ANNEX

In the table in Annex XIV to Regulation (EC) No 1907/2006, entry 42 concerning 4-(1,1,3,3 Tetramethylbutyl)phenol, ethoxylated (covering well-defined substances and UVCB substances, polymers and homologues) is amended as follows:

(1) the text of column 4 ‘Latest application date’ is replaced by the following text:

(a) 4 July 2019 (*);

(b) by way of derogation from point (a), 22 June 2022 for uses as follows:

— for the research, development and production of medicinal products falling within the scope of Directive 2001/83/EC or medical devices or accessories to medical devices falling within the scope of Directive 93/42/EEC, Regulation (EU) 2017/745, Directive 98/79/EC or Regulation (EU) 2017/746 of the European Parliament and of the Council[1], in view of their use for the diagnosis, treatment or prevention of the coronavirus disease (COVID-19),

— in medical devices or accessories to medical devices falling within the scope of Directive 93/42/EEC, Regulation (EU) 2017/745, Directive 98/79/EC or Regulation (EU) 2017/746, for the diagnosis, treatment or prevention of COVID-19.;

(2) the text of column 5 ‘Sunset date’ is replaced by the following text:

(a) 4 January 2021 (**);

(b) by way of derogation from point (a), 22 December 2023 for uses as follows:

— for the research, development and production of medicinal products falling within the scope of Directive 2001/83/EC or medical devices or accessories to medical devices falling within the scope of Directive 93/42/EEC, Regulation (EU) 2017/745, Directive 98/79/EC or Regulation (EU) 2017/746, in view of their use for the diagnosis, treatment or prevention of COVID-19,

— in medical devices or accessories to medical devices falling within the scope of Directive 93/42/EEC, Regulation (EU) 2017/745, Directive 98/79/EC or Regulation (EU) 2017/746, for the diagnosis, treatment or prevention of COVID-19.

(**1**) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).';

Status:
Point in time view as at 18/12/2020.

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) 2020/2160, ANNEX.