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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)OH, 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, in 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 from risks to their health and safety; (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 this occurs as an unavoidable by-
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	<p>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> <ul style="list-style-type: none"> (i) in the production of implantable medical devices within the scope of Directive 93/42/EEC; (ii) in photographic coatings applied to films, papers or printing plates; (iii) in photo-lithography processes for semiconductors or in etching processes for compound semiconductors; <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> <ul style="list-style-type: none"> (a) placed on the market before [<i>date – 3 years after entry into force of this Regulation</i>]; or (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>6. Paragraph 2(c) shall not apply to:</p> <ul style="list-style-type: none"> (a) articles placed on the market before [<i>date – 3 years after date of entry into force of this Regulation</i>]; (b) implantable medical devices produced in accordance with point (i) of paragraph 4(d); (c) articles coated with the photographic coatings referred to in point (ii) of paragraph 4(d);
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	(d) semiconductors or compound semiconductors referred to in point (iii) of paragraph 4(d).”
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