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ANNEX 1

ANNEX

to the

COMMISSION REGULATION (EU) .../... of XXX

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards perfluorooctanoic acid (PFOA), its salts and PFOA-related substances

ANNEX

In Annex XVII to Regulation (EC) No 1907/2006, the following entry is added:

<p>“68. Perfluorooctanoic acid (PFOA) CAS No 335-67-1 EC No 206-397-9 and its salts.</p> <p>Any related substance (including its salts and polymers) having a linear or branched perfluoroheptyl group with the formula C₇F₁₅- directly attached to another carbon atom, as one of the structural elements.</p> <p>Any related substance (including its salts and polymers) having a linear or branched perfluorooctyl group with the formula C₈F₁₇- as one of the structural elements.</p> <p>The following substances are excluded from this designation:</p> <ul style="list-style-type: none">• C₈F₁₇-X, where X= F, Cl, Br.• C₈F₁₇-C(=O)O-X' or C₈F₁₇-CF₂-X' (where X'=any group, including salts). <hr/>	<ol style="list-style-type: none">1. Shall not be manufactured, or placed on the market as substances on their own from [<i>date – 3 years after date of entry into force of this Regulation</i>].2. Shall not, from [<i>date – 3 years after date of entry into force of this Regulation</i>], be used in the production of, or placed on the market in:<ol style="list-style-type: none">(a) another substance, as a constituent;(b) a mixture;(c) an article, or any part thereofin a concentration equal to or above 25 ppb of PFOA including its salts or 1000 ppb of one or a combination of PFOA-related substances.3. Paragraphs 1 and 2 shall apply from:<ol style="list-style-type: none">(a) [<i>date - 5 years after entry into force of this Regulation</i>] to:<ol style="list-style-type: none">(i) equipment used to manufacture semi-conductors;(ii) latex printing inks.(b) [<i>date – 6 years after entry into force of this Regulation</i>] to:<ol style="list-style-type: none">(i) textiles for the protection of workers that must meet durable water repellency (DWR) performance standards;(ii) membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment;(iii) plasma nano-coatings.(c) [<i>date – 15 years after entry into force of this Regulation</i>] to medical devices other than implantable medical devices within the scope of Directive 93/42/EEC.4. Paragraphs 1 and 2 shall not apply to any of the following:<ol style="list-style-type: none">(a) perfluorooctane sulfonic acid and its derivatives, which are listed in Part A of Annex I to Regulation (EC) No 850/2004;(b) the manufacture of a substance where
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	<p>this occurs as an unavoidable by-product of the manufacture of fluorochemicals with a carbon chain equal to or shorter than 6 atoms;</p> <p>(c) a substance that is to be used, or is used as a transported isolated intermediate, provided that the conditions in points (a) to (f) of Article 18(4) of this Regulation are met;</p> <p>(d) a substance, constituent of another substance or mixture that is to be used, or is used:</p> <p>(i) in the production of implantable medical devices within the scope of Directive 93/42/EEC;</p> <p>(ii) in photographic coatings applied to films, papers or printing plates;</p> <p>(iii) in semiconductor photo-lithography processes or in etching processes for compound semiconductors;</p> <p>(e) concentrated fire-fighting foam mixtures that were placed on the market before <i>[date – 3 years after date of entry into force of this Regulation]</i> and are to be used, or are used in the production of other fire-fighting foam mixtures.</p> <p>5. Paragraph 2(b) shall not apply to fire-fighting foam mixtures which were:</p> <p>(a) placed on the market before <i>[date – 3 years after entry into force of this Regulation]</i>; or</p> <p>(b) produced in accordance with paragraph 4(e), provided that, where they are used for training purposes, emissions to the environment are minimised and effluents collected are safely disposed of.</p> <p>6. Paragraph 2(c) shall not apply to:</p> <p>(a) articles placed on the market before <i>[date – 3 years after date of entry into force of this Regulation]</i>;</p> <p>(b) implantable medical devices produced in accordance with point (i) of paragraph 4(d);</p> <p>(c) articles coated with the photographic coatings referred to in point (ii) of paragraph 4(d);</p> <p>(d) compound semiconductors referred to</p>
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	in point (iii) of paragraph 4(d).”
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