

REACH 附录 XVII 新增 C9-C14 PFCAs 限制

2021年8月5日，欧盟在其官方公报（OJ）发布法规(EU) 2021/1297，对欧盟 REACH 法规((EC) No 1907/2006) 附件 XVII 进行修订，将原第 68 项替换为 C9-C14 PFCA 及其盐类和 C9-C14 PFCA 相关物质的限制。该新法规将于欧盟官方公报发布后第 20 天生效。

具体限值要求如下：

物质	限制条件
<p>68.</p> <p>分子式为 $C_nF_{2n+1}-C(=O)OH$ 的直链和支链全氟羧酸，其中 $n=9、10、11、12、13$ 或 14 (即 C₉-C₁₄ PFCAs)，包括其盐类和任何组合；</p> <p>分子式为 C_nF_{2n+1} 的全氟基团，并直接连接在另一个碳原子上 (其中 $n = 8、9、10、11、12$ 或 13) 的 C₉-C₁₄ PFCA 相关物质，包括其任何组合；</p> <p>分子式为 C_nF_{2n+1} 的全氟基团，作为结构元素之一间接连接在另一个碳原子上 (其中 $n = 9、10、11、12、13$ 或 14) 的 C₉-C₁₄ PFCA 相关物质，包括其任何组合；</p> <p>以下物质不属于本范围：</p> <p>—分子式为 $C_nF_{2n+1}-X$，其中 $X=F、Cl$ 或 Br，且 $n= 9、10、11、12、13$ 或 14，包括其任何组合；</p> <p>—分子式为 $C_nF_{2n+1}-C(=O)OX'$，其中 $n>13$ 且 X' =任何基团，包括盐类。</p>	<ol style="list-style-type: none"> 自 2023 年 2 月 25 日起，禁止该类物质的生产或投放市场。 自 2023 年 2 月 25 日起，不得将物质用于或将其投放市场： <ol style="list-style-type: none"> 作为另一物质的组分； 混合物； 物品。 <p>除非物质、混合物或物品中 C₉-C₁₄ PFCA 及其盐类的总浓度小于 25 ppb，C₉-C₁₄ PFCA 相关物质的总浓度小于 260 ppb。</p> 作为第 2 段的豁免，C₉-C₁₄ PFCA 及其盐类和 C₉-C₁₄ PFCA 相关物质的总和的限值为 10ppm，如果它们存在于被运输的独立中间体的物质中，只要生产全氟碳链长度等于或小于 6 原子的含氟化合物且符合本法规第 18 (4) 条中第 (a) 至 (f) 点的条件。委员会应不迟于 2023 年 8 月 25 日审查该限值。 第 2 段的要求自 2023 年 7 月 4 日起适用于： <ol style="list-style-type: none"> 用于保护工人免受危害其健康和安全的危险液体伤害的防油防水纺织品； 聚四氟乙烯 (PTFE) 和聚偏氟乙烯 (PVDF) 的制造，用于生产： <ul style="list-style-type: none"> —高性能耐腐蚀的气体滤膜、水滤膜和医用纺织品用滤膜； —工业废热交换器设备； —能够防止挥发性有机化合物和 PM2.5 微粒泄漏的工业密封胶。 作为第 2 段的豁免，2025 年 7 月 4 日前，C₉-C₁₄ PFCA 及其盐类和 C₉-C₁₄ PFCA 相关物质允许用于： <ol style="list-style-type: none"> 半导体制造业中的光刻或蚀刻工艺； 用于胶片的感光涂层； 侵入式和可植入式医疗器械；

(iv) 已安装在移动或固定系统中用于抑制液体燃料蒸汽和液体燃料火灾 (B 级火灾) 的灭火泡沫, 但需满足以下条件:

- 含有或可能含有 C₉.C₁₄ PFCA 及其盐类和 C₉.C₁₄ PFCA 相关物质的灭火泡沫不得用于培训;
- 含有或可能含有 C₉.C₁₄ PFCA 及其盐类和 C₉.C₁₄ PFCA 相关物质的灭火泡沫不得用于测试, 除非其释放物能被控制;
- 自 2023 年 1 月 1 日起, 仅允许在可控制所有释放物的场所使用含有或可能含有 C₉.C₁₄ PFCA 及其盐类和 C₉.C₁₄ PFCA 相关物质的灭火泡沫;
- 含有或可能含有 C₉.C₁₄ PFCA 及其盐类和 C₉.C₁₄ PFCA 相关物质的灭火泡沫库存应按照法规(EU) 2019/1021 第 5 条管理。

6. 第 2 (c) 款不适用 2023 年 2 月 25 日之前投放市场的物品。

7. 在 2028 年 8 月 25 日之前, 第 2 款不适用于用于加压计量吸入器的罐涂层。

8. 第 2(c)款自 2023 年 12 月 31 日起适用于:

- (a) 半导体本身;
- (b) 半成品或成品电子设备中的半导体。

9. 自 2030 年 12 月 31 日起, 第 2(c)段适用于 2023 年 12 月 31 日之前投放市场的成品电子设备的备件或替换件中使用的半导体。

10. 在 2024 年 8 月 25 日之前, 针对含全氟烷氧基的氟塑料和氟弹性体中第 2 款所述的浓度限值应为 C₉.C₁₄ PFCAs 的总和 2000 ppb。在 2024 年 8 月 25 日起, 含全氟烷氧基的氟塑料和氟弹性体中 C₉.C₁₄ PFCAs 的浓度总和为 100 ppb。在生产和使用含全氟烷氧基的氟塑料和氟弹性体期间, 应避免所有 C₉.C₁₄ PFCAs 的排放, 如果不可能, 应在技术上和实践上尽可能减少排放。此项豁免不适用于第 2(c)段所述的条款。委员会应不迟于 2024 年 8 月 25 日审查这项豁免。

11. 存在于由电离辐射或热降解产生的聚四氟乙烯微粒, 以及由工业或专业使用的含有聚四氟乙烯微粒的混合物或物品中 C₉.C₁₄ PFCAs 关于第 2 段的限值为 1000ppb。在聚四氟乙烯微粒的制造和使用过程中, 应避免所有 C₉.C₁₄ PFCAs 的排放, 如果不可能, 应在技术上和实践上尽可能减少排放。委员会应不迟于 2024 年 8 月 25 日审查这项豁免。

12. 就本条目而言, C₉.C₁₄ PFCA 相关物质是指根据其分子结构, 被认为具有降解或转化为 C₉.C₁₄ PFCAs 风险的物质。

原文链接如下:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R1297&qid=1628228921957>

REACH Annex XVII add a Restriction on C9-C14 PFCAs

On 5 August 2021, the Official Journal of the European Union published Regulation (EU) 2021/1297 amending the Entry 68 of Annex XVII to REACH Regulation (EC) No 1907/2006 for restriction on perfluorocarboxylic acids containing 9 to 14 carbon atoms in the chain (C9-C14 PFCAs), their salts and C9-C14 PFCA-related substances. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

The specific revision content is summarized as follows:

Substance	Restriction
<p>68. Linear and branched perfluorocarboxylic acids of the formula $C_nF_{2n+1}-C(=O)OH$ where $n = 8, 9, 10, 11, 12, \text{ or } 13$ (C9-C14 PFCAs), including their salts, and any combinations thereof;</p> <p>Any C9-C14 PFCA-related substance having a perfluoro group with the formula $C_nF_{2n+1}-$ directly attached to another carbon atom, where $n = 8, 9, 10, 11, 12, \text{ or } 13$, including their salts and any combinations thereof;</p> <p>Any C9-C14 PFCA-related substance having a perfluoro group with the formula $C_nF_{2n+1}-$ that it is not directly attached to another carbon atom, where $n = 9, 10, 11, 12, 13 \text{ or } 14$ as one of the structural elements, including their salts and any combinations thereof.</p> <p>The following substances are excluded from this designation</p> <ul style="list-style-type: none"> — $C_nF_{2n+1}-X$, where $X = F, Cl, \text{ or } Br$ where $n = 9, 10, 11, 12, 13 \text{ or } 14$, including any combinations thereof, — $C_nF_{2n+1}-C(=O)OX'$ where $n > 13$ and X' = any group, including salts. 	<p>1. Shall not be manufactured, or placed on the market as substances on their own from 25 February 2023.</p> <p>2. Shall not, from 25 February 2023, be used in, or placed on the market in:</p> <ul style="list-style-type: none"> (a) another substance, as a constituent; (b) a mixture; (c) an article, <p>except if the concentration in the substance, the mixture, or the article is below 25 ppb for the sum of C9-C14 PFCAs and their salts or 260 ppb for the sum of C9-C14 PFCA-related substances.</p> <p>3. By way of derogation to paragraph 2, the concentration limit shall be 10 ppm for the sum of C9-C14 PFCAs, their salts and C9-C14 PFCA related substances, where they are present in a substance to be used as a transported isolated intermediate, provided that the conditions in points (a) to (f) of Article 18(4) of this Regulation are met for the manufacturing of fluorochemicals with a perfluoro carbon chain length equal to or shorter than 6 atoms. The Commission shall review this limit no later than 25 August 2023.</p> <p>4. Paragraph 2 shall apply from 4 July 2023 to:</p> <ul style="list-style-type: none"> (i) textiles for oil- and water-repellency for the protection of workers from dangerous liquids that comprise risks to their health and safety; (ii) the manufacture of polytetrafluoroethylene (PTFE) and polyvinylidene fluoride (PVDF) for the production of: <ul style="list-style-type: none"> — high performance, corrosion resistant gas filter membranes, water filter membranes and membranes for medical textiles; — industrial waste heat exchanger equipment; — industrial sealants capable of preventing leakage of volatile organic compounds and PM 2,5 particulates <p>5. By way of derogation to paragraph 2, the use of C9-C14 PFCAs, their salts and C9-C14 PFCA-related substances shall be allowed until 4 July 2025 for:</p> <ul style="list-style-type: none"> (i) photolithography or etch processes in semiconductor manufacturing; (i) photolithography or etch processes in semiconductor manufacturing; (ii) photographic coatings applied to films; (iii) invasive and implantable medical devices;

(iv) 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, subject to the following conditions:

- fire-fighting foam that contains or may contain C9-C14 PFCAs, their salts and C9-C14 PFCa-related substances shall not be used for training;
- fire-fighting foam that contains or may contain C9-C14 PFCAs, their salts and C9-C14 PFCa-related substances shall not be used for testing unless all releases are contained;
- from 1 January 2023, uses of fire-fighting foam that contains or may contain C9-C14 PFCAs, their salts and C9-C14 PFCa-related substances shall only be allowed to sites where all releases can be contained;
- fire-fighting foam stockpiles that contain or may contain C9-C14 PFCAs, their salts and C9-C14 PFCa-related substances shall be managed in accordance with Article 5 of Regulation (EU) 2019/1021.

6. Paragraph 2(c) shall not apply to articles placed on the market before 25 February 2023.

7. Paragraph 2 shall not apply to the can coating for pressurised metered-dose inhalers until 25 August 2028.

8. Paragraph 2 (c) shall apply from 31 December 2023 to:

- (a) semiconductors on their own;
- (b) semiconductors incorporated in semi-finished and finished electronic equipment.

9. Paragraph 2(c) shall apply from 31 December 2030 to semiconductors used in spare or replacement parts for finished electronic equipment placed on the market before 31 December 2023.

10. Until 25 August 2024, the concentration limit referred to in paragraph 2 shall be 2 000ppb for the sum of C9-C14 PFCAs in fluoroplastics and fluoroelastomers that contain perfluoroalkoxy groups. From 25 August 2024, 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). The Commission shall review this derogation no later than 25 August 2024.

11. The concentration limit referred to in paragraph 2 shall be 1 000ppb for the sum of C9-C14 PFCAs, where these are present in 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. The Commission shall review this derogation no later than 25 August 2024.

12. For the purposes of this entry, C9-C14 PFCa-related substances are substances that, based on their molecular structure, are considered to have the potential to degrade or be transformed to C9-C14 PFCAs.

Please see the below link for more details:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R1297&qid=1628228921957>



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