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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 perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds

ANNEX

In Part A of Annex I to Regulation (EU) 2019/1021, in the table, the fourth column ('Specific exemption on intermediate use or other specification') of the entry for perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds is amended as follows:

- (1) the first sentence of point 3 is replaced by the following:

‘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 perfluoro carbon chain equal to or shorter than 6 atoms.’;
- (2) the first sentence of point 4 is replaced by the following:

‘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 or by thermal degradation as well as in mixtures and articles for industrial and professional uses containing PTFE micropowders.’;
- (3) the following point (10) is added:

‘10. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of PFOA and its salts and/or PFOA-related compounds equal to or below 2 mg/kg (0,0002 % by weight) where they are present in medical devices other than invasive devices and implantable devices. This exemption shall be reviewed and assessed by the Commission no later than [OJ: please insert the date: two years after entry into force of this amending Regulation]’.