Council of the European Union

Brussels, 27 November 2020
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SAN 418
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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	27 November 2020
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	[…](2020) XXX draft - D 070073 ANNEX
Subject:	ANNEX to the COMMISSION REGULATION (EU) No…/.. of XXX amending Annex XIV to Regulation (EU) No 1907/2006 of the European Parliament and of the Council as regards the substance group 4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated (covering well-defined substances and substances of unknown or variable composition, complex reaction products or biological materials, polymers and homologues)

Delegations will find attached document […](2020) XXX draft - D 070073 ANNEX.

Encl.: […](2020) XXX draft - D 070073 ANNEX

EUROPEAN
COMMISSION

Brussels, XXX
D070073/02
[…](2020) XXX draft

ANNEX

ANNEX

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COMMISSION REGULATION (EU) No…/..

of XXX
amending Annex XIV to Regulation (EU) No 1907/2006 of the European Parliament and of the Council as regards the substance group 4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated (covering well-defined substances and substances of unknown or variable composition, complex reaction products or biological materials, polymers and homologues)

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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*[*OJ: this is an existing table note*];

(b) by way of derogation from point (a), … *[OJ: please enter the date – 18 months after entry into force of this amending Regulation]* 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 **, 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.

** 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).';

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

'(a) 4 January 2021**[*OJ: this is an existing table note*];

(b) by way of derogation from point (a), … [*OJ: please enter the date – 36 months after entry into force of this amending Regulation*] 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.'