

Note for the attention of Tim Bowmer, Chair of the Committee for Risk Assessment, and Maria Ottati, Chair of the Committee for Socio-economic Analysis

Ref: Request to the Committee for Risk Assessment and to the Committee for Socio-economic Analysis to prepare a supplementary opinion on some 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;

In accordance with Article 77 (3) (c) of the REACH Regulation, the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) are requested to prepare a supplementary opinion on:

- A.** Additional derogations requested by companies on the proposed restriction on C9-C14 PFCAs, their salts and related substances (hereafter C9-C14 PFCAs).
- B.** Review of some derogations of current RAC and SEAC opinion on C9-C14 PFCAs.
- C.** Consistency of the alignment of the derogated uses of C9-C14 PFCAs to the PFOA derogations in the EU POP Regulation.

The RAC and SEAC opinion should be based on an analysis to be prepared by ECHA, preferably in the form of a complement to the Annex XV dossiers which supported the PFOA and the proposed C9-C14 PFCAs restriction.

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 C9-C14 PFCAs), where a number of derogations for specific uses of C9-C14 PFCAs were proposed¹. Several of the proposed derogations from the restriction for C9-C14 PFCAs referred to derogated uses for PFOA and related substances included in entry 68 of Annex XVII of the REACH Regulation. However, with the listing of PFOA and related substances in Annex I of the EU POP Regulation², the restriction entry for PFOA

¹ 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>

The Opinion of SEAC (Included as Annex 1 to this document)

² Part A of Annex I to Regulation (EU) 2019/1021. Included as Annex 2 to this document.

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

under REACH will be deleted and some of the derogations (termed exemptions under the POP regulation) will be changed. This will, in turn, affect the proposed derogations from the restriction for C9-C14 PFCAs. Additionally, after the finalisation of the RAC and SEAC opinion on the proposed restriction for C9-C14 PFCAs, the Commission received two additional requests for derogations from industry.

In this context, the Commission has requested ECHA to prepare a study on a number of derogations related to the manufacture, placing on the market and use of C9-C14 PFCAs and submit the analysis in the form of a complement to the Annex XV dossiers that supported the PFOA and C9-C14 PFCAs restrictions. RAC and SEAC are requested to provide a supplementary opinion, based on the analysis to be 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.

A. Additional derogations requested by companies on the proposed restriction on C9-C14 PFCAs, their salts and related substances.

After the finalisation of the RAC and SEAC opinion, the Commission has received two additional requests for derogation from the proposed restriction on C9-C14 PFCAs.

1) Impurities of C9-C14 PFCAs in fluoropolymers and fluoroelastomers that contain perfluoroalkoxy-groups

In the opinion submitted to the Commission on 16 January 2019, a derogation for a higher limit value of C9-C14 PFCAs as impurities in fluoropolymers that contain perfluoropropoxy-groups or perfluoromethoxy-groups and are used in specific product groups (PTFE fine powders, fluoroelastomers and aqueous dispersions), has been added to allow continued production. Other producers of fluoropolymers have informed the Commission that this derogation only addresses the concerns of one company and they asked to modify the derogation (see below) to be able to also continue their production:

"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 perfluoroalkoxygroups 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) Impurities of C9-C14 PFCAs and PFOA in PTFE micro powders

In addition, another company has asked for a specific derogation for the impurities of C9-C14 PFCAs generated when PTFE micro powder is produced as follows:

"A 5-year exemption for the production, use and placing on the market of PTFE micro powder produced by ionising irradiation up to 400 kilograys as well as in mixtures and articles containing PTFE micropowders which are intended for industrial or professional use with a concentration limit of 1000 ppb for the sum of C9-C14 PFAS."

In addition to the request on a supplementary opinion on the additional derogations, RAC and SEAC should assess whether there is a risk from the manufacturing, use and placing on the market of PTFE micro powders manufactured by electromagnetic irradiation (or by any other means) that leads to formation of C9-C14 PFCAs and whether the proposed limit values are sufficient to control the risks.

4 August 2020

Information on uses of PTFE micro powders is currently limited. Therefore, ECHA gathered information in a call for evidence on all uses of PTFE micro powders, concentration levels of C9-C14 PFAS as impurities and alternative technologies to produce them with a lower level of impurities.

The Commission has proposed a similar derogation for the PFOA entry in Annex I of the POPs Regulation, which will replace the REACH restriction (provisional text):

"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) micropowders produced by ionising irradiation of up to 400 kilograys and thermal degradation, as well as mixtures and articles containing PTFE micropowders which are intended for industrial or professional use. All emissions of PFOA during the manufacture and use of PTFE micropowders shall be avoided and, if not possible, reduced as far as possible."

Assuming that both PFOA and C9-C14 PFCAs impurities are generated during the same production process of PTFE micro powders, and in order to ensure consistency between the two restrictions, RAC and SEAC are requested to assess in the same way also the presence of PFOA impurities in PTFE micro powders.

In addition, the Commission received information at the meeting of the Competent Authorities under the POP Regulation that indicate that PTFE micro powders might be used in consumer products such as cosmetic products. During public consultation for the amendment of the POP Regulation, the Commission received comments that PFOA concentration in PTFE micropowders can comply with the limit of 0.025 mg/kg, if the micropowders are treated after production. This information should be taken into account by RAC and SEAC in their evaluation of the information gathered by ECHA on the technical possibilities to reduce impurities in micro powders.

Finally, RAC and SEAC should evaluate the ECHA review of the definition of "fine powders" and "micro powders" so that the scope of the two different derogations is clear.

According to the concerned companies, the main reason for not asking for the derogations as outlined above already during the public consultations on the opinion development (20/12/2017-20/6/2018 and 19/9/2018-19/11/2018) relates to the absence of a validated and robust analytical/extraction method at that time, which prevented the detection of C9-C14 PFAS related substances as an impurity in the products. The information received during the restriction process suggested that a threshold for 260 ppb for the sum of C9-C14 PFCA related substance would be analytically feasible for mixtures and articles placed on the EEA market. ECHA should also gather information on chemical analyses of C9-C14 PFAS related substances as impurities in relevant matrices and confirm if the results are reliable on the basis of the methods used and if there are workable analytical methods to ensure compliance for the levels proposed (260 ppb) in mixtures and articles.

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

C9-C14 PFCAs as by-products and impurities during the production of short-chain fluorochemicals

RAC and SEAC are requested to evaluate the review prepared by ECHA on the derogations linked to by-products and impurities during the production of intermediates for the manufacture of fluorochemicals with a perfluoro carbon chain equal to or shorter than 6 atoms (hereafter short-chain alternatives).

1) Unavoidable by-products in the C6 telomerisation process

Unavoidable by-products consisting of PFOA and C9-C14 PFCAs are generated and separated during the production of short-chain alternatives in the C6 telomerisation process (thereafter PFOA/C9-C14 PFCA side fraction).

Under the Stockholm Convention, the manufacture of the fraction containing PFOA as unavoidable by-product (which concerns only one company in the EU) does not have a specific exemption. Therefore, this side-fraction can only be used for any exempted use of PFOA. It is then likely that, as soon as the PFOA exemptions expire, the company will need to dispose of the PFOA side fraction as a waste.

In the opinion on the C9-C14 PFCAs restriction proposal, there is a time-unlimited derogation for the C9-C14 PFCAs occurring as unavoidable by-product of the 4 manufacturing of short-chain alternatives in order to allow C9-C14 PFCAs to be reworked. However, the current assumption is that by-products are separated as one fraction containing both PFOA and C9-C14 PFCAs. If this is the case, then the provisions under the POP Regulation will apply for this side-fraction and the ECHA Committees are requested to consider the possibility to follow for the derogation under the C9-C14 restriction the same approach as for PFOA under the POP Regulation. ECHA has gathered information on how side-fractions containing C9-C14 PFCAs are used and on the concentration levels of PFOA and C9-C14 PFCAs in those side-fractions.

2) Impurities in short-chain alternatives

Both PFOA and C9-C14 PFCAs are present as impurities in intermediates used in the manufacturing of short-chain alternatives. The proposed text for the PFOA entry in the POPs Regulation sets an Unintentional Trace Contaminant (UTC) for the presence of PFOA in the intermediates and a review clause of 3 years:

"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) 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."

The opinion for the C9-C14 PFCAs restriction proposes a time-unlimited derogation for such impurities, without setting a limit. The ECHA Committees are requested to propose a limit value for the level of impurities for C9-C14 PFCAs in the intermediates for C6 alternatives production that is sufficiently low to limit the potential risks from the presence of C9-C14 PFCAs while allowing the manufacturing of the short-chain alternatives. The RAC and SEAC are requested to assess if the limit value for PFOA can be lowered.

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

C9-C14 PFCAs can occur as impurities in other substances or articles together with PFOA which is currently restricted under REACH (Annex XVII, entry 68). Several proposed derogations for C9-C14 PFCAs refer to the PFOA derogated uses in restriction entry 68 (Point 6 in Table 1). With the listing of PFOA in Annex I of the EU POP Regulation³, the restriction entry will be deleted. The listing will further change some of the derogations granted in the restriction on PFOA under REACH (Points 5 and 6 in 1 Regulation (EU) 1021/2019 of the European Parliament and the Council 5 Table 2).

For this reason, the Commission has asked ECHA's secretariat for 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. Please note that no RAC and SEAC discussion is needed for this analysis, unless new information is received.

2. Terms of Reference

The Committees are requested 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.

The RAC and SEAC opinions should be based on an analysis to be prepared by ECHA, preferably in the form of a complement to the Annex XV dossiers which supported the existing restriction.

3. Timescale for the RAC and SEAC opinions

ECHA shall enter the relevant intention for the possible review of the derogations of the C9-C14 PFCA and PFOAs restrictions into the Registry of Intentions (RoI) no later than one month following the receipt of the letter from the Commission (dated 2 March 2020) with the aim of having a first discussion and adoption in the December 2020 RAC and SEAC meetings.

Given the limited scope of the derogations and taking into account that the information on risk assessment, analysis of alternatives and socio-economic analysis has been already discussed by RAC and SEAC in the context of the development of the opinions on the C9-C14 PFCA and PFOAs restrictions, it is considered realistic that the supplementary opinion will be discussed and adopted by each of the Committees in one plenary meeting.

The supplementary opinion by RAC and SEAC should be submitted to the Commission by 15 December at the latest.

³ Regulation (EU) 1021/2019 of the European Parliament and the Council

4. Remuneration

The task for RAC and SEAC following from this request is not considered to fulfil any of the requirements of a transfer of funds to the competent authorities of the Member States pursuant to Article 14(1) of Regulation (EC) 340/2008 and therefore no remuneration will be paid by the Agency.

*(e-signed)*⁴

Bjorn Hansen
Executive Director

Cc: Jukka Malm, Peter van der Zandt

⁴ As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.