

Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion related to the request by the Executive Director of ECHA under Art. 77(3)(c) of REACH to prepare a supplementary opinion on:

Proposed derogations from the restrictions on C9-C14 perfluorocarboxylic acids (C9-C14 PFCA), their salts and related substances and on perfluorooctanoic acid (PFOA), its salts and PFOA-related substances

**ECHA/RAC/RES-O-0000006879-53-01/F
ECHA/SEAC/RES-O-0000006880-70-01/F**

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 30 November 2020) and SEAC's opinion (adopted 10 December 2020)

30 November 2020

ECHA/RAC/RES-O-000006879-53-01/F

10 December 2020

ECHA/SEAC/RES-O-000006880-70-01/F

SUPPLEMENTARY OPINION

Pursuant to Article 77(3)(c) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) have adopted their opinions on the request to prepare an opinion on additional derogations from the proposed restriction on C9-C14 PFCAs, and on the update of some derogations already included in the RAC and SEAC opinion on the C9-C14 PFCAs restriction and their alignment to the PFOA derogations included in Annex I of the POP Regulation.

I. PROCESS FOR ADOPTION OF THE OPINION

On 4 August 2020¹, the Executive Director of ECHA requested RAC and SEAC to prepare a supplementary opinion, based on the analysis prepared by ECHA with a view to potentially amending the conditions of the C9-C14 PFCAs restriction as proposed by SEAC and the exemptions for PFOA in the POP Regulation.

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

Rapporteur, appointed by SEAC: **BRIGNON Jean-Marc,**

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

In accordance with the mandate from the Executive Director of ECHA, the rapporteurs developed the opinions, summarising the justifications for amending the conditions of the C9-C14 PFCAs restriction as proposed by SEAC and the exemptions for PFOA in the POP Regulation.

The RAC opinion was adopted **by consensus** on **30 November 2020**.

The SEAC opinion was adopted **by consensus** on **10 December 2020**.

¹ <https://echa.europa.eu/fi/opinions-of-the-seac-adopted-under-specific-echa-s-executive-director-requests>

II. OPINION OF RAC AND SEAC

THE OPINION OF RAC

RAC has formulated its opinion based on an evaluation of information documented in the technical analysis prepared by ECHA². This opinion should be considered to be complimentary to the RAC opinions on the proposed C9-C14 PFCAs restriction³ and the PFOA restriction⁴, this latter now included in Annex I of the EU POP Regulation⁵ RAC supports the derogations for C9-C14 PFCAs and for PFOA as proposed by ECHA in their technical analysis. RAC recommends that the RAC opinion on the C9-C14 restriction and the PFOA derogations included in Annex I of the EU POP Regulation should be modified accordingly.

THE OPINION OF SEAC

SEAC has formulated its opinion based on an evaluation of information documented in the technical analysis prepared by ECHA⁶. This opinion should be considered to be complimentary to the SEAC opinions on the proposed C9-C14 PFCAs restriction and the PFOA restriction, this latter now included in Annex I of the EU POP Regulation. SEAC supports the derogations for C9-C14 PFCAs and for PFOA as proposed by ECHA in their technical analysis. SEAC recommends that the SEAC opinion on the C9-C14 PFCAs restriction and the PFOA derogations included in Annex I of the EU POP Regulation should be modified accordingly.

The derogations as proposed by RAC and SEAC are as follows:

Scope	Conditions
Derogation for C9-C14 PFCAs as impurities in fluoroplastics and fluoroelastomers that contain perfluoroalkoxy groups (Review of the derogation referred to in paragraph 10 of the SEAC opinion on the restriction proposal on C9-C14 PFCAs)	The concentration limit referred to in paragraph 2 shall be 2 000 ppb for the sum of C9-C14 PFCAs in fluoroplastics and fluoroelastomers that contain perfluoroalkoxy groups until 36 months after the entry into force of the restriction. From 36 months after the entry into force of the

² Analysis of derogations included in the restrictions on the manufacture, placing on the market and use of perfluorocarboxylic acids (PFCAs), their salts and related substances and perfluorocarboxylic acid (PFOA), its salts and related substances. August 2020. <https://echa.europa.eu/about-us/who-we-are/committee-for-risk-assessment/opinions-of-the-rac-adopted-under-specific-echa-s-executive-director-requests>

³ RAC and SEAC Opinion on an Annex XV dossier proposing restrictions on PFNA, PFDA, PFUnDA, PFDoDA, PFTTrDA, PFTDA; their salts and precursors: <https://echa.europa.eu/documents/10162/3336e40c-b52c-d9f6-3745-3b4caf61599e>

⁴ Entry 68 of Annex XVII of the REACH Regulation.

⁵ Part A of Annex I to Regulation (EU) 2019/1021.

<https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=uriserv:OJ.LI.2020.188.01.0001.01.ENG>

⁶ Analysis of derogations included in the restrictions on the manufacture, placing on the market and use of perfluorocarboxylic acids (PFCAs), their salts and related substances and perfluorocarboxylic acid (PFOA), its salts and related substances. August 2020. <https://echa.europa.eu/fi/opinions-of-the-seac-adopted-under-specific-echa-s-executive-director-requests>

Scope	Conditions
	<p>restriction, the concentration limit shall be 100 ppb for the sum of C9-C14 PFCAs in fluoroplastics and fluoroelastomers that contain perfluoroalkoxy groups. All emissions of C9-C14 PFCAs during the manufacture and use of fluoroplastics and fluoroelastomers that contain perfluoroalkoxy-groups shall be avoided and, if not possible, reduced as far as technically and practically possible. This derogation shall not apply to articles referred to in paragraph 2 (c).</p>
<p>Derogation for C9-C14 PFCAs and PFOA as impurities in PTFE micro powders</p> <p>(New derogation for C9-C14 PFCAs; review of the derogation referred to in paragraph 4 of the PFOA derogation in the POP Regulation)</p>	<p><i>For C9-C14 PFCAs:</i></p> <p>The concentration limit referred to in paragraph 2 shall be 1 000 ppb for the sum of C9-C14 PFCAs where these are present in polytetrafluoroethylene (PTFE) micro powders produced by ionising irradiation or by thermal degradation, as well as in mixtures and articles for industrial and professional uses containing PTFE micro powders. All emissions of C9-C14 PFCAs during the manufacture and use of PTFE micro powders shall be avoided and, if not possible, reduced as far as technically and practically possible. This derogation shall be reviewed and assessed by the Commission no later than [36 months after the entry into force of the restriction].</p> <p><i>For PFOA:</i></p> <p>For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of PFOA and its salts equal to or below 1 mg/kg (0.0001 % by weight) where they are present in polytetrafluoroethylene (PTFE) micro powders produced by ionising radiation or by thermal degradation, as well as in mixtures and articles for industrial and professional uses containing PTFE micro powders. All emissions of PFOA during the manufacture and use of PTFE micro powders shall be avoided and, if not possible, reduced as far as technically and practically possible. This exemption shall apply until 4 July 2022.</p>

Scope	Conditions
<p>Derogation for unintended by-products (C9-C14 PFCAs) in C6 telomerisation products</p> <p>(Review of the derogation referred to in paragraph 4a of the RAC and SEAC opinion on the restriction proposal on C9-C14 PFCAs)⁷</p>	<p>"4. Paragraphs 1 and 2 shall not apply to a) the manufacture of a substance where this occurs as an unavoidable by-product of the manufacture of fluorochemicals with a perfluoro carbon chain equal to or shorter than 6 atoms".</p> <p>This derogation shall be deleted.</p>
<p>Derogation for impurities in short-chain alternatives</p> <p>(Review of the derogation referred to in paragraph 4b of the RAC and SEAC opinion on the restriction proposal on C9-C14 PFCAs; review of the derogation referred to in paragraph 4 of the PFOA derogation in the POP Regulation)</p>	<p><i>For C9-C14 PFCAs:</i></p> <p>The concentration limit referred to in paragraph 2 shall be 10 ppm for the sum of C9-C14 PFCAs, their salts and C9-C14 PFCA related substances where they are present in a substance to be used as a transported isolated intermediate within the meaning of Article 3 point 15 (c) and fulfilling the strictly controlled conditions set out in Article 18(4)(a) to (f) for the production of fluorochemicals with a perfluorocarbon chain length equal to or shorter than 6 atoms. This derogation shall be reviewed and assessed by the Commission when the PFOA exemption is reviewed in 2022, or at the latest [two years after the entry into force of the restriction].</p> <p><i>For PFOA:</i></p> <p>For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of PFOA, its salts and PFOA-related compounds equal to or below 20 mg/kg (0.002 % by weight) where they are present in a substance to be used as a transported isolated intermediate within the meaning of Article 3 point 15 (c) of Regulation (EC) No 1907/2006 and fulfilling the strictly controlled conditions set out in Article 18(4)(a) to (f) of that Regulation for the production of fluorochemicals with a perfluorocarbon chain length equal to or</p>

⁷ A similar derogation for PFOA as unintended by-products in C6 telomerisation processes included in entry 68 of Annex XVII (REACH Restriction on PFOA) was not transposed in the PFOA restriction in the POP Regulation.

Scope	Conditions
	shorter than 6 atoms. This exemption shall be reviewed and assessed by the Commission no later than 5.7.2022.
Review of the derogations referred to in paragraph 6 of the RAC and SEAC opinion on the proposal restriction on C9-C14 PFCAs	The derogations referred to in paragraphs 5 and 6 of Part A of Annex I to Regulation (EU) 2019/1021 are applicable with the same conditions to the substances referred to in column 1, paragraph 1 of this restriction.

When PFOA and C9-C14 PFCAs are mentioned in this opinion, it should be read to include also their salts and related compounds, unless otherwise specified.

III. OPINION JUSTIFICATION

On 16 January 2019, ECHA submitted to the Commission the RAC and SEAC opinion on a restriction proposal on the manufacture, placing on the market and use of C9-C14 PFCAs that included proposals for a number of derogations for specific uses of C9-C14 PFCAs.

Several of the proposed derogations from the restriction on C9-C14 PFCAs relate to the presence of C9-C14 PFCAs as impurities in PFOA. These derogations were considered necessary to avoid interfering with some of the derogations included in the existing restriction on PFOA.

As PFOA has now been included in Annex I of the EU POP Regulation (with modified derogations) the restriction entry for PFOA under REACH will soon be deleted. These revisions, in turn, affect some of the derogations included in the proposed restriction on C9-C14 PFCAs.

Additionally, after the finalisation of the RAC and SEAC opinion on the proposed restriction on C9-C14 PFCAs, the Commission received two additional requests for derogations from industry.

In this context, the Commission requested ECHA to review several of the derogations included in the restrictions on C9-C14 PFCAs and PFOA and submit the analysis in the form of a complement to the Annex XV dossiers that supported the C9-C14 PFCAs and PFOA restrictions. The analysis, submitted in August 2020, is based on the data collected in a call for evidence launched by ECHA for this purpose, in which 16 stakeholders provided information.

The Commission has requested RAC and SEAC to provide a supplementary opinion on ECHA's new analysis with the view to amend the conditions of the C9-C14 PFCAs restriction recommended by SEAC and the exemptions for PFOA included in the POP Regulation.

ADDITIONAL DEROGATIONS REQUESTED BY COMPANIES

1. Derogation for C9-C14 PFCAs as impurities in fluoroplastics and fluoroelastomers that contain perfluoroalkoxy groups

1.1. Summary and conclusion from the ECHA technical analysis

The Commission requested ECHA to assess a proposal for a derogation for C9-C14 PFCAs as impurities in fluoroplastics and fluoroelastomers based on a request by industry. The request was submitted after the finalisation of the RAC and SEAC opinion on C9-C14 PFCAs. The text of the proposal reads as follows: *The concentration limit referred to in paragraph 2 shall be 2 000 ppb for the sum of C9-C14 PFCAs in fluoropolymers⁸ and fluoroelastomers that contain perfluoroalkoxy-groups until 36 months after the entry into force of the restriction. From 36 months after the entry into force of the restriction, the concentration limit shall be 400 ppb for the sum of C9-C14 PFCAs in fluoropolymers and fluoroelastomers that contain perfluoroalkoxy-groups. This derogation shall not apply to articles referred to in paragraph 2 (c).*"

The proposed derogation widens the scope of the present derogation proposed by SEAC for the content of C9-C14 PFCAs as impurities in fluoropolymers in the restriction for C9-C14 PFCAs. The new proposal covers fluoroplastics and fluoroelastomers that contain any perfluoroalkoxy-group while the derogation proposed by SEAC is limited to specific fluoroplastics (PTFE fine powders and aqueous dispersions) and fluoroelastomers containing perfluoropropoxy-groups or perfluoromethoxy-groups.

C9-C14 PFCAs are generated unintentionally in the polymerisation of fluoropolymers with perfluoroalkoxy-vinylethers. After polymerisation, C9-C14 PFCAs can be removed either by heat or by adsorption depending on the manufacturing process, although trace levels of C9-C14 PFCAs may remain as impurities.

Annual releases from the manufacture and use of fluoropolymers with perfluoroalkoxy groups containing C9-C14 PFCAs as impurities resulting from the derogation proposed by industry are estimated to be in the range of 2 kg/year and are considered to represent a limited risk to human health and the environment. As a worst-case scenario (sensitivity analysis), emissions in the order of 20 kg/year may result⁹, declining to 4 kg/year, once a concentration limit level of 400 ppb as proposed by industry is implemented.

According to the information provided in the call for evidence, best available technologies exist that can reduce C9-C14 PFCAs in fluoropolymers (fluoroplastics and fluoroelastomers) that contain perfluoroalkoxy groups to concentrations below 100 ppb. Since these technologies have been implemented by at least one company, ECHA concluded that similar technologies are also technically feasible for those companies in the process of implementing additional risk management measures to reduce the level of C9-C14 PFCAs in fluoropolymers. Therefore, ECHA proposed to set a concentration limit of 100 ppb for the sum of C9-C14 PFCAs as impurities in fluoroplastics and fluoroelastomers that contain perfluoroalkoxy groups

⁸ It should be noted that the term fluoropolymer is used as a synonym for fluoroplastic in the context of this derogation. However, since both fluoroplastics and fluoroelastomers are fluoropolymers, the term fluoropolymer should be replaced by fluoroplastic to provide a more precise description of the scope.

⁹ assuming the estimated volume of fluoropolymers falling within the scope of the derogation and the greatest concentration level of impurities, i.e. 2 000 ppb

after a transition period of 36 months in order to ensure that releases are minimised. The transition period would allow for the implementation of the best available technologies by the affected companies. It is estimated that the emissions resulting from a threshold level of 100 ppb for the sum of C9-C14 PFCAs would be well below 1 kg/year.

Nevertheless, emissions should be avoided or reduced as far as technically and practically possible during the manufacture and use of the fluoropolymers to prevent releases to the environment. Taking into account the specific properties of fluoropolymers containing perfluoroalkoxy groups and the lack of alternative materials that could substitute all applications, ECHA considers this approach to be proportionate.

An extension of the scope of the derogation to all fluoropolymers has not been justified. The identification of the presence of perfluoroalkoxy groups by the manufacturer of the fluoropolymers and communication through the supply chain for the purpose of the present restriction should ensure the implementability and enforceability of the restriction.

ECHA recognises that the absence of standardised analytical methods to measure the concentration of C9-C14 PFCAs in fluoropolymers may present a challenge for the compliance and enforcement of the threshold of 25 ppb for the sum of C9-C14 PFCAs set in the proposed restriction.

The extension of the scope of the original derogation to articles manufactured with fluoropolymers was discussed previously by RAC and SEAC and no additional information that would merit further discussion as part of this work was made available in the call for evidence.

Derogation proposed by ECHA for C9-C14 PFCAs as impurities in fluoroplastics and fluoroelastomers that contain perfluoroalkoxy groups:

"The concentration limit referred to in paragraph 2 shall be 2 000 ppb for the sum of C9-C14 PFCAs in fluoroplastics and fluoroelastomers that contain perfluoroalkoxy-groups until 36 months after the entry into force of the restriction. From 36 months after the entry into force of the restriction, the concentration limit shall be 100 ppb for the sum of C9-C14 PFCAs in fluoroplastics and fluoroelastomers that contain perfluoroalkoxy-groups. All emissions of C9-C14 PFCAs during the manufacture and use of fluoroplastics and fluoroelastomers that contain perfluoroalkoxy-groups shall be avoided and, if not possible, reduced as far as technically and practically possible. This derogation shall not apply to articles referred to in paragraph 2 (c)."

This derogation would substitute the derogation in paragraph 10 in the SEAC opinion on the restriction on C9-C14 PFCAs.

1.2. Justification for the opinion of RAC

1.2.1. RAC conclusion(s):

In the proposal above, RAC notes that the limit of 2 000 ppb proposed for C9-C14 PFCA impurities in perfluoropolymers was already supported by SEAC in their opinion on the C9-C14 PFCAs restriction with a more limited scope and based on socio-economic reasons.

RAC further notes that the focus on fluoropolymers containing *perfluoroalkoxy-groups* is questioned in the call for evidence, most clearly by comment #1313, but also by comments #1310, #1315, and #1320. As very large volumes of fluoropolymers are used, a low

concentration of C9-C14 PFCAs as impurities may still potentially lead to high emissions. On this basis, RAC does not support an extension of the scope to all fluoropolymers. According to comments #1310 and #315, C9-C14 PFCAs are generated unintentionally as impurities in the polymerisation of fluoropolymers containing perfluoroalkoxy-groups in a side reaction that is not fully understood. Although several purification steps are being implemented (comment #1310) or already in place (comment #1315) to remove the C9-C14 PFCa impurities resulting from this polymerisation process, impurities above the concentration limits proposed are present in certain products, depending on the manufacturer. Therefore, it seems that the greatest difficulties to achieve the permitted levels of C9-C14 PFCAs in fluoropolymers concern fluoropolymers containing perfluoroalkoxy-groups.

Although the information is rather uncertain on how common fluoropolymers containing perfluoroalkoxy-groups are, it seems to be a smaller part of all fluoropolymers (estimated at 10-20%). Thus, a transitional period of 36 months to implement purification methods and decrease the level of impurities from a maximum of 2 000 ppb to 100 ppb can be seen as reasonable although the estimated worst-case emissions of 20 kg/year resulting from a level of impurities of 2 000 ppb is not insignificant for these PBT/vPvB-substances.

However, RAC also notes that enforcement may not be able to identify these specific fluoropolymers using chemical analysis. As this derogation is specific for fluoropolymers containing *perfluoroalkoxy-groups*, enforcement may depend on written identification of the presence of perfluoroalkoxy-groups in the polymer by the manufacturer, and further communication of this information through the supply chain. The robustness of such a system may be questioned, making it important to ensure that the derogation becomes time-limited.

Based on the assumption that the PFCAs are removed by the processes used when the fluoropolymer mixtures are processed into articles, RAC supports that the derogation shall not apply to articles.

RAC supports reducing the limit to 100 ppb after 36 months.

In conclusion, RAC supports the derogation as proposed by ECHA for C9-C14 PFCAs as impurities in fluoroplastics and fluoroelastomers that contain perfluoroalkoxy groups.

1.2.2. Key elements underpinning the RAC conclusion:

According to information in the call for evidence, it seems that all fluoropolymers (both fluoroplastics and fluoroelastomers) may contain C9-C14 PFCAs as trace impurities at different levels, but the highest levels of C9-C14 PFCAs may be found in fluoropolymers containing perfluoroalkoxy-groups. The total group of fluoropolymers and fluoroelastomers is very large, potentially representing a use in the EU of 50 000-60 000 tonnes per year. The concentration of C9-C14 PFCAs is largely unknown. However, one company reports concentrations up to 1 500 ppb C9-C14 PFCAs in some types of fluoropolymers (PFOA not mentioned), and (probably a worst case estimate) that "a maximum of 104 kg C9-C14 PFCAs may be 'placed on the market' as trace impurities in fluoropolymers and fluoroelastomers per year". The restriction dossier for C9-C14 PFCAs describes increasing concentrations of C9-C14 PFCAs in the environment, largely in the absence of known active uses of C9-C14 PFCAs, so impurities in fluoropolymers are likely to be one source to the environment.

With a 400 ppb limit after 36 months, the company estimates that the amount of C9-C14 PFCAs releases would be reduced to 20 kg/year from all fluoropolymers.

In the call for evidence, information relating to concentrations of PFCAs in fluoropolymers and potential emissions were only obtained from two companies, with one presenting an estimate (2 000 ppb assumed as maximum concentration) and the other measured levels of 92 ppb in the fluoropolymer. Based on this information ECHA estimated potential emissions of PFCAs to 2 kg/year (see above), which thus is a very uncertain estimate.

The technical report has also estimated potential emissions using another approach. Based on very limited (and confidential) information from the call for evidence, ECHA has estimated that if only including fluoropolymers containing perfluoroalkoxy groups, the amount potentially falling within the scope of the derogation request is 10 000 tonnes, which based on an assumed maximum concentration of C9-C14 PFCAs of 2 000 ppb would potentially in worst case calculations result in annual release of 20 kg C9-C14 PFCAs, decreasing to 4 kg/year after 36 months when the limit is decreased to 400 ppm.

RAC concludes that all fluoropolymers, but especially fluoropolymers containing perfluoroalkoxy-groups, may contain C9-C14 PFCAs, and that the actual concentrations are largely unknown, and that emissions of PFCAs in the order of 1-100 kg/year in the EU are mentioned. Based only on the risks, and the very uncertain information obtained in the call for evidence for these PBT/vPvB chemicals, a broad derogation covering all fluoropolymers cannot be supported by RAC. Acknowledging the difficulties for enforcement (see below), RAC can only support a time-limited derogation of 36 months for fluoropolymers containing perfluoroalkoxy-groups to give the producers time to implement better purification and reduce the present level of impurities (i.e. 2 000 ppb). Considering that existing industrial experience shows that impurity levels below 100 ppb are possible to achieve, RAC supports that 100 ppb is an appropriate level for impurities in fluoropolymers, once appropriate technical measures have been implemented by the manufacturers.

In the call for evidence, companies requested to include all fluoropolymers in the derogation based on the potential content of C9-C14 PFCA impurities above the allowed limits. Additionally, industry claims that enforcement will not be able to distinguish fluoropolymers with or without perfluoroalkoxy groups.

RAC finds it likely that enforcement will not be able to distinguish fluoropolymers with or without perfluoroalkoxy groups using the commonly available analytical methods, and that users of fluoropolymers may not know whether the fluoropolymers they use contain perfluoroalkoxy groups (the later also indicated in the call for evidence). A document-based enforcement is a possibility, but may be difficult as well. Thus, RAC stresses the need to make the derogation time-limited, and strongly supports reducing the allowed concentration limit after 36 months.

Industry also challenge the need to exclude articles from the derogation, stating that if the fluoropolymers used in the articles are analysed and regulated, then additional analysis of the articles is not needed. RAC understand this argument when it comes to articles produced in the EU, but notes the huge import of articles to the EU containing fluoropolymers that may not have been produced using fluoroplastics and fluoroelastomers fulfilling the requirement of this legislation. Thus, RAC supports the current wording that C9-C14 PFCAs are only allowed in articles if the concentration of the sum of C9-C14 PFCAs is below 25 ppb and the concentration of the sum of C9-C14 PFCA related substances are below 260 ppb. A derogation for articles could potentially be considered for mixtures and articles produced using fluoropolymers (containing perfluoroalkoxy-groups) already fulfilling the legal requirements, but such a derogation would probably lead to significant problems for enforcement and is

therefore not supported. Furthermore, based on the assumption that the PFCAs are removed by the processes used when the fluoropolymer mixtures are processed into articles, as stated in the SEAC opinion, RAC supports that the derogation shall not apply to articles.

1.3. Justification for the opinion of SEAC

1.3.1. SEAC conclusion(s):

SEAC agrees that the derogation proposed by the ECHA is justified and proportionate from a socio-economic point of view based on the information provided in the call for evidence and the ECHA technical report.

However, SEAC notes that the socio-economic benefits and costs of the derogation are both very uncertain due to the limited information available and that it is not possible for SEAC to verify independently the information submitted by industry during the call for evidence.

It is also difficult to compare the additional benefits and costs of the 100 ppb limit, compared to the initial proposal of 400 ppb, since the consideration that best available technologies will allow to reach these thresholds appears to be based on limited information provided by one company. This taken into account, SEAC considers that it is justified to minimise remaining emissions and agrees that the concentration limit of 100 ppb is proportionate, especially taking a long-term perspective.

1.3.2. Key elements underpinning the SEAC conclusion(s):

Scope of the proposed derogation

Since comments during the call for evidence have shown that fluoropolymers containing different perfluoroalkoxy groups may contain C9-C14 PFCAs as impurities as a result of the manufacturing process, SEAC agrees it would be equally relevant to cover fluoropolymers containing also other types of perfluoroalkoxy groups, rather than those containing only perfluoropropoxy groups and perfluoromethoxy groups, by the derogation.

SEAC also agrees that the information submitted in the call for evidence to justify an extension of the derogation to all fluoropolymers and to mixtures and articles containing those fluoropolymers is not robust enough to support the request in line with the ECHA analysis.

Availability of alternatives

SEAC notes the conclusion by ECHA, based on a study by PlasticsEurope, that there are potentially numerous alternative materials but that none can provide a universal alternative. The study provided by PlasticsEurope also presents information that these alternative materials have in general lower performance than fluorinated polymers.

SEAC also notes that post-processing technologies or alternative chemical processes that can lower C9-C14 PFAS impurities are under development, as confirmed by several comments by major manufacturers (comments #1310 and #1313). Although the possibility to implement an alternative technology that could comply with the proposed limit in 36 months was confirmed by one respondent in comment #1313 but found uncertain by another respondent in comment #1310, the 36 months implementation period as proposed in the ECHA study was found to be overall appropriate by SEAC. It is to be noted that the overarching sectoral organisation PlasticsEurope did not mention issues with this implementation timeline.

Socio-Economic impacts

Given the conclusion that there are at present no technically feasible alternative materials or technology for some of the applications, the economic impact of not having the proposed derogation would depend on the reaction of supply chains. The economic impact is difficult to assess but SEAC agrees that it could include significant loss of functionality, and affected polymers are used for instance for healthcare, for safety in aviation, or for engines / fuel systems that meet the latest environmental emissions standards. SEAC notes that the applications of the possibly affected fluoropolymers are related to a very wide array of industry supply chains, including also in sectors that may present other environmental impacts (chemicals and materials in general, oil and gas extraction, etc.). Therefore, the socio-economic costs of not having the derogation in those sectors might be compensated by prevented environmental impacts and not be as significant as claimed by several comments. Another source of uncertainty is that the ability to comply with the 100 ppb threshold after the transition of 36 months is established for one stakeholder but less clear for another, who reported the possibility to go below 400 ppb but above 100 ppb for several fluoropolymers. Therefore, the costs associated with this stricter limit proposed by ECHA are not well understood.

Practicality and monitorability

SEAC notes that several stakeholders comment that there are currently technical challenges ahead to have analytical techniques in different matrices, and standardisation will still need to be carried out once these technical issues are overcome. SEAC regards this situation as a general practicality and monitorability issue for the whole restriction, and concluded in its opinion on the restriction proposal that a threshold of 25 ppb for the sum of C9-C14 PFCA and their salts, and of 260 ppb for the sum of C9-C14 PFCA related substances, are achievable.

Proportionality

SEAC notes that the derogation would, during the transition period of 36 months, imply maximum additional annual emissions of C9-C14 PFCA of 20 kg/y that should be compared to around 10 t/y of C9-C14 PFCA and related substances emissions avoided annually by the restriction as a whole.

After this period, the additional emissions would represent each year a maximum of a very small share of the total avoided emissions for a limit of 400 ppb, and even more so in case the limit is 100 ppb as proposed by ECHA.

These emissions could be a worst case since at least one company already implemented techniques to reduce emissions. However, it is not totally clear if after post-treatment no emission at all to the environment would occur.

Conversely the economic impacts of not having the derogation, despite being uncertain, as noted above, appear to be potentially significant, and there could also be loss of performance in some applications that relate to public health, safety, and environmental protection and climate change.

SEAC therefore finds that the proposed derogation is proportionate.

Industry seems overall to consider that the use of fluorinated polymers would continue for a long time, given that alternative materials often do not have comparable performance. Accordingly, these remaining emissions might continue for a long period. Therefore, SEAC considers that it is justified to minimise the remaining emissions and agrees that the concentration limit of 100 ppb is proportionate, especially taking a long-term perspective.

2. Derogation for C9-C14 PFCAs and PFOA as impurities in PTFE micro powders

2.1. Summary and conclusion from ECHA technical report

The Commission requested ECHA to assess a proposal for a derogation for C9-C14 PFCAs as impurities in PTFE micro powders based on a request by industry. The request was submitted after the finalisation of the RAC and SEAC opinion on C9-C14 PFCAs. The text of the proposal reads as follows:

"A 5-year derogation for the production, use and placing on the market of PTFE micro powder produced by electromagnetic irradiation [up to 400 kilograys] with a concentration limit of 1 000 ppb (0.0001 % by weight) for the sum of C9-C14 PFCAs".

Additionally, at the request of the Commission, ECHA has assessed the present derogation for PFOA as an impurity in PTFE micro powders (as included in Part A of Annex I to Regulation (EU) 2019/1021) with a view to ensure consistency with the derogation requested for C9-C14 PFCAs. The present exemption¹⁰ for PFOA reads as follows:

"For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of PFOA and its salts equal to or below 1 mg/kg (0,0001 % by weight) where they are present in polytetrafluoroethylene (PTFE) micro powders produced by ionising irradiation [of up to 400 kilograys]¹¹ or by thermal degradation as well as in mixtures and articles for industrial and professional uses containing PTFE micro powders. All emissions of PFOA during the manufacture and use of PTFE micro powders shall be avoided and, if not possible, reduced as far as possible. This exemption shall be reviewed and assessed by the Commission no later than 5.7.2022."

PTFE micro powders are finely divided low molar mass (104-106 g/mol) PTFE fragments with small particle sizes (1-20 µm). PTFE micro powders are used as additives in solid or liquid matrices to reduce surface friction and increase wear resistance. A wide variety of industries employ PTFE micro powders for their specific lubricant properties such as automotive, semi-conductors, electronics and industrial machinery.

The majority of PTFE micro powders (about 85% of those currently produced on a global

¹⁰ In the context of the POP Regulation the term exemption is used for a derogation from the conditions of the restriction.

¹¹ Section in square brackets scheduled to be deleted in upcoming amendment of POP regulation.

scale) are manufactured by the degradation of PTFE resin via controlled irradiation or thermal degradation to produce lower molecular weight PTFE. It is then ground to varying particle size ranges to suit specific applications. The manufacturing processes generates C9-C14 PFCAs and PFOA as unintended impurities. A post-treatment process is required to reduce the concentration of such impurities to concentration levels below 25 ppb.

PFOA

Processes have been developed to reduce the concentration of PFOA to below the 25 ppb threshold set out in the POP Regulation. These processes have been successfully implemented by most PTFE micro powder manufacturers. The derogation currently included in the POP regulation for PFOA impurities in PTFE micro powders allows the implementation of technical solutions within two years of the entry into force of the POP Regulation. However, rather than being reviewed prior to 05 Jul 2022 (as currently stated in the POP Regulation), it is proposed that because of rapid technical progress the derogation for PFOA becomes time-limited and apply only until 04 Jul 2022.

C9-C14 PFCAs

Similar processes for the reduction of C9-C14 PFCA impurities in PTFE micro powders are being, or have been, developed. These have indicated the potential to reduce the concentration of C9-C14 PFCAs from present levels of 1 000 ppb to levels below 400 ppb (in some cases to below 25 ppb). Several manufacturers are in the process of implementing and validating these technical solutions. Taking into account the time required for the implementation of technical measures to reduce the level of PFOA impurities in PTFE micro powders, it is estimated that these processes may be fully operational within two years.

Releases to the environment of 4 kg/year of C9-C14 PFCAs may arise as a result of a derogation (assuming a worst case scenario). This level of potential emissions presents a limited risk that, nevertheless, should be minimised. It is expected that the implementation of post-treatment processes at the manufacturing stage of PTFE micro powders may significantly lower the level of impurities and potential emissions.

The ban of the manufacture and use of PTFE micro powders containing C9-C14 PFCA impurities >25 ppb is considered to be disproportionate after taking into account the limited potential for releases, wide variety of applications and the lack of alternatives in general. A temporary derogation to allow the manufacture and use of PTFE micro powders containing a concentration of C9-C14 PFCA impurities below 1 000 ppb is considered to be justified.

Nevertheless, effective risk management measures should be in place to ensure that emissions to the environment are avoided as far as technically and practically possible during the manufacture and use of the PTFE micro powders, while the derogation is in place. The derogation should be reviewed in the future to determine whether C9-C14 PFCA impurities can be consistently reduced below 25 ppb. A 36 month period would provide enough time for the implemented processes to be fully validated and operational.

An extension of the scope of the derogation for C9-C14 PFCA impurities in PTFE micro powders to include mixtures and articles for industrial and professional uses containing PTFE micro powders, in line with the derogation for PFOA in the POP Regulation, is justified. It is to be noted that mixtures and articles containing PFOA impurities also contain C9-C14 PFCA impurities and therefore the proposed extension allows the derogation for PFOA to be fully effective. Nevertheless, any review of the derogation for C9-C14 PFCA impurities in PTFE micro powders in the future will require more data on the concentrations of C9-C14 PFCA

impurities in articles and mixtures.

An extension to the scope of the derogations to any manufacturing process of PTFE micro powders is supported. There is no evidence that the type and level of radiation affects the concentration of C9-C14 PFCA and PFOA impurities in the irradiated PTFE micro powders.

The absence of standardised analytical methods to measure the levels of PFOA and C9-C14 PFCAs may present a challenge for the compliance and enforcement of the threshold limits set up in the proposed derogations.

Derogation proposed by ECHA for C9-C14 PFCAs as impurities in PTFE micro powders:

"The concentration limit referred to in paragraph 2 shall be 1 000 ppb for the sum of C9-C14 PFCAs, their salts and PFCA related compounds where these are present in polytetrafluoroethylene (PTFE) micro powders produced by ionising irradiation or by thermal degradation, as well as in mixtures and articles for industrial and professional uses containing PTFE micro powders. All emissions of C9-C14 PFCAs during the manufacture and use of PTFE micro powders shall be avoided and, if not possible, reduced as far as technically and practically possible. This derogation shall be reviewed and assessed by the Commission no later than [36 months after the entry into force of the restriction]."

Revised exemption proposed by ECHA for PFOA as impurities in PTFE micro powders:

*"For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of PFOA and its salts equal to or below 1 mg/kg (0.0001 % by weight) where they are present in polytetrafluoroethylene (PTFE) micro powders produced by ionising radiation ~~of up to 400 kilograys~~ or by thermal degradation, as well as in mixtures and articles for industrial and professional uses containing PTFE micro powders. All emissions of PFOA during the manufacture and use of PTFE micro powders shall be avoided and, if not possible, reduced as far as technically and practically possible. **This exemption shall be reviewed and assessed by the Commission no later than 5.7.2022 apply until 4.7.2022.**"*

2.2. Justification for the opinion of RAC

2.2.1 RAC conclusion(s):

RAC supports the analysis made by ECHA and the above proposals.

2.2.2. Key elements underpinning the RAC conclusion:

There are different views expressed in the comments as to the production volumes and use of micro powders in the EU, but 4 000 tonnes per year seems reasonable.

The responses to the call for evidence show that micro powder are finely divided low molar mass (≥ 104 g/mol) PTFE-additives with small particle sizes, with size estimations ranging from (1-20 μm) to average size of 50 μm .

For PFOA, some comments may indicate that a limit of 1 000 ppb is unnecessary high, as many producers already have changed their processes and have a content of PFOA less than 25 ppb. However, at the same time, it is clear that 25 ppb cannot be reached yet by all

producers, leading to this request for a derogation. As it is not known where in between 25 and 1 000 ppb a more realistic limit may lie, RAC supports the proposed limit of 1 000 ppb. Allowing a content of 1 000 ppb for 2 years will in truly worst-case calculations result in maximum content of 10 kg PFOA in the micro powder used in two years, but it is acknowledged that this likely is a significant overestimation. Also, all PFOA may not be emitted from the different products to the environment.

It seems clear that levels of less than 25 ppb will be achievable in a short period of time, so a time-limited derogation until 2022 is supported. At this level, and assuming a use of 4 000 tonnes micro powder per year, the amount of PFOA in this micro powder would be in the order of 100 g/year.

C9-C14 PFCAs are also formed when producing micro powder, and the limited information received so far indicate that levels of C9-C14 PFCAs in micro powder is currently greater than that of PFOA, partly because there are six PFCAs, partly because the optimisation of production processes so far has been focused on PFOA. Allowing a maximum level of 1 000 ppb therefore seems justified for the time being, but since it is likely that the reduction of PFOA and C9-C14 PFCAs involves the same purification step (heating), it should be possible to reduce the content of C9-C14 PFCAs in micro powder over a relatively short period of time. RAC supports the proposed 36 months transition period, mainly based on the concern that it may take longer to reduce the concentration of the sum of six PFAS to 25 ppb than reduce the concentration of only one (PFOA) to 25 ppb. PFOA and C9-C14 PFCAs are formed in the production of micro powder by ionising irradiation and thermal degradation, irrespective of the type and level of energy applied. RAC sees no reason to treat the production processes differently, and therefore supports that the limit of 400 kilograys for the irradiation process identified in the PFOA exemption in the POPs Regulation is deleted from the derogation.

RAC supports that the derogation also should apply to mixtures and articles produced using micro powder.

In conclusion, RAC supports ECHA's proposals for the derogation for C9-C14 PFCAs and PFOA as impurities in PTFE micro powders.

2.3. Justification for the opinion of SEAC

2.3.1. SEAC conclusion(s):

SEAC agrees that the derogations proposed by ECHA are justified and proportionate from a socio-economic point of view based on the information provided in the call for evidence and the ECHA technical report.

One major manufacturer reports that, given the variability in impurities concentrations, a concentration limit of 2 000 ppb should be granted for the sum of C9-C14 PFCAs, but since other stakeholders implicitly support 1000 ppb, SEAC agrees with the proposal of 1000 ppb. SEAC finds there is lack of evidence from the call for evidence for ECHA to propose a lower limit of 1 000 ppb.

2.3.1. Key elements underpinning the SEAC conclusion(s):

Scope of the proposed derogation

Since PTFE micro powders are also used in mixtures and articles, SEAC agrees that they should also be derogated. However, concentrations of impurities in mixtures and articles are lower than in PTFE micro powders themselves. Therefore, a specific and lower concentration limit for mixtures and articles could have been proposed by ECHA, but SEAC acknowledges there would be scarce information to base that limit on.

Availability of alternatives

SEAC notes that several manufacturers of PTFE micro powders are in the process of implementing and validating technical solutions to reduce the level of impurities down to the limits of the restriction. The information from the call for evidence contains consistent statements by industrial stakeholders that there are no alternative materials to PTFE micro powders, but information to support this claim appears to be scarce.

Socio-Economic impacts

Given the conclusion that there are at present no technically feasible alternative materials or technology for some of the applications, the economic impact of not having the proposed derogations would depend on the reaction of supply chains. The economic value of what would be affected is very difficult to estimate, since information and justification are scarce and not detailed in the answers to the call for evidence. However, SEAC agrees that the economic impact could be in terms of significant loss of functionality, with possible negative socio-economic impacts when micro powders are used for instance for process safety and higher durability of materials in various applications.

Practicality and monitorability

SEAC notes that there are currently technical challenges to have analytical techniques in different matrices, and standardisation will still need to be carried out once these technical issues are overcome. SEAC regards this situation as a general practicality and monitorability issue for the whole restriction, and concluded in its opinion on the restriction that a threshold of 25 ppb for the sum of C9-C14 PFCAs and their salts, and of 260 ppb for the sum of C9-C14 PFCAs related substances, are achievable.

Proportionality

SEAC notes that the derogations would, during the transition period, imply maximum additional annual emissions of C9-C14 PFCA of 4 kg/y, and also of 4 kg/y for PFOA impurities. These values are quite uncertain (in particular due to uncertainties in releases, and in volumes of micro powders) but are considerably (several orders of magnitude) smaller than the emissions avoided by the restriction.

Conversely the economic impacts of not having the derogations, despite uncertain as noted above, appear to be potentially significant, and there could also be loss of performance in some applications that relate to safety, and environmental protection.

SEAC therefore finds that the proposed derogations are proportionate.

REVIEW OF SOME OF THE DEROGATIONS RECOMMENDED IN THE RAC AND SEAC OPINION ON THE PROPOSED RESTRICTION OF C9-C14 PFCAs

3. Derogation for unavoidable by-products (C9-C14 PFCAs) in C6 telomerisation products

3.1. Summary and conclusion from ECHA technical report

The derogation under the C9-C14 restriction proposed by RAC and SEAC for unavoidable by-products (C9-C14 PFCAs) in C6 telomerisation products currently reads as follows:

"4. Paragraphs 1 and 2 shall not apply to a) the manufacture of a substance where this occurs as an unavoidable by-product of the manufacture of fluorochemicals with a perfluoro carbon chain equal to or shorter than 6 atoms".

The Commission has requested ECHA to review this derogation noting that a similar derogation for PFOA (as an unavoidable by product) was not adopted under the POP Regulation.

Telomerisation is now the most commonly used process for manufacturing highly fluorinated substances, including short chain fluoro substances. The first step involves the reaction of a perfluoroalkyl iodide with a tetrafluoroethylene iodide to form a mixture of perfluoroalkyl iodides with longer perfluorinated chains. This mixture is further distilled which leads to the production of a long-chain side fraction (called PFOI side fraction) and a C6 main fraction. The long-chain side fraction is separated as an isolated intermediate and not used in the manufacture of C6 substances.

The PFOI side fraction consists mainly of long-chain substances with concentration levels as high as 40% of C10 to C14 compounds and represents approximately 20 % of the total volume manufactured, the other 80 % being the C6 main fraction.

The quantity of residual PFOI long-chain side fraction has been reduced in recent years and steps are being taken to reduce it even further. At present the PFOI long-chain side fraction is exported for use in applications covered by exemptions under the POP Regulation on PFOA. After expiry of these exemptions, the PFOI long-chain side fraction will be handled as waste and incinerated in an adequate facility.

It is estimated that the volume of PFOI long-chain side fraction is in the range of 100 to 1 000 tonnes/year. This estimate is based on the information provided by a single manufacturer.

The manufacturing of C6 chemistry generates 40 to 400 tonnes per year of long chain perfluorinated compounds (including C9-C14 PFCAs and C8 (PFOA)) as by-products. Once the restriction on C9-C14 PFCAs under REACH is adopted and enters into force, the use of C9-C14 PFCAs in the EU will be limited to the manufacture of derogated products until the time-limited derogations expire.

If the derogation proposed in the RAC and SEAC opinion¹² for C9-C14 PFCAs as unintentional by-products is adopted, the side fraction may be exported to be used in the manufacture of products not restricted under other legislation (as long as the fraction did not contain PFOA). In case the derogation is not granted, once the derogations for the use C9-C14 PFCAs in specific applications expire, the side fraction will be handled as waste and incinerated.

The socioeconomic impacts of this scenario have not been quantified although they may be significant as the long side fraction accounts for up to 20 % of the production volume at present. However, it is expected that the implementation of alternative technologies in the manufacture of C6 fluorosubstances will lead to a reduction in the volume of long chain perfluorinated compounds as by-products. According to the information available, these alternative technologies are already being implemented in the sector. On the other hand, although it is not possible to estimate the volume of releases that may result from the use outside the EU of 40 to 400 tonnes per year of long chain perfluorinated compounds, they will contribute significantly to the total volume of PFAS released to the environment at a global level. Taking into account the potential volume of releases of C9-C14 PFCAs to the environment, the long range transport potential and the availability of new technologies to reduce the generation of long chain perfluorinated compounds as by-products in the manufacture of short chain fluorosubstances, the current requirement is considered proportionate and there is no need for a derogation.

Accordingly, ECHA proposes to delete the derogation.

~~“4. Paragraphs 1 and 2 shall not apply to a) the manufacture of a substance where this occurs as an unavoidable by-product of the manufacture of fluorochemicals with a perfluoro carbon chain equal to or shorter than 6 atoms”.~~

3.2. Justification for the opinion of RAC

3.2.1. RAC conclusion(s):

RAC supports the analysis made by ECHA and the proposal to delete the derogation.

3.2.2. Key elements underpinning the RAC conclusion:

In the production of C6 products, C8 and C9-C14 perfluorinated carboxylic acids (PFCAs) are

¹² RAC and SEAC Opinion on an Annex XV dossier proposing restrictions on PFNA, PFDA, PFUnDA, PFDoDA, PFTTrDA, PFTDA; their salts and precursors: <https://echa.europa.eu/documents/10162/3336e40c-b52c-d9f6-3745-3b4caf61599e>

formed. The long-chain PFCAs is separated into a side fraction, and the derogation concerns whether further use of this side fraction should be allowed, e.g. in the manufacture of products derogated from the PFOA and C9-C14 PFCAs restriction.

In the call for evidence, only one comment was received from a manufacturer of C6 PFAS, making clear that the company is implementing a new technology platform limiting the residual long-chain side fraction to the extent that no derogation is needed. This is in line with the PFOA restriction, where there were no requests for derogations. Whether there are other C6 PFAS manufacturers in the EU producing C9-C14 by-products is not clear from the information available to RAC. However, as the side fraction can constitute up to 20% of manufactured PFAS, potentially large amounts of by-products can be produced (many tonnes/year) and used in applications covered by exemptions, eventually available to environmental release and contributing to environmental contamination at a global level. Considering the large amounts that could be potentially produced and released to the environment, RAC does not support a derogation that can lead to the release of many tonnes of PBT/vPvB substances. Thus, RAC concludes in line with ECHA's technical analysis that no derogation should be allowed in either the C9-C14 restriction or in the PFOA restriction. The side fraction containing C9-C14 PFCAs will therefore be incinerated as waste once the restrictions enter into force and derogations for the use of C9-C14 PFCAs in specific applications expire.

In conclusion, RAC supports ECHA's proposal to delete the derogation on C9-C14 PFCAs for unavoidable by-products in C6 telomerisation products.

3.3. Justification for the opinion of SEAC

3.3.1. SEAC conclusion(s):

SEAC considers that under the present circumstances, considering technological advances and the impacts brought about by the inclusion of PFOA in the Stockholm Convention, this derogation is not justified.

3.3.2. Key elements underpinning the SEAC conclusion(s):

SEAC regards that the effect of this derogation, if applied, would be that the long-chain side fraction produced in the manufacture of C6 intermediates could be further exported when application-specific derogations in the EU have expired. Without this derogation, considering article 5 of Directive 2008/98/EC on waste, the long-chain side fraction will have to be considered waste and handled accordingly once the exemptions of applications of C9-C14 PFCAs have expired.

Availability of alternatives

SEAC notes that according to the ECHA report, alternative technologies for the manufacture of short-chain fluorochemicals, enabling lower volumes of C9-C14 PFCAs and PFOA produced as by-products, are available. One C6 manufacturer has already implemented a new technology platform to significantly reduce the long-chain side fraction in their manufacturing process. There is no information available for SEAC on the actual performance level of this technology. SEAC, however, understands that the technology has been recently implemented and will be refined to further limit the volume of the long-chain side fraction unintentionally

produced. Also, the applicability of the respective technologies for different actors and in different circumstances is not clear from the ECHA report. However, based on the outcome of the call for evidence, SEAC understands that the number of actors affected by the derogation is very low and potentially only one.

Socio-Economic impacts

The conclusion on economic consequences in the ECHA report was based on qualitative considerations of economic impacts in terms of profit losses relating to the forgone sales of the C9-C14 PFCAs. Also, potentially high costs of incinerating the respective volume of the substances and impacts on actors down the supply chain were highlighted in the ECHA report but were not further estimated due to lack of data. SEAC agrees that where quantitative information is not available, it is appropriate to base conclusions on qualitative or semi-quantitative considerations. SEAC also agrees that the above-mentioned cost factors appear to be the most relevant ones to consider. The conclusion in the ECHA report was that the economic impacts may be significant. Given the share of the long-chain side fraction in the product (20%) and the estimated volume of product to be handled as waste instead of exported (40 to 400 tonnes/year, exact figure confidential), SEAC agrees that the expected economic consequences may indeed be high as evaluated based on the performance of the current technology. However, based on the available information SEAC understands that these impacts can be greatly alleviated in a short period of time by implementing and refining existing alternative technologies.

SEAC understands that the long-chain side fraction also includes a C8 fraction. Based on the ECHA report that can be expected to be >60% out of the 20% share of the long-chain side fraction. The presence of a C8 fraction means that the long-chain side fraction cannot be used in countries having ratified the Stockholm Convention. The inclusion of PFOA, its salts and PFOA-related substances in the Stockholm Convention means that there are restrictions on their uses much more widely in the world than earlier. Also, exemptions applied under the POP Regulation in the EU are fewer and generally shorter in duration than what was the case under REACH restriction entry 68, limiting potential uses of the long-chain side fraction. This limits the possibilities to sell the long-chain side fraction and thereby limits the economic benefits of applying the derogation. SEAC notes that in principle it could be possible to separate the C8 fraction out from the long-chain side fraction to enable benefiting from the sales of the latter one. No information is available on the profitability of such operations. However, SEAC assumes that it might not be an attractive business opportunity due to the relatively high proportion of C8 in the product.

Practicality and monitorability

No consequences on the practicality of the restriction of C9-C14 PFCAs by not granting the derogation were identified in the ECHA report. SEAC considers that allowing the derogation might alleviate any implementation issues at C6 manufacturers, whilst no difference is expected in terms of enforceability or monitorability.

Proportionality

Considering the high amounts of long-chain substances that can be produced (40 to 400 tonnes per year), the progress with availability of alternatives and the prospects with possibilities to sell the long-chain side fraction, SEAC does not support the derogation, in line with the proposal by ECHA.

Whilst SEAC considers that every proposal must be evaluated against the baseline applicable at the time of making the proposal, SEAC however highlights that also the manufacture, use and placing on the market of C6 substances might be restricted in the near future. A restriction proposal on PFHxA, its salts and related substances is currently being evaluated by the ECHA committees. Accordingly, any benefits from the derogation evaluated now might be of short duration.

4. Derogation for impurities in short-chain alternatives

4.1. Summary and conclusion from ECHA technical report

Both PFOA and C9-C14 PFCAs are present as impurities in intermediates used in the manufacturing of fluorochemicals with a perfluorocarbon chain length equal to or shorter than six atoms. The opinion of SEAC on the proposal for a C9-C14 PFCAs restriction under REACH includes an open-ended derogation for such impurities, without setting a maximum concentration limit:

"Paragraph 1 shall not apply to a substance that is to be used, or is used as a transported isolated intermediate, provided that the conditions in Article 18(4) lit. a) to f) of this Regulation are met".

On the other hand, the exemption for PFOA (as included in Part A of Annex I to Regulation (EU) 2019/1021) reads as follows (see Annex 2):

"For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of PFOA-related compounds equal to or below 20 mg/kg (0.002 % by weight)[20 ppm] where they are present in a substance to be used as a transported isolated intermediate within the meaning of Article 3 point 15 (c) of Regulation (EC) No 1907/2006 and fulfilling the strictly controlled conditions set out in Article 18(4)(a) to (f) of that Regulation for the production of fluorochemicals with a carbon chain equal to or shorter than 6 atoms. This exemption shall be reviewed and assessed by the Commission no later than 5.7.2022."

The Commission has requested ECHA to identify a concentration limit value for the level of C9-C14 PFCAs impurities in substances to be used as intermediates for the production of short chain fluorinated compounds. This concentration limit value should be sufficiently low to limit the potential risks from the presence of C9-C14 PFCAs while allowing the manufacturing of the short-chain fluorinated substances. Additionally, the Commission requested an assessment as to whether the concentration limit value for PFOA impurities in intermediates can be lowered.

The derogation for the use of C6 fluorotelomers as transported isolated intermediates is required to allow the further processing of the intermediates off site. At present, a limit of 20 ppm for PFOA impurities is identified in the derogation of the POP Regulation on PFOA. Based on the information provided in the call for evidence, a limit value of 10 ppm for C9-C14 PFCA impurities is proposed to be included in any derogation for these substances. In addition, the present limit value of 20 ppm for PFOA impurities is the lowest that can be complied with, taking into account the technological solutions available.

The implementation of strictly controlled conditions (as set out in article 18 of the REACH Regulation) should ensure that releases are minimised as far as possible during the manufacture and use of the substances. Nevertheless, it is expected that further technological solutions can be implemented to reduce the level of PFOA and C9-C14 PFCA impurities in C6

fluorotelomers. It is reported that C6 monomers are imported into the European market with level of impurities below the thresholds set out in the POP Regulation and the proposed C9-C14 PFCAs restriction (PFOA: 25 ppb; PFOA-related substances: 1ppm ; sum of C9-C14 PFCAs: 25 ppb; C9-C14 related substances: 260 ppb). Thus, it is proposed that the derogation for the use of C6 fluorosubstances as transported isolated intermediates is time limited and is reviewed by the Commission after two years of the entry into force of the restriction. This time will allow the manufacturers of short chain alternatives to assess and implement additional measures to reduce the level of C9-C14 PFCAs impurities in the C6 fraction of the telomerisation process.

Derogation proposed by ECHA for C9-C14 PFCAs as impurities in intermediates used for the production of fluorochemicals with a perfluorocarbon chain length equal to or shorter than 6 atoms:

*"The concentration limit referred to in paragraph 2 shall be **10 ppm for the sum of C9-C14 PFCAs, their salts and PFOA related substances** where they are present in a substance to be used as a transported isolated intermediate within the meaning of Article 3 point 15 (c) and fulfilling the strictly controlled conditions set out in Article 18(4)(a) to (f) for the production of fluorochemicals with a carbon chain equal to or shorter than 6 atoms. **This exemption shall be reviewed and assessed by the Commission no later than [two years after the entry into force of the restriction]**".*

Similarly, ECHA proposes to clarify the scope of the exemption for PFOA (as included in Part A of Annex I to Regulation (EU) 2019/1021) as follows:

*"For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of **PFOA, its salts and PFOA-related compounds** equal to or below 20 mg/kg (0.002 % by weight) where they are present in a substance to be used as a transported isolated intermediate within the meaning of Article 3 point 15 (c) of Regulation (EC) No 1907/2006 and fulfilling the strictly controlled conditions set out in Article 18(4)(a) to (f) of that Regulation for the production of fluorochemicals with a carbon chain equal to or shorter than 6 atoms. This exemption shall be reviewed and assessed by the Commission no later than 5.7.2022."*

4.2. Justification for the opinion of RAC

4.2.1. RAC conclusion(s):

RAC supports the analysis made by ECHA and the above proposal. However, it should be considered if a review of the limit could be set at the same time point as stipulated by the PFOA exemption in the POP Regulation, i.e. in 2022.

4.2.2. Key elements underpinning the RAC conclusion:

This derogation concerns whether C6 products should be allowed to contain unlimited amounts of C9-C14 PFCAs without any time limits.

The POP-regulation (EU 2019/1021) will allow 20 ppm PFOA in C6-products, with a review in 2022, since EU-producers of C6 products are likely to have adjusted their processes such that they within two years can produce C6 products with a low content of PFOA. In contrast, the

C9-C14 restriction proposal is based on a proposal from SEAC, suggesting that any levels of C9-C14 will be allowed in C6-products without any time-limits.

The call for evidence indicates that there are imported monomers for production of C6-products that fulfil the requirements of the restrictions for PFOA and C9-C14 PFCAs, i.e., containing levels of C8-C14 PFCAs and related substances below the concentration limits proposed. However, the only EU producer responding to the call for evidence cannot fulfil those requirements and therefore would require a derogation to continue their production of C6 products.

Although the scope of this derogation only concerns some C6 intermediates ("transported isolated intermediate within the meaning of Article 3 point 15 (c) and fulfilling the strictly controlled conditions set out in Article 18(4)(a) to (f)" for the production of C6 chemicals), there is a risk that the derogation will be interpreted to concern any C6 products. Since the amount of C6 used in the EU is in the order of 10 000-100 000 tonnes per year, having no limit on the content of C9-C14 PFCAs may with time lead to high environmental emissions. It is noted that the 'strictly controlled conditions' mentioned in the proposed derogation only concerns the use of the C6 intermediates in the manufacturing of the C6 products, and that nothing is known regarding emission potential at the use stage of the C6 products containing the C9-C14 PFCAs. Thus, RAC cannot support that no limits are set on the content of C9-C14 PFCAs in C6-based products.

Based on the call for evidence, manufacturers can already achieve a 10 ppm limit, but since they are currently improving their processes a review of any limits in 2022 in line with the PFOA restriction seems reasonable, or at the latest within two years after entry into force.

In conclusion, RAC supports ECHA's proposal for a derogation for C9-C14 PFCAs as unintentional by-products in C6 telomerisation products. The term "carbon chain length equal or shorter than 6 atoms" used in the ECHA's proposal (and in the PFOA exemption in the POP Regulation) is proposed to be replaced by the term "perfluorocarbon chain length equal or shorter than 6 atoms" in line with the RAC and SEAC opinion on the restriction proposal on PFCAs (paragraph 4a of the conditions of the restriction as proposed by RAC and SEAC).

RAC's proposal reads as follows:

*"The concentration limit referred to in paragraph 2 shall be **10 ppm for the sum of C9-C14 PFCAs, their salts and PFCA related substances** where they are present in a substance to be used as a transported isolated intermediate within the meaning of Article 3 point 15 (c) and fulfilling the strictly controlled conditions set out in Article 18(4)(a) to (f) for the production of fluorochemicals with a perfluorocarbon chain length equal to or shorter than 6 atoms. **This exemption shall be reviewed and assessed by the Commission when the PFOA exemption is reviewed in 2022, or at the latest [two years after the entry into force of the restriction]**".*

RAC also supports ECHA's proposal to clarify the scope of the derogation for PFOA (as included in Part A of Annex I to Regulation (EU) 2019/1021). Additionally and similar to RAC's proposal for the derogation for PFCAs, RAC considers that the term "carbon chain length equal or shorter than 6 atoms" should be replaced by the term "perfluorocarbon chain length equal or shorter than 6 atoms". Therefore, RAC's proposal reads as follows:

*"For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of **PFOA, its salts and PFOA-related compounds** equal to or below 20 mg/kg (0.002 % by weight)*

where they are present in a substance to be used as a transported isolated intermediate within the meaning of Article 3 point 15 (c) of Regulation (EC) No 1907/2006 and fulfilling the strictly controlled conditions set out in Article 18(4)(a) to (f) of that Regulation for the production of fluorochemicals with a perfluorocarbon chain length equal to or shorter than 6 atoms. This exemption shall be reviewed and assessed by the Commission no later than 5.7.2022.”

4.3. Justification for the opinion of SEAC

4.3.1. SEAC conclusion(s):

C9-C14 PFCAs, their salts and PFCAs-related substances:

Considering that RAC finds appropriate to set up a concentration limit of 10 ppm for the level of C9-C14 PFCAs impurities present in C6 intermediates from the risk perspective, and that no negative socio-economic consequences relating to this limit have been identified by the ECHA based on the information gathered in a call for evidence, SEAC supports the proposal.

SEAC takes note and supports RAC proposal to consider if a review of the limit could be set at the same time point as stipulated by the PFOA exemption in the POP Regulation, i.e. in 2022.

PFOA, its salts and PFOA-related compounds:

SEAC considers that the evidence available does not allow to conclude that a limit value of less than 20 ppm would be currently feasible and therefore supports to maintain the concentration limit of the derogation at 20 ppm, as presently defined.

Whilst SEAC is not fully aware of practices and interpretations under Regulation (EU) 2019/1021, SEAC considers that it appears beneficial in terms of practicality to clarify in the text of the PFOA restriction that the derogation applies to both PFOA, its salts and PFOA-related compounds. Furthermore, it could foster practicality to apply the limit value to the sum of all of these compounds instead of to concentrations of separate species.

4.3.2. Key elements underpinning the SEAC conclusion(s):

SEAC considers that the effect of this derogation is that manufactured C6 intermediates can only be transferred into another facility for further use if the concentration of long-chain impurities is below certain limit values and the manufacture and use of the C6 intermediates takes place under strictly controlled conditions.

C9-C14 PFCAs, their salts and PFCAs related substances:

Availability of alternatives

According to the ECHA report, technologies enabling the manufacture of C6 intermediates containing lower amounts of C9-C14 PFCAs exist. Also it was highlighted by a company in the call for evidence that the level of impurities in C6 monomers imported into the EU comply with the limits set in the proposed restriction for C9-C14 PFCAs (i.e. 25 ppb for C9-C14 PFCAs and salts, 260 ppb for related substances) and for PFOA under the POP Regulation. It is not clear from the available information whether purification steps are necessary to achieve those values. Nevertheless, the manufacturing process used in the EU seems to currently need a derogation for the placing on the market of C6 intermediate substances. SEAC notes that according to the ECHA report, the necessity of a derogation appears to apply to about 1% of transported isolated intermediates used in the EU in the manufacture of C6 substances (100 to 1 000 tonnes per year out of 10 000 to 100 000 tonnes per year of C6 intermediates). This corresponds to the share of C6 intermediates manufactured in the EU.

SEAC considers that the available technologies should be adopted by manufacturers as feasible and agrees that it is useful to clearly indicate a date for a **review**. SEAC agrees that the period should be short because the necessary technologies already exist.

Socio-Economic impacts

SEAC notes that according to the ECHA report, the concentration of C9-C14 PFCAs in C6 substances is already below 10 ppm. With this limit there would be no negative economic impacts, and the manufacture of C6 substances (using C6 intermediates) by downstream users could continue. In case a lower limit was applied, the C6 intermediates could not be placed on the EU market and only be used on-site. The related economic impacts have not been quantified in the ECHA report, but it is noted that downstream users might need to turn to suppliers outside the EU.

Proportionality

SEAC notes that RAC considered that without a concentration limit, high environmental emissions can result. According to RAC, there is a risk that the derogation will be interpreted to concern any C6 products. Since the amount of C6 used in the EU is in the order of 10 000-100 000 tonnes per year, having no limit on the content of C9-C14 PFCAs may with time lead to high environmental emissions.

Considering that no negative economic effects relating to a limit value of 10 ppm for C9-C14 PFCAs have been identified, SEAC finds the addition of that limit value proportionate.

Overall, SEAC considers that the issues currently hindering the full exploitation of the existing technologies resulting in lower levels of impurities should be solved without delay and supports RAC's proposal to review the limit in 2022 in line with the PFOA exemption in the POP Regulation, or at the latest within two years after entry into force of the C9-C14 PFCAs restriction.

PFOA, its salts and PFOA-related compounds:

According to the proposed change, the derogation in the POP regulation would cover **PFOA, its salts** and PFOA related compounds in the future. It is not clear to SEAC if it was the intention of the legislator to exclude PFOA and its salts from the derogation originally.

Availability of alternatives

SEAC notes that according to the ECHA report, alternative technologies allowing the manufacture of C6 substances with concentration levels below the limits set in the POP Regulation on PFOA (0.025 ppm for PFOA and its salts, 1 ppm for related substances) are available. Indeed it was highlighted by a company in the call for evidence that the level of impurities in C6 monomers imported into the EU comply with the limits for PFOA set in the POP Regulation on PFOA as well as with the limits for C9-C14 PFCAs set in the C9-C14 PFCAs restriction. The information available to SEAC does not indicate whether and how effective purification procedures need to be applied to get to that purity level. Anyhow, the manufacturing process used in the EU seems to currently need a derogation.

Socio-Economic impacts

It is claimed in the ECHA report that *lowering the limit value* for PFOA and its salts below 20 ppm would jeopardise the placing on the market of 100 to 1 000 tonnes of short chain fluorinated intermediates. Complying with a lower limit value does not appear feasible. Even complying with the current limit value of 20 ppm requires an additional purification step.

Although not mentioned in the ECHA report, SEAC considers that *including PFOA salts and PFOA-related compounds in the derogation* could bring about some economic benefits to industry, since product streams including those substances as impurities could also benefit from the derogation.

Practicality and monitorability

SEAC expects that stating explicitly that PFOA and its salts are covered by the derogation and specifying that the limit value applies to the sum of the substances instead of individual substances would help improve the practicality and implementability of the restriction.

Proportionality

Considering that no negative economic effects relating to a limit value of 20 ppm for PFOA, its salts and PFOA-related substances have been identified, SEAC finds the application of that limit value proportionate. The available information does not allow a full evaluation of the proportionality of a lower limit value. However, SEAC notes that the ECHA report concluded that 20 ppm for PFOA impurities is the lowest that can be complied with currently, implying that a lower limit value might not be proportionate.

ALIGNMENT OF THE DEROGATED USES OF C9-C14 PFCAs WITH THE SPECIFIC EXEMPTIONS FOR PFOA INCLUDED UNDER THE EU POP REGULATION

5. Derogations referred to in paragraph 6 of the RAC and SEAC opinion on the proposed of C9-C14 PFCAs

5.1. Summary and conclusion from ECHA technical report

The derogation proposed in paragraph 6 of the RAC and SEAC opinion on the C9-C14 restriction reads as follows:

"The derogations referred to in paragraphs 3, 4(a), (d), (e), 5 and 6 of Regulation (EC) No

1907/2006 Annex XVII, entry 68 are applicable with the same conditions to the substances referred to in column 1, paragraph 1 of this restriction.

Paragraphs 3, 4(a), (d), (e), 5 and 6 of Regulation (EC) No 1907/2006 Annex XVII, entry 68 have been replaced by paragraphs 5 and 6 in Part A of Annex I to Regulation (EU) 2019/1021 (see Annex 2).

"5. By way of derogation, the manufacturing, placing on the market and use of PFOA, its salts and PFOA-related compounds shall be allowed for the following purposes [...]

6. By way of derogation, the use of PFOA, its salts and PFOA-related compounds shall be allowed in fire-fighting foam for liquid fuel vapour suppression and liquid fuel fire (Class B fires) already installed in systems, including both mobile and fixed systems, until 4 July 2025, subject to the following conditions [...]."

The Commission requested ECHA to provide a technical analysis on any possible effect this deviation from the RAC and SEAC opinion on the proposed restriction could have for the derogated uses of C9-C14 PFCAs and to confirm whether an alignment with the derogations for PFOA in the EU POP Regulation is warranted.

A number of respondents to the call for evidence expressed concern with regard to the text of paragraph 5 e) in the EU POP Regulation on PFOA (see Annex 2): *"By way of derogation, the manufacturing, placing on the market and use of PFOA, its salts and PFOA-related compounds shall be allowed for the following purposes: (e) manufacture of polytetrafluoroethylene (PTFE) and polyvinylidene fluoride (PVDF) for the production of [.....] until 4 July 2023"*.

- (i) high-performance, corrosion-resistant gas filter membranes, water filter membranes and membranes for medical textiles,*
- (ii) industrial waste heat exchanger equipment,*
- (iii) industrial sealants capable of preventing leakage of volatile organic compounds and PM2.5 particulates,*

According to these respondents, fluoropolymer manufacturers have developed alternatives to PFOA and related long-chain polymerisation aids that can be used as polymerisation aids for the production of all types of fluoropolymers, regardless of their final application. Additionally, there are no fluoropolymer manufacturers in the EU that still use PFOA as a polymerisation aid, and therefore the derogation is not required, either for the PFOA restriction under the POP Regulation or for the proposed restriction of C9-C14 PFCAs under REACH.

ECHA notes that the RAC and SEAC opinion on the proposed restriction on C9-C14 PFCAs states that the derogation included in paragraph 6 is intended to ensure that the derogations, which apply for PFOA in entry 68 to Annex XVII of REACH, will also apply for C9-14 PFCAs (with the same conditions as in the PFOA restriction). On the other hand, the assessment on whether the derogation under paragraph 5 e) in the EU POP Regulation on PFOA should be deleted is outside the scope of the technical analysis. The derogation under paragraph 5 e) in the EU POP Regulation on PFOA should also be included in the restriction on C9-C14 PFCAs to ensure consistency between both regulations.

No additional issues were raised related to the alignment between the C9-C18 derogation included in paragraph 6 of the RAC and SEAC opinion and the derogations set out in paragraphs 5 and 6 of the PFOA derogation in the EU POP Regulation.

It is proposed to align the derogations described in paragraph 6 of the RAC and SEAC opinion on the C9-C14 PFCAs restriction to the derogations set out in paragraphs 5 and 6 of the PFOA derogation in the EU POP Regulation.

The text proposed by ECHA to replace paragraph 6 of the RAC and SEAC opinion on the C9-C14 restriction reads as follows:

"The derogations referred to in paragraphs 5 and 6 of Part A of Annex I to Regulation (EU) 2019/1021 are applicable with the same conditions to the substances referred to in column 1, paragraph 1 of this restriction."

5.2. Justification for the opinion of RAC

5.2.1. RAC conclusion(s):

RAC supports the alignment in order to reach consistency.

5.2.2. Key elements underpinning the RAC conclusion:

RAC notes that the alignment is not a scientific or risk assessment issue and therefore outside RAC's ordinary tasks. However, PFOA and C9-C14 PFCAs probably occur together in the different PFAS products used in most of the uses mentioned in articles 5 and 6 of the PFOA restriction (EU 2019/1021). Purification of products or substitution efforts will therefore be similar for both PFOA and C9-C14 PFCAs, and similar general derogations should apply in both restrictions. RAC therefore supports the alignment of these derogations.

Although outside the scope of the RAC mandate, RAC notes the comments from industry in the call for evidence challenging the need for derogation 5(e), as there is no use of PFOA and C9-C14 PFCAs in this use in Europe. Thus, RAC notes that this derogation is not needed and suggests considering deleting them in the future.

In conclusion, RAC supports the text proposed by ECHA to replace paragraph 6 of the RAC and SEAC opinion.

5.3. Justification for the opinion of SEAC

5.3.1. SEAC conclusion(s):

SEAC agrees with the derogation proposed by ECHA, in order to align the derogations described in paragraph 6 of the RAC and SEAC opinion on the C9-C14 PFCAs restriction to the derogations set out in paragraphs 5 and 6 of the PFOA derogation in the EU POP Regulation.

5.3.2. Key elements underpinning the SEAC conclusion(s):

SEAC notes that PFOA and C9-C14 PFCAs are generated and generally occur simultaneously in PFAS products, and thereby the same applications are governed by both restrictions. Therefore, SEAC considers it reasonable to have the concerned derogations aligned.

Relating to point 5e in the PFOA restriction in EU POP regulation, from the ECHA report and

answers to the call for evidence it appears that fluoropolymer manufacturers have developed alternatives to the use of PFOA as polymerisation aid for all types of fluoropolymers, regardless of their final application. There is also enough evidence that no fluoropolymer manufacturers in the EU still use PFOA in the polymerisation process, and therefore the derogation is not required, either for the PFOA restriction under the POP Regulation or for the C9-C14 PFCA's proposed restriction under REACH.