EUROPEAN
COMMISSION

Brussels, 27.10.2022
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COMMISSION IMPLEMENTING DECISION

of 27.10.2022

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Zoetis Belgium S.A and Delpharm Biotech for certain uses of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO)

(Only the English text is authentic)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 Article 64(8) thereof,

Whereas:

(1) 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (‘4-tert-OPnEO’) is listed in Annex XIV to Regulation (EC) No 1907/2006 and uses of that substance are subject to the authorisation requirement in Article 56(1), point (a), of that Regulation.

(2) On 26 June 2019, Zoetis Belgium S.A. and Delpharm Biotech ('the applicants') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for certain uses of 4-tert-OPnEO. The uses for which authorisation was sought are industrial use as a surfactant in a lysis buffer for the release of proteins and antigens from biological material used in the manufacture of three SERELISA veterinary in vitro diagnostic devices for detecting infectious disease in farm animals (‘use 1’); industrial use in formulation of kits, kit reagents and buffer solutions in two WITNESS and three SERELISA veterinary in vitro diagnostic devices used for detecting certain diseases in pets and farm animals (‘use 2’); professional use as a surfactant in kits, kit reagents and buffer solutions in 18 veterinary in vitro diagnostic devices including one SERELISA, six ProFLOK, six WITNESS and five VetScan (the use is carried out by professional users in diagnostic laboratories and veterinary clinics to detect certain diseases in pets and farm animals) (‘use 3’); and industrial use as a viral inactivating agent in the manufacture of two veterinary biologic drugs for treatment of osteoarthritis in cats and dogs (‘use 4’).

(3) On 28 June 2021, the Commission received the opinions on the application adopted by the Committee for Risk Assessment (RAC) and by the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency[2] and sent to it pursuant to Article 64(5), third subparagraph, of Regulation (EC) No 1907/2006.

[1] OJ L 396, 30.12.2006, p. 1.

[2] https://echa.europa.eu/documents/10162/94b3ad2f-21ba-55c2-0e54-101cdb9f0c16

(4) RAC concluded in its opinion that it is not possible to determine a predicted no-effect concentration for the endocrine disrupting properties for the environment of 4-tert-OPnEO in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore 4-tert-OPnEO is a substance for which it is not possible to determine a threshold for the purposes of Article 60(3), point (a), of that Regulation. As a result, Article 60(2) of Regulation (EC) No 1907/2006 does not apply to that substance and authorisations may therefore only be granted with respect to that substance under paragraph 4 of that Article.

(5) RAC noted that the risk to the environment cannot be excluded for non-threshold substances, even at low exposure levels. Consequently, RAC takes the emissions of the substance as a proxy for the risk.

(6) In its opinions on uses 1, 2 and 4, RAC concluded that the risk management measures and operational conditions described in the application are appropriate and effective to limit the risk to the environment. RAC noted that solid and almost all liquid waste containing 4-tert-OPnEO is disposed of for incineration, thus the applicants have demonstrated that releases to environmental compartments have been prevented or minimised as far as technically and practically possible. However, as regards use 4, RAC identified shortcomings on the clearance studies (limited data sets and assay variability), as well as a lack of monitoring data of the wastewater prior to release to the municipal wastewater treatment plant. Therefore, also with the view to confirm that releases are reduced as far as technically and practically possible, RAC recommended monitoring arrangements. Having evaluated the RAC's assessment, the Commission agrees with its conclusion and recommendations.

(7) In its opinion on use 3, RAC concluded that the risk management measures and operational conditions described in the application are not appropriate and effective to limit the risk to the environment. RAC is of the view that the safety data sheet and the instructions included with each in vitro diagnostic kit are not enough to ensure appropriate handling of the materials containing 4-tert-OPnEO by the downstream users. Therefore, RAC recommended the collection of all solid waste and wastewater for adequate treatment as condition for authorisation, specifying that release into the sewer system or to surface waters is not considered to constitute adequate treatment. Having evaluated RAC assessment, the Commission agrees with that conclusion and recommendation.

(8) In its opinions on all uses, SEAC concluded that it has no substantial reservations on the quantitative and qualitative elements of the applicant's assessment of the socio-economic benefits and the risk to the environment associated with the continued uses of the substance. Taking into account the SEAC's assessment, the estimated combined emissions of up to a few kilograms of the substance per year, the estimated quantitatively assessed combined benefits due to avoided profit losses, job losses and relocation costs at minimum in the order of millions of euros and tens of millions of euros over the entire review period, the estimated combined costs of avoiding the remaining releases of the substance in the order of millions and tens of millions of euros per kilogram, the qualitatively assessed additional socio-economic benefits of the continued use due to avoided job losses and continued availability of veterinary products used in disease detection and the treatment of osteoarthritis, as well as any

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https://echa.europa.eu/documents/10162/16a3d4dd-6f52-45c3-1f7d-bfe8abd75284
https://echa.europa.eu/documents/10162/aca4ca9e-41f8-8a7e-b1d7-8af7e09ace4c
https://echa.europa.eu/documents/10162/d596be8d-731b-8f2b-57a7-9b28c298f3bf

relevant distributional impact, the Commission concludes that the applicants have demonstrated that the socio-economic benefits of the continued uses of the substance outweigh the risk to human health and the environment arising from those uses.

(9) A suitable alternative should be safer, available, and technically and economically feasible. Where suitable alternatives are available in the Union, but not technically or economically feasible for the applicant or its downstream users, an authorisation may be granted if the applicant for authorisation submits a substitution plan. An alternative that provides the functionality and level of technical performance necessary for the use applied for should be considered to be technically feasible.

(10) In its opinions on all uses, SEAC concluded that there were no suitable alternative substances or technologies available for the applicant by the sunset date. The Commission, having evaluated SEAC's assessment and all relevant information available, acknowledges that substitution activities are currently still at an early stage since extensive testing is still necessary to obtain the required regulatory approvals. The Commission therefore considers that the identified alternatives do not allow the functionality needed for the uses applied for. Thus, the Commission agrees with SEAC's conclusion and considers that the applicants have discharged their burden of proof in demonstrating the absence of suitable alternatives both in the Union and for the applicant.

(11) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the uses of 4-tert-OPnEO described in the application, provided that the risk management measures and operational conditions described in the chemical safety report, as well as the condition set out in this Decision, are fully applied. However, for the sake of clarity, the description of use 3 authorised by this Decision should be 'professional use as a surfactant in kits, kit reagents and buffer solutions in 18 veterinary in vitro diagnostic devices including one SERELISA, six ProFLOK, six WITNESS and five VetScan, in diagnostic laboratories and veterinary clinics for detecting certain diseases in pets and farm animals'.

(12) The Commission has based its assessment on all relevant scientific evidence currently available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, based its conclusions on a sufficient amount of material and reliable information allowing it to conclude. Nevertheless, additional scientific evidence would allow the Commission to perform its assessment on a more robust or broad evidentiary base in the future. Hence, it is appropriate to require additional exposure and emission information be generated.

(13) In its opinions, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 should be set at ten years for uses 1 and 2, and at 12 years for uses 3 and 4. The Commission agrees with those recommendations, taking into account the relevant elements from RAC's and SEAC's assessments, and, in particular, the socio-economic benefits of the continued uses of the substance, the emissions, the lack of suitable alternatives within a shorter timeline, as well as the testing and regulatory approvals necessary for veterinary products.

(14) The language used to describe the risk management measures and operational conditions in the application for authorisation may be different from the official language of the Member State where the use takes place. Therefore, in order to facilitate supervision and enforcement of compliance with the authorisation, it is appropriate to require the authorisation holder to submit, upon request, a brief summary of those risk management measures and operational conditions to the

competent authority of that Member State in an official language of that Member State.

(15) This Decision does not affect the obligation of the authorisation holder to ensure that a use of a substance does not adversely affect human health or the environment, having regard to the principle set out in Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, this Decision does not affect the obligation of the authorisation holder under Article 60(10) of that Regulation to ensure that the exposure is reduced to as low a level as is technically and practically possible or the obligation of the employer to eliminate or reduce to a minimum risks to the health and safety of workers at work involving hazardous chemical agents in accordance with Article 5(2) of Council Directive 98/24/EC[3]. This Decision does not affect the application of Union law in the area of health and safety at work, in particular Council Directives 89/391/EEC[4], 92/85/EEC[5], 94/33/EC[6] and 98/24/EC, or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

(16) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC of the European Parliament and of the Council[7] or Directive 2010/75/EU of the European Parliament and of the Council[8], nor any obligation to comply with emission limit values set to achieve compliance with the environmental quality standards established by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[9] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[10]. Compliance with the provisions of this Decision does not necessarily imply compliance with emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.

(17) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006,

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3 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

4 Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

5 Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 348, 28.11.1992, p. 1).

6 Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work (OJ L 216, 20.8.1994, p. 12).

7 Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1).

8 Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17).

9 Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

10 Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84).

HAS ADOPTED THIS DECISION:

Article 1

An authorisation is hereby granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 to the following persons for the following uses of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO):

Authorisation number	Authorisation holder	Authorised use
REACH/22/41/0 REACH/22/41/1	Zoetis Belgium S.A. Delpharm Biotech	Industrial use as a surfactant in a lysis buffer for the release of proteins and antigens from biological material used in the manufacture of three SERELISA veterinary in vitro diagnostic devices for detecting infectious disease in farm animals
REACH/22/41/2 REACH/22/41/3	Zoetis Belgium S.A. Delpharm Biotech	Industrial use in formulation of kits, kit reagents and buffer solutions in two WITNESS and three SERELISA veterinary in vitro diagnostic devices used for detecting certain diseases in pets and farm animals
REACH/22/41/4	Zoetis Belgium S.A.	Professional use as a surfactant in kits, kit reagents and buffer solutions in 18 veterinary in vitro diagnostic devices including one SERELISA, six ProFLOK, six WITNESS and five VetScan, in diagnostic laboratories and veterinary clinics for detecting certain diseases in pets and farm animals
REACH/22/41/5	Zoetis Belgium S.A.	Industrial use as a viral inactivating agent in the manufacture of two veterinary biologic drugs for treatment of osteoarthritis in cats and dogs

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety reports[11], and to the condition set out in Article 2 of this Decision.

Article 2

The authorisation bearing number REACH/22/41/4 shall be subject to the following condition: the authorisation holder and its downstream users shall collect all solid waste and

[11] https://ec.europa.eu/docsroom/documents/46113
https://ec.europa.eu/docsroom/documents/46114

wastewater contaminated with 4-tert-OPnEO for adequate treatment. The treatment shall minimise releases of 4-tert-OPnEO to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters does not constitute adequate treatment.

Article 3

1. As regards the authorisation bearing numbers REACH/22/41/0 to REACH/22/41/3, the review period shall expire on 4 January 2031.

   The authorisation shall cease to be valid on 4 January 2031 with respect to any holder of the authorisation who has not submitted the review report for those uses in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 4 July 2029.

2. As regards the authorisation bearing numbers REACH/22/41/4 and REACH/22/41/5, the review period shall expire on 4 January 2033.

   The authorisation shall cease to be valid on 4 January 2033 with respect to any holder of the authorisation who has not submitted the review report for those uses in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 4 July 2031.

Article 4

1. As regards the authorisation bearing number REACH/22/41/5, the monitoring arrangements referred to in paragraphs 2 to 5 shall apply.

2. The authorisation holder shall carry out a monitoring programme measuring the concentrations 4-tert-OPnEO and its principal degradation products in the wastewater prior to release to the municipal wastewater treatment plant. The monitoring programme shall:

   (a) provide an initial sampling frequency which is sufficient to demonstrate daily fluctuations;

   (b) once established, be carried out at least four times per year and during the time of operation. The frequency of the measurements shall be such as to capture the variability in concentrations of the substance and its principal degradation products in the wastewater due to changes or operational fluctuations in the process;

   (c) be based on an analytical method capable of adequately characterising the substance and its principal degradation products in wastewater, with appropriately low limit of quantification;

   (d) be recorded so as to include details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values.

3. The authorisation holder shall carry out a mass balance analysis. This analysis shall be based on the outcome of the measurements referred to in paragraph 2, be carried out annually and include:

   (a) details of the calculations carried out;

   (b) the assumptions made, if any;

   (c) corresponding release values.

4. The authorisation holder shall use the information gathered in accordance with paragraphs 2 and 3 and related contextual information to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions and, if needed, to introduce measures to further reduce emissions of 4-tert-OPnEO to a level as low as technically and practically possible.

5. The authorisation holder shall document and keep the information obtained in accordance with paragraphs 2 and 3, as well as the outcome and conclusions of the review and of any action taken in accordance with paragraph 4. The authorisation holder shall submit that information, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 5

Where the authorisation holder submits a review report, it shall include the following:

(a) the information obtained pursuant to Article 4(5);

(b) as regards the authorisation bearing number REACH/22/41/4, a representative survey concerning the downstream users' effort to collect the solid waste for adequate treatment and to ensure that wastewater is subject to adequate treatment, with the treatment methods implemented.

Article 6

Upon request, the authorisation holders shall submit a brief summary of the applicable risk management measures and operational conditions described in the chemical safety report to the competent authority of the Member State where the authorised use takes place in an official language of that Member State.

Article 7

This Decision is addressed to:

(1) Zoetis Belgium S.A., Rue Laid Burniat 1, 1348 Louvain-La-Neuve, Belgium;

(2) Delpharm Biotech, 2 Rue Alexander Fleming, 69366 Lyon, France.

Done at Brussels, 27.10.2022

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION