of C8 impurities will be avoided with the concentration limits suggested by RAC.

Automotive industry

The German Association of Car Manufacturers and The European Automobile Manufacturers' Association (ACEA) requested a specific exemption for spare parts. Their concern relates to the possibility to place on the market and use in the EU spare parts already manufactured. According to their comments, in the absence of derogation, those spare parts would be lost

and 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.

Other requests by the automotive industry relate to the concentration limit of 2 ppb being too low for some automotive parts, however, these issues are expected to be solved with the higher concentration limits proposed by RAC. Textiles containing PFOA and/or PFOA-related substances used in cars are covered by the discussion on the textile sector (later in this section).

Cookware

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

Firefighting foams (FFF)

SEAC proposes to derogate **FFF 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 Consultation 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 liter 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).

Regarding the **placing on the market of new FFF**, SEAC notes that during the Public Consultation, some stakeholders (firefighting services, foams manufacturers) requested higher concentration limits for PFOA-related substances and PFOA, or total exemption of fire fighting 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. Furthermore, another manufacturer (Dynax, also a member of the FFFC) informed in the Public Consultation 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 FFFs. Several comments, especially from organisations of fire fighting 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 Consultation 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 FFFC⁵ 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 Consultation 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 Consultation. However, it seems that currently only a few airports are using them and the use has been started quite recently. The experience is rather new, and availability issues could arise. SEAC considers that fluorine-free foams can be taken into account on a long-term basis but cannot be relied on for the coming years for such a critical use. SEAC notes also that the Dossier Submitter did not provide any cost assessment of substituting fluorine-containing FFFs with fluorine-free alternatives. Other comments received during the Public Consultation strongly indicate that C6 alternatives are sufficient for use in airports.

SEAC recognises that use of FFF 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 FFF 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**, 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.

This SEAC proposal (including the higher concentration limit of 1 000 ppb for PFOA) will also apply to **FFF 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 FFF for training, SEAC shares this view with RAC.

Photolithography 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 Consultation 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.

⁵ "Fact sheet on AFFF fighting foams agents" dated 2014.

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.

Professional textiles for individual protection

During the Public Consultation, 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 for firefighters, the military, policemen, and workers exposed to risks from oil and chemicals. 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 coatings with C6 technology do not resist high temperature washing and reapplication of C6 coatings after each washing is 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 this sector. 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.

Outdoor textiles

Some stakeholders requested a derogation for outdoor textile for consumer use (leisure), including articles such as tents, automotive textiles (car capotes), awnings, tarpaulins, pergolas, sails, canopies and textiles for buildings. They claim that C6 alternatives do not provide the adequate durability for these articles, whereas there are some comments conveying the opposite information. The Dossier Submitter and RAC proposed to include these articles in the restriction, considering also that they are used outdoors and contribute to direct emissions to the environment. SEAC notes that these uses are much less critical for safety (compared to protective clothing) and that the durability is of varying concern depending on the articles. As alternatives are being used by the outdoor clothing sector (for instance signatories of the Bluesign® label), SEAC does not find that an extended

transitional period longer than the proposed 36 months is justified.

Medical devices

Information submitted during the Public Consultation 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 transition period of a minimum of 5 years, but warn that for some devices this transition 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 transition period than requested would not be cost-effective.

Based on the information from the Public Consultation, 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 transition 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 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 Consultation 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)⁶.

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 transition 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 Consultation 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 Consultation⁷). 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.

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

⁶ "DuPont™ TechnologyBank™" page "Teflon® Paraffin Low Friction Wax for All Snow Conditions".

⁷ In one comment, a paper manufacturer seems to use the Norwegian threshold for PFOA as a reference for paper articles, which is expressed in $\mu\text{g}/\text{m}^2$ and not in w/w, so not easily comparable with the proposed threshold in this restriction proposal.

submitted through the Public Consultation of the Annex XV dossier.

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 professional textiles for individual protection), which is currently uncertain.
- To re-assess the time-limited 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.

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 Consultation 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. 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 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, 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 Consultation 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.

SEAC 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 Consultation, 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 t/y for PFOA and 35.2 t/y 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.

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 DecaBDE⁸. 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 substances⁹, 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 other factors reinforce the conclusion that the proposed restriction is proportionate:

- 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,
- Human exposure has been demonstrated (including long elimination half-life of PFOA in human blood) combined with several human health endpoints identified with societal significance. 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.
- The fact that 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. SEAC agrees that this is a specific concern. SEAC agrees that reducing the risk of similar future pollution occurring is a justification for the restriction.
- 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 agrees that the voluntary action is a clear indication of feasibility, and willingness of society to substitute PFOA and PFOA-related substances in many applications.
- 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

⁸ (€125 and €4000 per kg DecaBDE emitted).

⁹ (Oosterhuis and Brouwer, 2015; to be published).

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

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 Consultation 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.

Monitorability

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 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, and the addition of derogations for semiconductor photolithography processes, photographic coatings applied to films, papers or printing plates, implantable medical devices, the use of firefighting foams already placed on the market on the entry into force, 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 for automobiles, 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 Consultation that has been reflected in the justification to the opinion and the revised Background Document.