Tuesday 15 December 2020

OPINIONS

EUROPEAN PARLIAMENT

P9_TA(2020)0349

Non-objection to an implementing measure: The substance group 4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated

European Parliament decision to raise no objections to the draft Commission regulation amending Annex XIV to Regulation (EC) 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) (D070073/02 — 2020/2898(RPS))

(2021/C 445/22)

The European Parliament,

— having regard to the draft Commission regulation amending Annex XIV to Regulation (EC) 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) (D070073/02,

— having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning 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 [1], and in particular Articles 58 and 131 thereof,

— having regard to the opinion delivered on 20 November 2020 by the committee referred to in Article 133 of the above regulation,

— having regard to the Commission's letter of 23 November 2020 asking Parliament to declare that it will raise no objections to the draft regulation,

— having regard to the letter from the Committee on the Environment, Public Health and Food Safety to the Chair of the Conference of Committee Chairs of 2 December 2020,

— having regard to Article 5a(3) of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [2],

— having regard to Rule 112(4)(d) and Rule 111(6) of its Rules of Procedure,

— having regard to the recommendation for a decision of the Committee on the Environment, Public Health and Food Safety,

— having regard to the fact that no objections have been raised within the period laid down in the third and fourth indents of Rule 111(6) of its Rules of Procedure, which expired on 15 December 2020,

A. whereas the substance group 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated ('the substance group') meets the criteria set out in point (f) of Article 57 of Regulation (EC) No 1907/2006 and is listed in Annex XIV to that Regulation; whereas the latest application date for the substance group was 4 July 2019 and the sunset date is set for 4 January 2021;

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[1] OJ L 396, 30.12.2006, p. 1.
[2] OJ L 184, 17.7.1999, p. 23.

B. whereas the substance group is used for the production of in-vitro diagnostic kits and in the development of vaccines to combat COVID-19 and possibly also in the production of these vaccines; whereas it is therefore of paramount importance to ensure that the substance group can continue to be used for specific purposes, for the diagnosis, treatment or prevention of COVID-19 after 4 January 2021, as an exceptional measure for the protection of public health;

C. whereas, on 27 November 2020, the Commission transmitted to Parliament the draft Commission regulation, which opened the scrutiny period for Parliament to object to that regulation;

D. whereas, inter alia, the draft Commission regulation introduces a postponement of the latest application date for the substance group until 18 months after the entry into force of that regulation in order to allow for the preparation of applications for authorisation for certain uses and accordingly, also a postponement of the sunset date for the substance group until 36 months after its entry into force;

E. whereas the draft Commission regulation should enter into force as a matter of urgency and apply retroactively as from 4 July 2019, in order to avoid a gap in the period during which applications for uses for the research, development and production of medicinal products, medical devices or accessories to medical devices, including in vitro diagnostic medical devices, in view of their use for the diagnosis, treatment or prevention of COVID-19 and use in such medical devices or accessories can be validly submitted so that the use is covered by point (d) of Article 56(1) of Regulation (EC) No 1907/2006;

F. whereas the present decision is granted as an exceptional measure for the protection of public health, to ensure that the substance group can continue to be used for specific purposes, for the diagnosis, treatment or prevention of COVID-19 after 4 January 2021;

1. Declares that it has no objections to the draft Commission regulation;

2. Instructs its President to forward this decision to the Commission, and, for information, to the Council.