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

30 August 2020

1. Background

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, their salts and related substances (hereafter referred to as 'C9-C14 PFCAs' unless otherwise stated), that included proposals for a number of derogations for specific uses of C9-C14 PFCAs[1].

Several of the proposed derogations from the restriction on C9-C14 PFCAs relate to the presence of C9-C14 PFCAs as impurities in PFOA, their salts and related substances (hereafter referred to as 'PFOA' unless otherwise stated). These derogations were considered necessary to avoid interfering with some of the derogations included in the existing restriction on PFOA[2].

As PFOA has now been included in Annex I of the EU POP Regulation (with modified derogations)[3] the restriction entry for PFOA under REACH will soon be. These revisions, in turn, affects 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.

According to the Commission, a supplementary opinion by RAC and SEAC on ECHA's new analysis will be useful as the Commission consider the need to amend the conditions of the C9-C14 PFCAs restriction recommended by SEAC or the exemptions for PFOA included in the POP Regulation.

This report analyses if the existing derogations remain justified. The analysis is based on the data collected in a call for evidence launched by ECHA on 6 May 2020 in which 16 stakeholders provided information[4].

2. Proposed derogations

The following derogations were considered:

A. Additional derogations requested by companies

1. <u>Derogation for C9-C14 PFCAs as impurities in fluoropolymers and fluoroelastomers that contain perfluoroalkoxy groups:</u>

   Proposed derogation:

[1] RAC and SEAC Opinion on an Annex XV dossier proposing restrictions on PFNA, PFDA, PFUnDA, PFDoDA, PFTrDA, PFTDA; their salts and precursors: https://echa.europa.eu/documents/10162/3336e40c-b52c-d9f6-3745-3b4caf61599e.
[2] Entry 68 of Annex XVII of the REACH Regulation.
[3] 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
[4] https://echa.europa.eu/documents/10162/034d97c3-7975-19f5-3739-76c288ad2b0c

"The concentration limit referred to in paragraph 2 shall be 2000 ppb for the sum of C9-C14 PFCAs in fluoropolymers 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).

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

Proposed derogation for C9-C14 PFCAs:

"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 1000 ppb for the sum of C9-C14 PFCAs".

Derogation for PFOA (as included in Part A of Annex I to Regulation (EU) 2019/1021):

"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][5] 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."

B. 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:

Proposal to follow the same approach as for PFOA under the POP Regulation and not recommend a derogation.

4. Derogation for impurities in short-chained alternatives:

Proposal to identify a concentration limit value for C9-C14 PFCAs in intermediates used for the production of C6 alternatives that is sufficiently low to limit the potential risks from the presence of C9-C14 PFCAs while allowing the manufacturing of the short-chained alternatives, similar to the specific exemption proposed for PFOA under Annex I of the POPs Regulation.

C. 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 restriction of C9-C14 PFCAs

[5] *'of up to 400 kilograys'* text scheduled to be deleted in an upcoming amendment of the PFOA entry in Annex I of the POPs Regulation.

Proposal to align the derogations described in paragraph 6 of the RAC and SEAC opinion on the C9-C14 PFCAs restriction to the specific exemptions set out in paragraphs 5 and 6 of the PFOA entry in Annex I of the EU POP Regulation.

3. Assessment of derogations

This section presents the analysis of the derogations described in section 2 above. The analysis is based on the information received in a call for evidence launched by ECHA on 6 May 2020 to which 16 organisations provided input. The justifications and the conclusions are presented individually for each of the derogations.

A. Additional derogations requested by companies

3.1. Derogation #1

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

3.1.1. Scope of the proposal

Proposed derogation for C9-C14 PFCAs:

"*The concentration limit referred to in paragraph 2 shall be 2 000 ppb for the sum of C9-C14 PFCAs in fluoropolymers 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. 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.

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 polymers, the term fluoropolymer could be replaced by fluoroplastic in the text of the derogation to provide a more precise description of the scope.

Description of the use

Fluoroplastics and fluoroelastomers containing perfluoroalkoxy groups result from the polymerisation of fluoromonomers with perfluoroalkoxy-vinylethers as comonomers. Multiple perfluoroalkoxy-vinylethers are used as comonomers in different concentrations to produce specialty materials used in demanding applications.

C9-C14 PFCAs are generated unintentionally in the polymerisation of fluoroplastics and fluoroelastomers 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.

Some of the uses and applications of fluoroplastics and fluoroelastomers include:

- 'Modified PTFEs', incorporating perfluroalkoxy groups, are used in liners, valves and other processing equipment and can be welded and allow more complex designs for enhanced functionality. Perfluoroalkoxy-groups increase the performance of PTFE as a permeation barrier in chemical process industry applications for corrosion protection.
- Wet chemistry processes in semiconductor manufacturing. Several applications in semiconductor manufacturing rely on the chemical resistance, purity, temperature resistance, translucency of modified PTFEs and fluorothermoplastics that rely on perfluoroalkoxy-groups for their properties.
- Fluoroelastomers and perfluorelastomers with perfluoralkoxy-groups are used as seals in wet chemistry or dry processes like plasma etching, reactive ion etching, cleaning processes, photolithography processes and vapour deposition processes.
- Perfluoroalkoxy-groups are also critical for low temperature seals that are used in automotive, aerospace and oil and gas applications to enable low temperature sealing.
- Perfluoroalkoxy-groups in fluoroplastics enable high temperature coatings that are used in cook and bakeware as well as pharmaceutical containers that maintain the purity of the pharmaceutical inside and can sustain the rigorous conditions required for sterilisation.

Concentration of C9-C14 PFCAs impurities in fluoropolymers containing perfluoroalkoxy groups

The concentration of C9-C14 PFCAs impurities in fluoropolymers containing perfluoroalkoxy groups, as reported in the call for evidence, are shown in Table 1 below.

Table 1. Concentration of C9-C14 PFCAs impurities in fluoropolymers containing perfluoroalkoxy group

Type of polymer	Highest current level of impurities (sum of C9-C14 PFCAs in ppb) reported in the call for evidence		Lowest current level of impurities (sum of C9-C14 PFCAs in ppb) reported in the call for evidence
	Highest current level	After implementation of new technology	
Fluoroplastics containing perfluoroalkoxy groups, including: -Modified PTFE (fine powder. micro powder, aqueous dispersion grades) -PFA -FEP -Perfluorosulfonic acid ionomers -PVdF -CPT	<2 000	<400	<100
Fluoroelastomers containing perfluoroalkoxy groups, including: -FKM	<2 000	<400	LOD*

-FFKM			

Table adapted from confidential data presented in the call for evidence
*LOD (Limit of Detection) not specified

The list of fluoroplastics and fluoroelastomers included in Table 1 is considered to be illustrative of the most widely used fluoropolymers containing fluoroalkoxy groups. However, it is expected that other fluoropolymers containing fluoroalkoxy groups may also be in use, depending on the specific uses and applications.

Use volumes of fluoropolymers that contain perfluoroalkoxy groups

The overall use volumes of fluoroplastics and fluoroelastomers that contain perfluoroalkoxy groups are difficult to estimate since they are commonly used in specialty products which are only a small subsegment of a larger product category.

According to Chemours (comment #1313), a total of over 7 700 tonnes of fluoroelastomers and over 56 000 tonnes of fluoroplastics were used in Europe in 2018. However, based on confidential data provided in the call for evidence, it is estimated that less than 10 000 tonnes per year of fluoropolymers would fall within the scope of the proposed derogation. It is to be noted, however, that this value is based on very limited information and should therefore be considered as highly uncertain.

3.1.2. Justification

3.1.2.1. Environmental impacts

Based on the information submitted in the call for evidence, the estimated EU emissions resulting from the derogation, should it be adopted, would be to be less than 2 kg/year. According to the company reporting the lowest current level of C9-C14 PFCAs in fluoropolymers within the scope of the proposed derogation, best available technologies are applied to minimise the generation of C9-C14 PFCAs. The residual impurities cannot be removed further under the current manufacturing processes and further modification may adversely affect the properties of the products or increase the costs or production times beyond economic feasibility. Companies that report greater concentrations of C9-C14 PFCAs in fluoropolymers within the scope of the proposed derogation are working on the implementation of additional technologies to further reduce the level of impurities. These technologies include post-polymerisation processing techniques as well as alternative polymerisation conditions and chemistries.

It should be noted that there is some uncertainty regarding the level of emissions that would result from the proposed derogation, as it is based on data from only two respondents to the call for evidence. Additional emissions may result from other manufacturers. A worst-case scenario (sensitivity analysis), assuming the estimated volume of fluoropolymers falling within the scope of the derogation and the greatest concentration of impurities, emissions in the order of 20 kg/year may result during the initial 36 months declining to 4 kg/year.

3.1.2.2. Economic impacts

Plastics Europe (comment #1316) estimates that the fluoropolymer industry generates total revenues of around €780m per year in terms of sales on the EU market [2015 data], with the values of exports (€380m) around 18% higher than the sales value of imports (€310m). These revenues correspond only to the sales value of fluoropolymers in basic

form; i.e. the first stage of the value chain. The value of the final products made using fluoropolymers are estimated to be in the order of several billion Euros per year. Around 31 700 people are employed in companies in the fluoropolymer sector in the EU.

According to 3M Belgium (comment #1310)], if the proposed restriction on C9-C14 PFCA was adopted without this derogation, there would be a substantial possibility that production and use of these relatively low-volume, yet high-impact, specialty fluoropolymers might have to be discontinued in the EU, thereby disrupting EU-based downstream user supply chains.

The implementation of the proposed restriction without the derogation for C9-C14 PFCAs as impurities in fluoropolymers would not only impact the products within the scope of the derogation, but also other products and product lines at the manufacturer's sites due to shared manufacturing equipment and costs. This could jeopardize jobs, not only at the manufacturer, but also at their customers and suppliers. 3M's direct customers may also need to make similar decisions as to the manufacture of their products. Some of these materials are critical for the development of strategic sectors in Europe like semiconductors, or for retaining the competitiveness of the automotive and aerospace sectors.

3.1.2.3. Analysis of alternatives

Fluoropolymers are widely used in various specific components; each serves a slightly different purpose and hence requires different characteristics. Overall, whilst some alternatives might have a similar performance to fluoropolymers for a particular parameter or property, it is the combination or range of properties required for the applications where fluoropolymers are used that is the key characteristic. In sectors such as chemical and power, pharmaceuticals or transport, fluoropolymers provide resistance to a wide range of low and high temperatures and universal chemical resistance. This "universal resistance" to chemicals is a crucial characteristic of fluoropolymers that is not present in any of the alternatives, according to Plastics Europe (comment #1316). Potential alternatives include steel and other metals; high nickel alloys, polypropylene, PVC, glass, ceramics, mica, polyether sulfone, polyimide, ethylene propylene diene monomer (M-class) rubber (known as EPDM rubber), nitrile rubber (NBR), hydrogenated nitrile rubber (HNBR), acrylic rubber (ACM), Ethylene-acrylic rubber (AEM rubber), fluorosilicone (FVMQ)127, graphite, aramid, and slip agents. Each would only be a possible alternative for some of the applications of fluoropolymers, but there is not one drop-in alternative that is universally suitable.

On the other hand, several companies (3M Belgium, comment #1310; Chemours, comment #1313; other confidential) state that they are developing technologies, both engineering and chemical, to reduce C9-C14 PFCA impurities below 400 ppb in the manufacture of fluoropolymers. These technologies include post-polymerisation processing techniques as well as alternative polymerisation conditions and chemistries. The implementation time is estimated to be 36 months (from the call for evidence).

3.1.2.4. Practicality and monitorability

3M Belgium (comment #1310) and Chemours (comment #1313) consider that the proposed derogation is implementable within the timeframe of 36 months. Preparations are undergoing for the implementation of technological changes that will allow for the reduction of the level of impurities to below 400 ppb (sum of C9-C14 PFCA). However, further information provided by another company points out that a level of impurities below 100 ppb (sum of C9-C14 PFCA) can be achieved by applying best available technology.

Plastics Europe (comment #1316) and several companies claim that the proposed

derogation is not enforceable since it will be impossible for enforcement authorities to determine whether fluoropolymers contain perfluoroalkoxy groups and request an extension of the scope of the derogation to all fluoropolymers. Additionally, several respondents to the call for evidence claim that the present analytical methods do not allow to ensure compliance of fluoroplastics and fluoroelastomers with the threshold of 25 ppb (sum of C9-C14 PFCAs) set in the proposed restriction for C9-C14 PFCAs and the proposed derogation should be extended to all fluoropolymers independently of whether they contain perfluoroalkoxy groups or not. According to one company, the limit of detection for the sum of C9-C14 PFCAs in fluoropolymers is 60 ppb at present.

Furthermore, Plastics Europe (comment #1316) states that the exclusion of articles in the proposed derogation would present compliance difficulties for the downstream sectors and would also create double analytical work. In case the derogation is not extended to articles, for example to automotive parts such as O-rings, wires and cables, these would still have to comply with the thresholds of 25 ppb/260 ppb, as these limit values apply at the first point where fluoroelastomers are used for production of articles. Since these can be various matrices, the concentration of C9-C14 PFCAs can also differ between articles, depending on the analytical (including sampling and sample preparation) methods used. Currently, there is no guidance on how to sample from an article and no validated analytical methodology that ensures detection limits would be achievable to demonstrate compliance. The extension of the derogation to articles would ensure a smooth supply of materials in the EU and would also be consistent with the exemption of PTFE micro powders under the PFOA restriction of EU POP Regulation. The extension of the derogation to articles is further supported by a number of respondents to the call for evidence.

In general terms, it is pointed out that standard analytical methods (ISO, or similar) to measure the content of C9-C14 PFCAs, their salts and related substances, in articles and mixtures are not yet available. According to 3M Belgium (comment #1310) current methods that are validated and available for analysis of PFOA and C9-C14 PFCAs focus on analysis in water. The analysis of the said substances at ppb levels in solids and many liquids is technically still very difficult.

3.1.3. Conclusions on derogation #1

ECHA Secretariat considers that the estimated annual releases in the range of 2 kg/year of C9-C14 PFCAs resulting from the manufacture and use of fluoropolymers with perfluoroalkoxy groups containing C9-C14 PFCAs as impurities represent a limited risk to human health and the environment. The releases could be up to 4 kg/year, assuming a worst case scenario where all fluoropolymers within the scope of the derogation have a concentration of impurities of 400 ppb for the sum of C9-C14 PFCAs.

According to the information provided, best available technologies exist for the reduction of C9-C14 PFCAs in fluoroplastics and fluoroelastomers that contain perfluoroalkoxy groups to a concentration of below 100 ppb. Since these technologies have been implemented at at least in one company, it can be assumed that similar technologies are 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, the ECHA Secretariat proposes 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 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 in the companies affected. It is estimated that the level of emissions resulting from a threshold level of 100 ppb for the sum of C9-C14 PFCAs would be well below 1 kg/year.

The ECHA Secretariat considers that 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, the ECHA Secretariat considers this approach to be proportionate.

The ECHA Secretariat does not support the extension of the scope of the derogation to all fluoropolymers since it has not been justified that the presence of C9-C14 PFCAs as impurities in fluoropolymers other than those containing perfluoroalkoxy groups cannot be avoided through the implementation of an adequate manufacturing process. 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.

Nevertheless, the ECHA Secretariat recognises that the absence of standardised analytical methods to measure the levels 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. A summary of the information compiled in the call for evidence regarding the availability of analytical methods is presented in Appendix 1 to this report.

The extension of the scope of the derogation to articles manufactured with fluoropolymers within the scope of the derogation was already discussed 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 #1 as proposed by ECHA Secretariat would read as follows:

"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.

3.2. Derogation #2

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

3.2.1. Scope of the proposal

Proposed derogation for C9-C14 PFCAs:

"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".

Present derogation for PFOA (as included in Part A of Annex I to Regulation (EU) 2019/1021):

"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][6] 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."

Description of the use

The following definition is proposed for PTFE micro powder:

"PTFE micro powders are finely divided low molar mass (104-106 g/mol) PTFE-additives with small particle sizes (1-20 µm)."[7]

PFTE fine powder distinguishes from PFTE micro powders in that they form agglomerates with an average particle size 300 – 800 µm and are typically used as matrix polymers to be incorporated into, for instance, tube, electric wire and filters. Furthermore, PTFE fine powder is produced by dispersion polymerisation followed by coagulation, isolation and drying while PFTE micro powders are mainly produced by irradiation or heat degradation of PTFE resins.

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. Some applications include:

- Thermoplastics: parts made with the addition of micro powders, like gears, benefit from improved wear resistance, reduced friction, and elimination of stick-slip behaviour.
- Elastomers: Standard elastomer processing methods can be used to incorporate PTFE micro powders to enhance wear resistance, reduce friction and facilitate mould release.
- Lithographic, flexographic, and gravure inks: PTFE micro powders give better image protection and higher productivity, on top of better slip and surface smoothness.
- Greases: PTFE micro powders properties, such as chemical inertness and non-flammability, are key elements for greases to obtain approval to operate in environments where gases and other hazardous products are present.
- Coatings: PTFE micro powders provide abrasion resistance and anti-friction properties, especially important on coatings for industrial applications.
- Paints: containing PTFE micro powders to paints are more easily cleaned as a result of improved anti-fouling properties, and present a greater spreading rate.

The majority of PTFE micro powders (about 85% of those currently produced on a global scale) are manufactured by the degradation of PTFE resin. In the degradation process, the PTFE resin is degraded via a controlled irradiation or via thermal degradation to produce a lower molecular weight PTFE. After degradation, the low molecular weight PTFE is ground to varying particle size ranges to suit specific applications. The manufacturing processes by degradation methods generate C9-C14 PFCAs and PFOA as unintended impurities. A

[6] Section in square brackets scheduled to be deleted in upcoming amendment of POPs regulation.

[7] "Organic fluoropolymers" in Ullmann's Encyclopaedia of Industrial Chemistry January 31, 2014 7th ed. DOI: 10.1002/14356007.a11_393.pub2.

post-treatment process is required to reduce the concentration of such impurities in the PTFE micro powder to concentration levels below 25 ppb.

It is to be noted that PTFE micro powders can be manufactured by degradation from virgin or recycled PTFE resin. However, the use of recycled PTFE resin in the manufacture of PTFE micro powders requires higher irradiation in comparison with virgin PTFE. According to one respondent to the call for evidence (confidential), setting a maximum threshold for the radiation process of 400 kilograys may prevent the use of recycled PTFE as feedstock in certain production processes.

PTFE micro powders can also be manufactured by emulsion polymerisation. PTFE micro powders that are polymerised as micro powders have lower levels of impurities of C9-C14 PFCAs and PFOA. However, the polymerisation process does not produce the wide range and special properties needed for most lubricating powder applications and cannot be considered equivalent to the other degradation type manufacturing processes.

Concentration of C9-C14 PFCAs and PFOA impurities in PTFE micro powders.

Several respondents in the call for evidence claim (Chemours, comment #1313; others confidential) that the concentration of PFOA in PTFE micro powders manufactured by degradation is currently below 25 ppb, in compliance with the threshold set in entry 68 of Annex XVII to the REACH Regulation. According to these respondents, the derogation for the presence of PFOA impurities above 25 ppb in PTFE micro powders is not required or should be limited to a level of 100 ppb.

One respondent (confidential) claims that their present level of PFOA impurities in PTFE micro powders manufactured by degradation is below 500 ppm and will be below 25 ppb after implementation of an additional step in the manufacturing process for the removal of C9-C14 PFCAs and PFOA impurities. According to the information provided, the new process is installed, and trials are already ongoing at customer facilities and their downstream users. A derogation until at least July 2022 is required for completion of these trials. The same manufacturer estimates that the present level of C9-C14 PFCAs impurities in PTFE micro powders manufactured by degradation is in the order of 1 000 ppb (exact data confidential) but will be reduced to below 25 ppb after the new technology is fully implemented.

Chemours (comment #1313) states that the production of PTFE micro powders that contain C9-C14 PFCAs (in sum) below 400 ppb seems to be technically feasible but additional time will be required to validate the effectiveness and reproducibility of the post-processing technology. In line with the derogation proposed for fluoropolymers (see derogation #1), Chemours (comment #1313) proposes that a higher threshold of 2 000 ppb be granted for 36 months for the sum of C9-C14 PFCAs generated as unintentional trace contaminant(s) during the production process of PTFE micro powder using ionizing radiation. Following that 36 month time period, Chemours (comment #1313) proposes that the threshold be lowered to 400 ppb.

Another manufacturer (confidential) points out that although initial studies show that the manufacture of PTFE micro powders containing C9-C14 PFCAs below a combined concentration limit of 1 000 ppb is technically feasible by applying specific processing conditions, this needs to be confirmed yet at commercial scale. They claim that a concentration level below 300 ppb for the sum of C9-C14 PFCAs may be achievable in irradiated PTFE micro powders.

In general terms, Inhance technologies (comment #1308) states that there is technology available for the reduction of PFAS (including PFOA) down to non detectable quantities in fluoropolymers, including irradiated PTFE micro powders.

Volumes in use of PTFE micro powders

Based on the information provided in the call for evidence it is estimated that the volume of PTFE micro powders in use in the EU is approximately 4 000 tonnes. This data is based on limited information provided by one respondent to the call for evidence (confidential) and should be considered as highly uncertain.

3.2.2. Justification

3.2.2.1. Environmental impacts

Assuming a level of impurities of 1 000 ppb and a total volume of PTFE micro powders in use in the EU of 4 000 tonnes per year, the level of emissions resulting from the derogation for PFOA can be estimated to be below 4 kg/year. Since the derogation is to be reviewed in 2 years' time following the entry into force of the POP Regulation, the total PFOA emissions resulting from the derogation until a potential review are estimated to be less than 8 kg. This level of emission represents a worst case scenario, where all PTFE micro powders placed on the market contain the maximum permitted concentration of PFOA impurities and the substance is fully released to the environment during downstream use.

Since most of respondents to the call for evidence report concentrations of PFOA below 25 ppb in PTFE micro powders, this scenario is highly unlikely and leads to a significant overestimation of emissions of PFOA to the environment. According to the derogation proposed, emissions during manufacture should be avoided or reduced as much as technically and practically possible and therefore no releases resulting from this step are taken into account.

Similarly, the level of emissions resulting from the proposed derogation for C9-C14 PFCAs as impurities in PTFE micro powders can be estimated to be below 4 kg/year as a worst case scenario. Since the derogation is proposed for five years, a total worst-case of 20 kg of C9-C14 PFCAs may be released to the environment as a result of the proposed derogation. Additional releases may occur in the post treatment process of PTFE micro powders to reduce the level of impurities if adequate risk management measures are not in place at the manufacturing stage. These releases are not provided in the estimations since the level of C9-C14 PFCAs as impurities resulting from the manufacturing process and potentially released to the environment at this stage is unknown. According to one manufacturer (confidential) abatement techniques with a 95% effectiveness are implemented to reduce emissions to air resulting from the post-treatment of PTFE micro powders to remove PFAS (both PFOA and C9-C14 PFCAs) impurities.

3.2.2.2. Economic impacts

PTFE micro powders are specialty additives used in a variety of industrial sectors for their specific lubricant properties and ability to extend product life, enhance process safety and reduce waste. Key sectors which use PTFE micro powders are the automotive and aerospace, industrial machinery and coating and semiconductors. Lubricants made from PTFE micro powders are virtually immune to chemical degradation, do not absorb water, have a wide temperature range (-190 °C to +260 °C), and have excellent weathering and ageing characteristics. They also possess very low coefficients of friction, allowing for excellent non-stick and sliding properties.

The derogation for the presence of PFOA impurities above the set limit of 25 ppb for a transition period of 2 years included in the POP Regulation would allow the implementation of technical measures by those manufacturers that require an additional post-processing step to meet the specified concentration limit. According to the information provided in the call for evidence by one manufacturer (confidential), the implementation of this post-processing step will increase the production cost by 10-20 % and requires an one-off investment in the range of €250 000. Notably, most manufacturers (representing around

75% of the volume in use of PTFE micro powders in the EEA) already have these measures in place to comply with the Annex XVII restriction for PFOA under REACH and would not be affected by the proposed derogation.

PTFE micro powders contain both PFOA and C9-C14 PFCAs impurities as a result of the manufacturing process by degradation. Taking into account that the concentration of C9-C14 PFCAs present are above the proposed limit of 25 ppb set, a derogation would be required to allow the continued manufacture and placing on the market of PTFE micro powders. The socio-economic impacts of not granting the derogation have not been quantified by any of the respondents to the call for evidence and there is not enough data available to provide an estimate of the potential costs of not granting the derogation.

Nevertheless, it is evident that the lack of availability of PTFE micro powders would lead to an increased consumption of various materials in different applications because of reduced product lifetime. Safety and performance issues may also be encountered in environments with extreme weather and chemical conditions. Furthermore, it has been pointed out that the impact of not being able to have wear resistant engineered parts will be significant as these parts are critical for the safe and efficient operations of aerospace and transportation vehicles, medical devices, electronics and printers, as well as for high temperature lubricating greases that enable robotic assemblies that provide for smooth and efficient production in multiple industries.

3.2.2.3. Analysis of alternatives

PTFE micro powder is a specialty additive that has a varied spectrum of fit-for-use specifications and is irreplaceable by other materials due to its specific physical properties. No alternative material has been identified that is capable of providing the same characteristics in a wide variety of applications.

PTFE micro powders that are directly polymerised as micro powders have lower levels of impurities and could be a potential alternative technology. According to one respondent to the call for evidence (confidential), they could be a potential alternative for irradiated micro powders, but their manufacturing costs and market prices are greater and are currently used only in a small segment of the market. According to other respondents (Chemours, comment #1313; others confidential) polymerised PTFE micro powders can only be used for certain applications and do not constitute suitable substitutes to PTFE micro powders produced via irradiation or thermal degradation.

3.2.2.4. Practicality and monitorability

The majority of industrial actor have already implemented technical measures to reduce the level of PFOA impurities below the 25 ppb threshold set in the POP Regulation. Concentrations of PFOA below 600 ppb have been reported by two manufacturers, i.e. below the 1 000 ppb limit defined in the derogation. These manufacturers expect to achieve a concentration level of PFOA below 25 ppb by July 2022.

The level of C9-C14 PFCA impurities in PTFE micro powders reported in the call for evidence is currently in the region of 1 000 ppb. Several manufacturers are working in the implementation and validation of a post-treatment process to reduce the impurities C9-C14 PFCA impurities generated at the degradation step. According to the information provided in the call for evidence, once this process has been implemented, the level of C9-C14 PFCA impurities may be reduced to 300-400 ppb. No information has been provided regarding the time needed for the full validation of the manufacturing process, although Plastics Europa (comment #1316) and Performance Fluoropolymer Partnership (comment #1322) have expressed their support for a five year derogation.

Additionally, Plastics Europa (comment #1316) and Performance Fluoropolymer

Partnership (comment #1322) recommend that the production process description is limited to "ionising irradiation or thermal degradation" without establishing a maximum limit of *400 kilograys to* the radiation applied. According to one respondent to the call for evidence (confidential), the irradiation threshold may prevent the use of recycled feedstock of PTFE resin. In addition, it is claimed that the use of kilograys as unit of measurement may be irrelevant for certain process (e.g. electron beam irradiation). Downstream processors and enforcement agencies will not be able to discern whether PTFE micro powder was manufactured via this specific process, therefore making compliance and enforcement measures impossible to accomplish.

Performance Fluoropolymer Partnership (comment #1322) points out that the text of the proposed derogation for C9-C14 PFCA impurities in PTFE micro powders should include mixtures and articles containing PTFE micro powders consistent with the derogation for PFOA. It is understood that the request to extend the scope to articles and mixtures containing PTFE micro powders is based on the implementability of the derogation for PFOA impurities. However, no information on the level of C9-C14 PFCA impurities in articles and mixtures containing PTFE micro powders was provided in the call for evidence. No reference is made to consumer articles or mixtures by any respondent, so it is understood that the articles and mixtures are limited to industrial and professional uses as defined in the PFOA derogation in the POP Regulation.

The lack of standardised and validated analytical methods, including identification of 'preparation of samples' and 'measurement protocols', is also highlighted in relation with the implementation and enforceability of derogation #2. According to several respondents to the call for evidence, the analysis of PFOA and C9-C14 PFCAs at ppb levels in solids and many liquids is technically difficult.

3.2.3. Conclusions on derogation #2

Processes have been developed to bring the concentration of PFOA to below the 25-ppb threshold set out in the POP Regulation. These processes have been succesfully implemented by most PTFE micro powder manufacturers. The derogation of the 25 ppb threshold for PFOA impurities in PTFE micro powders allows the implementation of technical solutions within two years of the entry into force of the POP Regulaton. The ECHA Secretariat proposes that after this transitional period, the derogation is repealed.

Similar processes are being developed for the reduction of C9-C14 PFCAs impurities in PFTE micro powders. These processes have indicated the potential to reduce the concentration of C9-C14 PFCAs from present levels of 1 000 ppb to levels below 400 ppb. Several manufacturers are in the process of implementation and validation of these technical solutions. Taking into account the time required for the implementation of technical measures to reduce the level of PFOAs impurities in PTFE micro powders, ECHA Secretariat estimates that these processes may be fully operational within two years. It is also considered that the post-treatment processes put in place for the reduction of PFOA impurities may reduce C9-C14 PFCAs impurities in PTFE micro powders to similar trace levels, and no additional technical measures may be required.

Assuming a worst case scenario where all of C9-C14 PFCAs impurities are released in the environment, 4 kg/year of C9-C14 PFCAs may be emitted as a result of the implementation of the derogation. This level of potential emissions presents a limited risk that, nevertheless, should be addressed. It is expected that the implementation of post-treatment processes at the manufacturing stage of PFTE micro powders may significantly lower the level of impurities and potential emissions. According to information provided in the call for evidence, technical processes are already available for the manufacture of irradiated PFTE micro powders with PFOA and C9-C14 PFCAs impurities below the 25 ppb

limit proposed in the Annex XVII restriction under REACH. Several manufacturers claim that the implementation of a post-treatment step in the production of PTFE micro powders will reduce the levels of C9-C14 PFCAs impurities to 300-400 ppb.

The ban of the manufacture and use of PTFE micro powders containing C9-C14 PFCAs impurities is considered disproportionate by the ECHA Secretariat, taking into account the wide variety of applications and the lack of alternatives in general. A temporary derogation to allow for the manufacture and use of PTFE micro powders containing a concentration of C9-C14 PFCAs impurities below 1 000 ppb is considered the most proportionate measure at this stage. 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. Once the transitional period is over, the derogation should be reviewed to determine whether the technical processes implemented are effective in reducing the concentration of C9-C14 PFCAs impurities below the 25 ppb threshold set up in the Annex XVII restriction under REACH. The transitional period should allow manufacturers to implement adequate processes for the reduction of C9-C14 PFCAs impurities in PTFE micro powders. A 36 month transitional period as proposed in derogation #1 will provide enough time for the implemented processes to be fully validated and operational.

ECHA Secretariat supports the 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. 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, the ECHA Secretariat points out that for the review of the derogation for C9-C14 PFCA impurities in PTFE micro powders, more data regarding the levels of C9-C14 PFCAs impurities in articles and mixtures are required to determine the potential emissions resulting from these sources.

ECHA Secretariat also supports to widen the scope of the derogations to any manufacturing process of PTFE micro powders by ionising radiation, independently of the level of energy applied. No evidence has been found that the type and level of radiation affects the resulting level of C9-C14 PFCA and PFOA impurities in the irradiated PTFE micro powders.

Finally, the ECHA Secretariat recognises that 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, similar to derogation #1. The information compiled in the call for evidence regarding the availability of analytical methods is presented in Appendix 1 to this report.

Derogations #2 as proposed by ECHA Secretariat would read as follows:

Proposed derogation for C9-C14 PFCAs:

"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 exemption shall be reviewed and assessed by the Commission no later than [36 months after the entry into force of the restriction]."

Proposed update of the present derogation for PFOA (as included in Part A of Annex I to Regulation (EU) 2019/1021):

"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~~*** *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.***

B. Review of some derogations of the current RAC and SEAC opinion on C9-C14 PFCAs

3.3. Derogation #3

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

3.3.1. Scope of the proposal

The derogation under the C9-C14 restriction proposed by RAC and SEAC for unavoidable by-products (C9-C14 PFCAs) in C6 telomerisation products 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 and assess the possibility of not supporting it, in line with the approach adopted for PFOA under the POP Regulation.

Description of the use

Telomerization 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

According to one manufacturer (confidential, comment#1319) the amount of this residual PFOI long-chain side fraction has been reduced during the last years. In addition, further steps are being taken to reduce it even further. The manufacturer states that 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 the PFOI long-chain side fraction unintentionally produced is in the range of 100 to 1 000 tonnes/year (confidential). This estimate may be highly uncertain since it is based on the information provided by only one manufacturer.

3.3.2. Justification

3.3.2.1. Environmental impacts

Based on the information provided in the call for evidence, 40 to 400 tonnes per year of PFOA and C9-C14 PFCAS may be manufactured as an unintentional by-products of C6 telomerisation. Once the restrictions for PFOA under the POP Regulation and for C9-C14 PFCAs under REACH enter into force, these substances can only be used in the EU for the manufacture of those products that are already exempted. However, under the proposed derogation for the manufacture of C9-C14 PFCAs as unintentional by-products, C9-C14 PFCAs may be exported and used outside the EU for the production of articles and mixtures already restricted in the EU, but not under other national legislations (as long as the side fraction does not contain PFOA). Although it is not possible to estimate the level of emissions of C9-C14 PFCAs that may result from these uses outside the EU, these releases will contribute to the load of PFAS at an international level.

If the derogation is not granted, the use of C9-C14 PFCAs will be limited to the exempted uses under the proposed restriction under REACH. Once the exemptions for these uses expire, the long side fraction containing C8-C14 substances will be disposed of as waste and incinerated. The resulting releases from the incineration of the long chain side fraction have not been estimated and may be considered uncertain.

3.3.2.2. Economic impacts

C9-C14 PFCAs and PFOA are manufactured as by-products in the production of C6 chemistries. Should the derogation for the unintentional manufacture of C9-C14 PFCAs not be granted, manufacturers will have to dispose of the substances as waste once the exemptions for the manufacture of specific products with C9-C14 PFCAs expire.

The socioeconomic impacts of not granting the derogation have not been quantified by respondents to the call for evidence.

However, taking into account that the long side fraction may be as high as 20 % of the total production volume, the manufacturers' profit losses resulting from the cessation of sales of C9-C14 PFCAs may be significant. Additionally, the incineration of 20 % of the production volume will increase the manufacturing costs of C6 fluoro substances, which may be or may not be passed down the supply chain. Additional economic impacts to other actors down the supply chain may be expected as a result of not granting the derogation, but no further information is available to produce a quantitative or qualitative estimate of these impacts.

According to EURATEX (comment #1314), C6 chemistry is currently the only technically feasible and available alternative to the already restricted C8 substances that can deliver water, oil, dirt and chemical repellence required for specific textile applications. Additionally, its resistance to bacteria makes the chemistry essential for medical textiles. Shorter chain fluorinated chemistry and non-fluorinated alternatives cannot fulfil these requirements. EURATEX claims that the derogation, as set out in the conditions proposed by RAC and SEAC in the restriction on C9-C14 PFCAs under REACH, is required to maintain the European production of specialised textiles. However, the basis for the support of the derogation by EURATEX are not fully clear since the long side fraction that is generated as by-product in the manufacture of C6 telomers is separated at an early stage in the process and not used in the manufacture of C6 fluoro substances. According to one manufacturer

of C6 telomers (confidential) the long side fraction containing C8 and C9-C14 PFCAs will be handled as waste and incinerated as soon as the exemptions for the use of PFOA and C9-C14 PFCAs in the production of specific articles and mixtures expire. The manufacturer claims that the derogation is not needed and supports not granting it.

3.3.2.3. Analysis of alternatives

Alternative technologies for the production of short-chain fluorochemicals with lower concentrations of C9-C14 PFCAs and PFOA in the side-fractions are available. According to the information submitted in the call for evidence, a new technology platform has already been implemented by a C6 manufacturer to reduce the PFOI long-chain side fraction. No further information on the feasibility of these alternative technologies has been provided.

3.3.2.4. Practicality and monitorability

The proposal of not granting the derogation for the manufacture of C9-C14 PFCAs as unintentional by-products does not have any impact in the implementation and enforceability of the restriction of C9-C14 PFCAs under REACH.

3.3.3. Conclusions on derogation #3

The manufacturing of C6 chemistry generates in 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 opinion 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 legislations (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 the ECHA Secretariat considers that they may be significant taking into account that at present the long side fraction accounts for up to 20 % of the production volume. 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, ECHA Secretariat considers that the current requirement is proportionate and there is no need for a derogation.

Accordingly, ECHA Secretariat proposes to delete derogation #3:

~~***"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".***~~

3.4. Derogation #4

Derogation for impurities in short – chain alternatives.

3.4.1. Scope of the proposal

Both PFOA and C9-C14 PFCAs are present as impurities in intermediates used in the manufacturing of short-chain alternatives. The opinion of SEAC on the proposal for a C9-C14 PFCAs restriction under REACH includes a time-unlimited derogation for such impurities, without setting a 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 derogation for PFOA (as included in Part A of Annex I to Regulation (EU) 2019/1021) reads as follows:

"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 limit value for the level of C9-C14 PFCAs impurities in substances to be used as intermediates for the production of short chain fluoro compounds. This 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 fluoro substances. Additionally, it will be assessed whether the limit value for PFOAs impurities in intermediates can be lowered.

Description of the use

A described in section 3.3.1, short chain fluoro substances containing 6 fluorocarbon atoms or less are manufactured by telomerisation. Fluorinated telomer intermediates generated at different steps of the manufacturing process are used as onsite or transported isolated intermediates in the production of a variety of fluorinated products, including monomers for resin modification.

According to one manufacturer (confidential, comment #1319) the highest level of impurities of fluorinated intermediates are well above 20 ppm for PFOA and for C9-C14 PFCAs at present (confidential). This manufacturer is implementing a process to reduce to less than 20 ppm the content of PFOA-related substances in fluorinated intermediates to be used as transported isolated intermediates by producers of C6 fluorochemicals in the EU. Fluorinated intermediates generated further down the manufacturing process of C6 fluoro substances, including C6 monomers, present levels of PFOA and C9-C14 PFCAs impurities below 20 ppm and 10 ppm respectively.

Another company (AGC Chemicals Europe, Ltd. comment #1320) states that the level of impurities in C6 monomers imported into the EU comply with the limits for PFOA and C9-C14 PFCAs set in the POP Regulation on PFOA and the proposed restriction for C9-C14 PFCAs under REACH. According to this company, these derogations are not required.

The volume of transported isolated intermediates used in the EU in the manufacture of C6 is estimated to be in the range of 10 000 to 100 000 tonnes per year. From the information provided, 100 to 1 000 tonnes per year (exact figure confidential) would fall within the

scope of the derogation for PFOA and C9-C14 PFCAs impurities in transported isolated intermediates.

No information is available regarding the level of impurities in fluorotelomer intermediates used in the manufacture of short chain fluoro substances with less than 6 carbons.

3.4.2. Justification

3.4.2.1. Environmental impacts

The use of fluorotelomers as transported isolated intermediates with a level of 20 ppm of PFOA and 10 ppm of C9-C14 PFCAs impurities will result in a maximum level of emissions of 20 kg per year of PFOA and 10 kg per year of C9-C14 PFCAs. These values are calculated assuming a worst case scenario where all the impurities present in the fluorochemicals are released in the environment. However, this scenario is highly unrealistic. The derogations, both for PFOA and for C9-C14 PFCAs, establish the requirement that the substances should be used under strictly controlled conditions as defined in Article 18(4)(a) to (f) of the REACH Regulation. According to this requirement, the manufacture and the use of the substances should take place under rigorous containment. Additionally, a combination of technical measures, operating procedures and management systems should be in place to minimise emissions and exposure during the whole lifecycle of the substance. The implementation of strictly controlled conditions for the manufacture and use of the substances as isolated intermediates was confirmed in the information provided in the call for evidence (further details confidential).

Under these conditions, it is expected that the level of emissions of PFOA and C9-C14 PFCAs will be minimised. Unfortunately, no relevant information is available regarding the releases that result from the manufacture and use of the substances and no realistic estimation can be provided.

3.4.2.2. Economic impacts

The derogation will allow the manufacture and use of C6 fluorosubstances as transported isolated intermediates as far as strictly controlled conditions for the manufacture and use of the substances are implemented. The setting of a limit of 20 ppm for PFOA impurities (as identified in the POP Regulation) requires an additional purification step in the manufacturing process that is already being implemented, according to one respondent of the call for evidence (confidential, comment #1319). Reducing the limit below 20 ppm would jeopardise the placing on the market of 100 to 1 000 tonnes of short chain fluorinated intermediates, which are used in the manufacturing of short chain alternatives to PFOA.

According to the information provided in the call for evidence, the concentration of PFCAs impurities in these fluorinated intermediates is estimated to be below 10 ppm and can be as low as 5 ppm for specific compounds. A derogation with a limit of 10 ppm for PFCAs impurities would allow the use of these fluorinated intermediates in the manufacture of fluorosubstances by downstream users under strictly controlled conditions. In case the derogation would be granted with lower limits for PFOA and PFCAs, the C6 intermediates could not be placed on the market as transported isolated intermediates but could be used on-site in the manufacture of fluorosubstances. The economic impacts of this scenario are not quantified. It is expected that this would impact downstream users of C6 intermediates that would have to rely on alternative suppliers outside the EU. It is to be noted that these downstream users will have to implement strictly controlled condition for the use of the intermediate substances containing PFOA and PFCAs impurities within the scope of the derogations.

3.4.2.3. Analysis of alternatives

Alternative technological solutions for the production of short-chain fluorochemicals with lower concentration levels of C9-C14 PFCAs and PFOA are available. These technologies, result in the manufacturing of C6 monomers with concentration levels for PFOA and C9-C14 PFCAs below the limits set in the POP Regulation on PFOA and the proposed restriction for C9-C14 PFCAs under REACH (further details confidential).

3.4.2.4. Practicality and monitorability

A limit of 20 ppm for PFOA impurities and of 10 ppm for C9-C14 PFCAs impurities is proposed for fluorosubstances used as intermediates in the manufacturing of short chain fluorochemicals. One manufacturer (confidential, comment #1319) states that although lower limits (10 ppm for PFOA and 5 ppm for C9-C14 PFCAs) may be achievable for specific C6 intermediate substances, the absence of robust analytical methods to measure the full range of substances within the scope of the derogation may hinder their compliance.

Additionally, the scope of the derogation for PFOA should be further clarified. The derogation should specify whether the limit of impurities identified refer to PFOA, their salts and related substances or only to PFOA related substances. Similarly, in case a limit is proposed for C9-C14 PFCAs impurities, the derogation should identify which substances should comply with the threshold proposed. According to Chemours (comment #1313), both the POP Regulation on PFOA and the proposed restriction for C9-C14 PFCAs under REACH should include the list of substances (both PFOA and C9-C14 PFCAs) that should be measured to demonstrate compliance with the derogations.

3.4.3. Conclusions on derogation #4

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, ECHA Secretariat proposes a limit value of 10 ppm for C9-C14 PFCAs impurities to be included in the proposed derogation for these substances. Additionally, The ECHA Secretariat considers that the present limit value of 20 ppm for PFOA impurities is the lowest that can be complied with, taking into account the technological solutions in place to reduce the level of impurities in the sector. 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 PFCAs 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 C9-C14 PFCAs proposed restriction (PFOA: 25 ppb; PFOA-related substances: 1ppm ; sum of C9-C14 PFCAs: 25 ppb; C9-C14 related substances: 260 ppb). Thus, ECHA Secretariat 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 #4 as proposed by ECHA Secretariat would read as follows:

The concentration limit referred to in paragraph 2 shall be 10 ppm for the total sum of C9-C14 PFCAs, their salts and PFCAs 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 Secretariat proposes to clarify the scope of the derogation 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."*

C. Alignment of the derogated uses of C9-C14 PFCAs to the PFOA derogations in the EU POP Regulation

3.5. Derogation #5

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

3.5.1. Scope of the proposal

A proposal is made 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 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).

"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 has 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.

No RAC and SEAC discussion is needed for this analysis unless new information is received.

3.5.2. Technical assessment

Several organisations have provided their input in the call for evidence regarding the potential alignment of the derogations (Chemours, comment #1313;Euratex, comment #1314; Plastics Europe, comment #1316; AGC Chemicals Europe, Ltd., comment #1320; Performance Fluoropolymer Partnership, comment #1322).

A number of respondents have expressed their concern with regard to the text of paragraph 5 e) in the EU POP Regulation on PFOA: *"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,

until 4 July 2023."

According to these respondents, fluoropolymer manufacturers have developed alternatives to PFOA and related long-chain polymerization aids that can be used as polymerization 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 polymerization aid, and therefore the derogation is not required, either for the PFOA restriction under the POP Regulation or for the C9-C14 PFCAs proposed restriction under REACH.

The ECHA Secretariat 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 present study. The ECHA Secretariat considers therefore that 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 technical issues have been raised by any of the respondents to the call for evidence 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.

3.5.3. Conclusions on derogations #5

ECHA Secretariat supports the proposal 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.

Derogation #5 as proposed by ECHA Secretariat would read 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."

Appendix 1. Analytical methods

Compilation of the information received in the call for evidence regarding the availability of analytical methods for the measurement of C9-C14 PFAs in substances, mixtures and articles and their limits of detection:

- Current methods that are validated and available for analysis of PFOA and C9-C14 PFCAs focus on analysis in water. The analysis of these substances at ppb levels in solids and many liquids is still technically very difficult.
- There are no approved standard analytical methods for the analysis of PFOA and C9-C14 PFCAs (including sample preparation and extraction). Several laboratories claiming to use the same method are reporting data that vary widely. There is no agreed upon practical, validated method and different laboratories use their own adaptations.
- The use of the European Technical Specification CEN/TS 15968:2010[8] for the analysis of PFOA and C9-C14 PFCAs is reported by one company with a limit of detection of 1 ppb per substance.
- The use of in-house developed methods is reported by two companies with limits of detection of 7 to 10 ppb depending on the method and substance.
- The respondents support the inclusion of the available analytical methods in the "Compendium on analytical methods recommended by the ECHA Forum"[9] so that authorities or industry may use these methods to assess compliance of chemicals and articles manufactured, used or placed on the European market.

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[8] Determination of extractable perfluorooctanesulphonate (PFOS) in coated and impregnated solid articles, liquids and fire fighting foams – Method for sampling, extraction and analysis by LC-qMS [quadrupole mass spectrometry] or LC-tandem/MS [liquid chromatography-tandem mass spectrometry].

[9] https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwjQxuiZjqnrAhVmpIsKHcd-DwUQFjABegQIBRAB&url=https%3A%2F%2Fecha.europa.eu%2Fdocuments%2F10162%2F13577%2Fcompendium_of_analytical_methods_en.pdf&usg=AOvVaw1d4rF2hCbFzbh6eLwVM12j.