

Regulatory Alert

EU REACH Annex XVII (Restrictions) Entry 68 Amendment

Perfluorocarboxylic Acids Containing 9 to 14 Carbon Atoms in the Chain (C₉-C₁₄ PFCAs), their salts and their related substances

Region: European Union

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INTENDED AUDIENCE

This Regulatory Alert is intended for IAEG members who are involved in the manufacturing of and/or placing on the market (in the European Union [EU]) perfluorocarboxylic acids (PFCAs) as substances on their own, in a mixture, or in an article in the Aerospace and Defense (A&D) industry.

EXECUTIVE SUMMARY

On 4 August 2021, the European Commission (EC) amended Entry 68 of Annex XVII to the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) No. 1907/2006. The Amendment, which is documented in Commission Regulation (EU) 2021/1297, now restricts PFCAs containing 9 to 14 carbon atoms (C₉-C₁₄ PFCAs), their salts, and their related substances as substances on their own, in a mixture, or in an article. The restrictions came into force on 24 August 2021. This replaces perfluorooctanoic acid (PFOA), its salts, and PFOA-related substances, which were previously listed in Entry 68 of Annex XVII to REACH (until December 2020) – these are now regulated under the Regulation (EC) No. 2019/1021 on persistent organic pollutants.

This Regulatory Alert provides an overview of the Commission Regulation (EU) 2021/1297 and its implications in the EU.

BACKGROUND ON REGULATION

The REACH Regulation (EC) No. 1907/2006, which came into force on 1 June 2007, plays an important role in the control and management of chemicals in the EU. Its main aims include:

- protection of human health and the environment from risks associated with the use of chemicals;
- ensuring that anyone who places chemicals on the market (manufacturers and importers) takes responsibility for understanding and managing risks posed by chemical use; and
- promoting alternative methods for the chemical hazard assessment of substances, which can help to reduce the need for animal testing (e.g. quantitative structure-activity relationships and read-across^a).

A wide range of companies covering various sectors (manufacturing, importing, distributing, and using chemicals as raw materials and/or finished products) are impacted by the REACH Regulation. All the actors in the supply chain (manufacturers, importers and downstream users) are required to communicate information concerning the safe use of chemicals. Manufacturers and importers must also ensure chemical substances, which are manufactured or imported into the EU in quantities greater than 1 tonne per year, are registered with the European Chemicals Agency (ECHA). Further obligations may apply under the REACH Regulation for companies.

Annex XVII of the REACH Regulation contains a list of restricted substances (not addressed by other REACH processes) and its specific conditions for restriction. The restrictions apply to the manufacture, placing on the market, and use of certain chemical substances (including mixtures and articles) that pose an unacceptable risk to human health or the environment.

The EC or EU Member States can make changes to existing restrictions or propose new restrictions under Annex XVII of the REACH Regulation. This will result in the substance moving through the following regulatory process:

- Registry of restriction intentions;
- Submitted restrictions under consideration;
- Restriction public consultations; and
- Substances restricted under REACH (Annex XVII).^b

^a *Read-across* is another non-testing method (avoids/reduces animal testing) that can be employed to predict endpoint information for a substance (“target substance”) based on the same endpoint data from another substance (“source substance”). The target substance must be structurally similar to the source substance.

^b This section provides substances with restrictions under Annex XVII of the REACH Regulation that are adopted until the publication date.

APPLICABILITY

The Commission Regulation (EU) 2021/1297 applies to manufacturers and importers of C₉-C₁₄ PFCAs, their salts, and their related substances.^c It covers the following PFCAs substances:

- linear and branched PFCAs with the formula C_nF_{2n+1}-C(=O)OH, where n = 8, 9, 10, 11, 12, or 13 (C₉-C₁₄ PFCAs), including their salts, and any combinations thereof;
- any C₉-C₁₄ PFCAs-related substance having a perfluoro group (directly attached to another carbon atom) with the formula C_nF_{2n+1}, where n = 8, 9, 10, 11, 12, or 13, including their salts and any combinations thereof; and
- any C₉-C₁₄ PFCAs-related substance having a perfluoro group (NOT directly attached to another carbon atom) with the formula C_nF_{2n+1}, where n = 9, 10, 11, 12, 13 or 14 as one of the structural elements, including their salts and any combinations thereof.

The aforementioned C₉-C₁₄ PFCAs substances are based on the following:^d

- Perfluorononanoic acid (PFNA; C₉-PFCA; CAS Number: 375-95-1);
- Nonadecafluorodecanoic acid (PFDA; C₁₀-PFCA; CAS Number: 335-76-2);
- Heneicosaflluoroundecanoic acid (PFUnDA; C₁₁-PFCA; CAS Number: 2058-94-8);
- Tricosaflluorododecanoic acid (PFDoDA; C₁₂-PFCA; CAS 307-55-1);
- Pentacosaflluorotridecanoic acid (PFTrDA; C₁₃-PFCA; CAS Number: 72629-94-8); and
- Heptacosaflluorotetradecanoic acid (PFTDA; C₁₄-PFCA; CAS Number: 376-06-7).

The following substances are excluded from the scope for PFCAs substances:

- C_nF_{2n+1}-X, where X = F, Cl, or Br and n = 9, 10, 11, 12, 13 or 14, including any combinations thereof; and
- C_nF_{2n+1}-C(=O)OX', where n > 13 and X' = any group, including salts.

^c C₉-C₁₄ PFCAs-related substances have the potential to degrade or be transformed to C₉-C₁₄ PFCAs based on their molecular structure.

^d ECHA has not provided a definitive list of CAS/EC numbers for this listing – the substance list provided is not exhaustive. Other examples can be found in the ECHA Annex XV Restriction Report – Proposal for a Restriction on C₉-C₁₄ PFCAs (see Useful Links section below).

RELEVANT DATES

- ❖ **Entry 68 Published:** 4 August 2021
- ❖ **Entry 68 In force:** 24 August 2021

Other relevant dates for specific C₉-C₁₄ PFCAs restrictions are given in the section below.

REGULATORY OBLIGATIONS - RESTRICTIONS

The following restrictions apply for the Commission Regulation (EU) 2021/1297:

1. C₉-C₁₄ PFCAs, their salts, and their related substances are prohibited from being manufactured or placed on the market as substances on their own

(Effective: From 25 February 2023); and

2. C₉-C₁₄ PFCAs, their salts, and their related substances are prohibited from being used or placed on the market in:^e
 - (i) another substance, as constituents;
 - (ii) mixtures; and
 - (iii) articles**(Effective: From 25 February 2023).**

By way of derogation to restriction #2 above, the following concentration limits apply under the following circumstances:

- for a substance to be used as a transported isolated intermediate – where C₉-C₁₄ PFCAs, their salts, and their related substances are present – concentration shall be below 10 parts per million (ppm) for the sum of C₉-C₁₄ PFCAs, their salts and their related substances;^f
- for fluoroplastics and fluoroelastomers that contain perfluoroalkoxy groups,^g concentration shall be below 2 ppm for the sum of C₉-C₁₄ PFCAs (Effective: Until 25 August 2024),^h concentration shall be below 0.1 ppm for the sum of C₉-C₁₄ PFCAs **(Effective: From 25 August 2024);**^h and
- for polytetrafluoroethylene (PTFE) micro powders (as a substance, mixture, or article) produced by ionizing irradiation or by thermal degradation, where C₉-C₁₄ PFCAs are present, concentration shall be below 1 ppm for the sum of C₉-C₁₄ PFCAs **(Effective: Until 25 August 2024).**

Restriction 2 above is extended under the following situations:

- textiles for oil- and water-repellency for the protection of workers from dangerous liquids **(Effective: From 4 July 2023);**
- manufacture of PTFE and polyvinylidene fluoride for the production of:
 - (i) high performance, corrosion resistant gas filter membranes, water filter membranes, and membranes for medical textiles;
 - (ii) industrial waste heat exchanger equipment; and
 - (iii) industrial sealants capable of preventing leakage of volatile organic compounds and PM_{2.5} particulatesⁱ **(Effective: From 4 July 2023);**
- photolithography or etch processes in semiconductor manufacturing **(Effective: From 4 July 2025);**
- invasive and implantable medical devices **(Effective: From 4 July 2025);**
- firefighting foam for liquid fuel vapor suppression and liquid fuel fire (Class B fires),^j which are already installed in systems (including mobile or fixed systems) and contain or may contain C₉-C₁₄ PFCAs, their salts, and their related substances **(Effective: From 4 July 2025);**
- can coating for pressurized metered-dose inhalers **(Effective: From 25 August 2028);** and
- semiconductors used in spare or replacement parts for finished electronic equipment placed on the market before 31 December 2023 **(Effective: From 31 December 2030).**

^e Exceptions apply if the concentration in the substance, mixture or article is:

- below 25 parts per billion (ppb) for the sum of C₉-C₁₄ PFCAs and their salts; or
- below 260 ppb for the sum of C₉-C₁₄ PFCA-related substances.

^f The EC shall review this limit no later than **25 August 2023**.

^g This derogation does not apply to articles.

^h The EC shall review this limit no later than **25 August 2024**.

ⁱ PM_{2.5} stands for Particulate Matter (also referred to as Particle Pollution). This is a mixture of solid particles and liquid droplets present in air (e.g. dust, dirt, soot, and smoke). The particles are fine, inhalable, and have a diameter of 2.5 microns (µm) or smaller.

^j This is subject to the following conditions:

- shall not be used for training;
- shall not be used for testing unless releases are contained; and
- starting **from 1 January 2023**, sites shall be permitted to use the substances only if all releases of the substances can be contained.

RISKS TO AEROSPACE AND DEFENSE

Violation of the EU REACH Annex XVII (Restrictions) Entry 68 Update may result in penalties such as fines (determined by individual Member States) as well as damage to the company's reputation.

USEFUL LINKS

Regulation (EC) No 1907/2006 (REACH Regulation):

<https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32006R1907>

Commission Regulation (EC) No 2021/1297 (Entry 68 of Annex XVII – PFCAs):

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R1297>

Registry of Restriction Intentions:

<https://echa.europa.eu/registry-of-restriction-intentions>

Submitted Restrictions Under Consideration:

<https://echa.europa.eu/restrictions-under-consideration>

Restriction Public Consultations:

<https://echa.europa.eu/consultations/current>

Substances Restricted Under REACH (Annex XVII):

<https://echa.europa.eu/substances-restricted-under-reach>

Annex XV Restriction Report – Proposal for a Restriction on C₉-C₁₄ PFCAs:

https://www.iaeg.com/elements/pdf/Annex_XV_Restriction_Report%E2%80%93Proposal_for_a_Restriction_on_C9-C14_PFCAs.pdf

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