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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:

“68. Perfluorooctanoic acid (PFOA) CAS No 335-67-1 EC No 206-397-9 and its salts. 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. 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. The following substances are excluded from this designation: • C₈F₁₇-X, where X= F, Cl, Br. • C₈F₁₇-C(=O)O-X' or C₈F₁₇-CF₂-X' (where X'=any group, including salts).	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: (a) another substance, as a constituent; (b) a mixture; (c) an article, or any part thereof 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: (a) [<i>date - 5 years after entry into force of this Regulation</i>] to: (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: (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: (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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	this occurs as an unavoidable by-product of the manufacture of fluorochemicals with a carbon chain equal to or shorter than 6 atoms; (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; (d) a substance, constituent of another substance or mixture that is to be used, or is used: (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 semiconductor photo-lithography processes or in etching processes for compound semiconductors; (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. 5. Paragraph 2(b) shall not apply to fire-fighting foam mixtures which were: (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. 6. Paragraph 2(c) shall not apply to: (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); (d) compound semiconductors referred to
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	in point (iii) of paragraph 4(d).”
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