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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) 2017/1000, ANNEX. (See end of Document for details)

## **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  $C_7F_{15}$ - 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  $C_8F_{17}$ - as one of the structural elements.

The following substances are excluded from this designation:

C<sub>8</sub>F<sub>17</sub>-X, where X = F, Cl, Br. C<sub>8</sub>F<sub>17</sub>-C(=O)OH, C<sub>8</sub>F<sub>17</sub>-C(=O)O-X ' or C<sub>8</sub>F<sub>17</sub>-CF<sub>2</sub>-X' (where X' = any group, including salts).

- 1. Shall not be manufactured, or placed on the market as substances on their own from 4 July 2020.
- 2. Shall not, from 4 July 2020, be used in the production of, or placed on the market in:
- (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 1 000 ppb of one or a combination of PFOA-related substances.

- 3. Points 1 and 2 shall apply from:
- (a) 4 July 2022 to:
  - (i) equipment used to manufacture semiconductors;
  - (ii) latex printing inks.
- (b) 4 July 2023 to:
  - (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) 4 July 2032 to medical devices other than implantable medical devices within the scope of Directive 93/42/EEC.
- 4. Points 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 this occurs as an unavoidable by-product of the manufacture of fluorochemicals with a carbon chain equal to or shorter than 6 atoms;

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- (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 photo-lithography processes for semiconductors or in etching processes for compound semiconductors;
- (e) concentrated fire-fighting foam mixtures that were placed on the market before 4 July 2020 and are to be used, or are used in the production of other fire-fighting foam mixtures.
- 5. Point 2(b) shall not apply to fire-fighting foam mixtures which were:
- placed on the market before 4 July 2020; or
- (b) produced in accordance with point 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. Point 2(c) shall not apply to:
- (a) articles placed on the market before 4 July 2020;
- (b) implantable medical devices produced in accordance with point 4(d)(i);
- (c) articles coated with the photographic coatings referred to in point 4(d)(ii);
- (d) semiconductors or compound semiconductors referred to in point 4(d)(iii).

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