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#### COVER NOTE

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From: Secretary-General of the European Commission,  
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 8 April 2020

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of  
the European Union

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Subject: ANNEX to the COMMISSION DELEGATED REGULATION (EU) .../...  
amending Annex I to Regulation (EU) 2019/1021 of the European  
Parliament and of the Council as regards the listing of perfluorooctanoic  
acid (PFOA), its salts and PFOA-related compounds

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Delegations will find attached document C(2020) 1973 final - Annex.

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Encl.: C(2020) 1973 final - Annex



Brussels, 8.4.2020  
C(2020) 1973 final

ANNEX

**ANNEX**

**to the**

**COMMISSION DELEGATED REGULATION (EU) .../...**

**amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds**

## ANNEX

**In Part A of Annex I to Regulation (EU) 2019/1021, the following entry is added:**

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
<p>“Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds</p> <p>Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds” means the following:</p> <ul style="list-style-type: none"><li>(i) perfluorooctanoic acid, including any of its branched isomers;</li><li>(ii) its salts;</li><li>(iii) PFOA-related compounds which, for the purposes of the Convention, are any substances that degrade to PFOA, including any substances (including salts and polymers) having a linear or branched perfluoroheptyl group with the moiety (C<sub>7</sub>F<sub>15</sub>)C as one of the structural elements.</li></ul> <p>The following compounds are not included as PFOA-related compounds:</p> <ul style="list-style-type: none"><li>(i) C<sub>8</sub>F<sub>17</sub>-X, where X= F, Cl, Br;</li><li>(ii) fluoropolymers that are covered by CF<sub>3</sub>[CF<sub>2</sub>]<sub>n</sub>-R', where R'=any group, n&gt;16;</li><li>(iii) perfluoroalkyl carboxylic acids (including their salts, esters, halides and anhydrides) with ≥8 perfluorinated carbons;</li><li>(iv) perfluoroalkane sulfonic acids and perfluoro phosphonic acids (including their salts, esters, halides and anhydrides) with ≥9</li></ul>	335-67-1 and others	206-397-9 and others	<p>1. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of PFOA or any of its salts equal to or below 0,025 mg/kg (0,000025 % by weight) where they are present in substances, mixtures or articles.</p> <p>2. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of any individual PFOA-related compound or a combination of PFOA-related compounds equal to or below 1 mg/kg (0,0001 % by weight) where they are present in substances, mixtures or articles.</p> <p>3. 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. This exemption shall be</p>

<p>perfluorinated carbons;</p> <p>(v) perfluorooctane sulfonic acid and its derivatives (PFOS), as listed in this Annex.</p>		<p>reviewed and assessed by the Commission no later than [... <i>Publications Office: please insert date that is 2 years after entry into force of this amending Regulation</i>]</p> <p>4. 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 or by thermal degradation as well as in mixtures and articles for industrial and professional uses containing PTFE micropowders. All emissions of PFOA during the manufacture and use of PTFE micropowders 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 [... <i>Publications Office: please insert date that is 2 years after entry into force of this amending Regulation</i>].</p> <p>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:</p> <p>(a) photolithography or etch processes in semiconductor manufacturing, until 4 July 2025;</p> <p>(b) photographic coatings applied</p>
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			<p>to films, until 4 July 2025;</p> <p>(c) textiles for oil- and water-repellency for the protection of workers from dangerous liquids that comprise risks to their health and safety, until 4 July 2023;</p> <p>(d) invasive and implantable medical devices, until 4 July 2025;</p> <p>(e) manufacture of polytetrafluoroethylene (PTFE) and polyvinylidene fluoride (PVDF) for the production of:</p> <ul style="list-style-type: none"> <li>(i) high-performance, corrosion-resistant gas filter membranes, water filter membranes and membranes for medical textiles,</li> <li>(ii) industrial waste heat exchanger equipment,</li> <li>(iii) industrial sealants capable of preventing leakage of volatile organic compounds and PM2.5 particulates,</li> </ul> <p>until 4 July 2023.</p> <p>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:</p> <ul style="list-style-type: none"> <li>(a) fire-fighting foam that contains or may contain</li> </ul>
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		<p>PFOA, its salts and/or PFOA-related compounds shall not be used for training;</p> <p>(b) fire-fighting foam that contains or may contain PFOA, its salts and/or PFOA-related compounds shall not be used for testing unless all releases are contained;</p> <p>(c) as from 1 January 2023, uses of fire-fighting foam that contains or may contain PFOA, its salts and/or PFOA-related compounds shall only be allowed in sites where all releases can be contained;</p> <p>(d) fire-fighting foam stockpiles that contain or may contain PFOA, its salts and/or PFOA-related compounds shall be managed in accordance with Article 5.</p> <p>7. By way of derogation, the use of perfluorooctyl bromide containing perfluorooctyl iodide for the purpose of producing pharmaceutical products shall be allowed, subject to review and assessment by the Commission by 31 December 2026, every four years thereafter and by 31 December 2036.</p> <p>8. Use of articles already in use in the Union before 4 July 2020 containing PFOA, its salts and/or PFOA-related compounds shall be allowed. Article 4(2), third and</p>
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		<p>fourth subparagraphs shall apply in relation to such articles.</p> <p>9. By way of derogation, the use of PFOA, its salts and/or PFOA-related compounds shall be allowed until 3 December 2020 in the following articles:</p> <p>(a) medical devices other than implantable ones, within the scope of Regulation (EU) 2017/745*;</p> <p>(b) latex printing inks;</p> <p>(c) plasma nano-coatings.</p> <p>-----</p> <p>*Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. ”.</p>
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