Council of the
European Union

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13707/20

COMPET 616
ENT 148
ENV 778
CHIMIE 62
MI 551
SAN 453
CONSOM 211
PROCED 33

'I' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
No. Cion doc.:	ST 13278/20 + ADD 1 - D070073
Subject:	Commission Regulation (EU) …/…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) - Decision not to oppose adoption - Decision to use the written procedure

1. In view of its high importance and urgency, on 23 November 2020 an advanced copy was issued in English by the Commission and on 27 November 2020, the above draft Regulation was submitted to the Council in all languages.[1]

[1] ST 13278/20 + ADD 1

2. The latest application date for the substance group, subject of the draft Regulation and listed in Annex XIV of Regulation (EC) 1907/2006[2], was 4 July 2019, and the sunset date is set at 4 January 2021. In accordance with Article 56(1) of Regulation (EC) No 1907/2006, uses of the substance group are not allowed after the sunset date unless an authorisation is granted for a particular use. The latest application date of 4 July 2019 passed before the onset of the COVID-19 pandemic, and applications for longer authorisation of the substance group could not have been submitted before that date.

3. In the present situation of public health emergency, a major interest of the Union lies in the safe and effective medicinal products, suitable for the diagnosis, treatment or prevention of COVID-19, which can be developed, produced, made available, and used in the Union as soon as possible. The substance group considered in the draft Regulation is used in the development of vaccines to combat COVID-19, and is expected to be used in their production. Allowing the continued use of the substance group for those specific purposes after 4 January 2021 would contribute to the fulfilment of the objectives of the EU Strategy for COVID-19 vaccines[3].

4. The draft Regulation should therefore enter into force as a matter of urgency, and apply retroactively in order to ensure the continued use of the substance group after 4 January 2021 for the same purposes related to the treatment of COVID-19.

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[2] Regulation (EC) 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1);

[3] Communication from the Commission to the European Parliament, the European Council, the Council and the European Investment Bank of 17 June 2020 EU Strategy for COVID-19 vaccines - COM (2020) 245 final.

5. The draft Regulation amends Annex XIV of Regulation (EC) 1907/2006 in accordance with its Articles 58 and 133, with reference to Article 5a of Council Decision 1999/468/EC[4]. The measures provided for in this draft Regulation are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006. Pursuant to Article 5a(3) of Council Decision 1999/468/EC, if neither the European Parliament nor the Council oppose the measures envisaged by the Commission within three months from the date of referral to them, the draft Regulation shall be adopted by the Commission.

6. In view of the above, the Council and the Parliament have been asked to act within very tight deadlines in order to confirm the non-opposition to the draft Regulation before the end of 2020. Therefore, a short time limit was allocated in the Council for comments by delegations.

7. On 27 November 2020, delegations of the Working Party on Technical Harmonisation were asked, via written consultation, to indicate by 4 December 2020 their possible opposition to the draft Regulation as set out in document ST 13278/20 + ADD 1. In the Council, no delegation has raised any grounds for opposition by the set deadline.

8. On 1 December 2020, the Environment Committee of the European Parliament voted in favour of an early non-objection by an overwhelming majority, with 75 in favour, 1 against, and 4 abstentions. At the Plenary this month, Parliament will hold a final vote on the non-objection to the draft Regulation.

[4] Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (latest consolidated version - 23/07/2006)

9. Against this background, the Permanent Representatives Committee is invited to:

- confirm its non-opposition to the draft Regulation set out in document ST 13278/20 + ADD 1, and

- decide, in accordance with the first sub-paragraph of Article 12(1) of the Council's Rules of Procedure[5] and Article 1 of Council Decision 2020/430[6], that the Council use the written procedure to confirm that there are no grounds for opposing the draft Regulation as set out in document ST 13278/20 + ADD 1.

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[5] Council Decision 2009/937/EU of 1 December 2009 adopting the Council's Rules of Procedure (OJ L 325, 11.12.2009, p. 35);

[6] Council Decision (EU) 2020/430 of 23 March 2020 on a temporary derogation from the Council's Rules of Procedure in view of the travel difficulties caused by the COVID-19 pandemic in the Union (OJ L 881, 24.3.2020, p. 1), as most recently extended by Decision (EU) 2020/970 of 4 September 2020 (OJ L 294, 8.9.2020, pp. 1–2).