EUROPEAN
COMMISSION

Brussels, 26.10.2022
C(2022) 7525 final

COMMISSION IMPLEMENTING DECISION

of 26.10.2022

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Idexx Montpellier SAS and Idexx B.V. for certain uses of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) and for a use of 4-Nonylphenol, branched and linear, ethoxylated (4-NPnEO)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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') and 4-Nonylphenol, branched and linear, ethoxylated ('4-NPnEO') are listed in Annex XIV to Regulation (EC) No 1907/2006 and uses of those substances are subject to the authorisation requirement in Article 56(1), point (a), of that Regulation.

(2) On 19 June 2019, Idexx Montpellier SAS and Idexx Europe B.V.[2] ('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 and for a use of 4-NPnEO. The uses for which authorisation was sought are 4-tert-OPnEO as detergent in the technical manufacturing of in vitro diagnostic veterinary ELISA Plate tests (plate coating) to prevent the non-specific binding of unwanted macromolecules ('use 1'); formulation of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated in the manufacture of sample diluents and standard solutions used in in vitro diagnostic veterinary ELISA Plate tests used for the detection of infectious diseases in livestock and poultry ('use 2'); 4-tert-OPnEO and 4-NPnEO in in vitro diagnostic veterinary products (SNAP tests and ELISA Plate tests) as an ingredient in the wash solutions, sample diluents, control solutions, conjugate solutions, SNAP wash solutions, tissue soaking buffers and detection solutions ('use 3').

(3) On 21 August 2020, the Commission received the opinions on the application adopted by the Committee for Risk Assessment (RAC) and by the Committee for Socio-

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

[2] Idexx Europe B.V. subsequently changed its corporate name to Idexx B.V.

economic Analysis (SEAC) of the European Chemicals Agency[3] and sent to it pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006.

(4) RAC concluded in its opinions that it is not possible to determine a predicted no-effect concentration for the endocrine disrupting properties of 4-tert-OPnEO and 4-NPnEO for the environment in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore 4-tert-OPnEO and 4-NPnEO are substances 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 those substances and authorisations may therefore only be granted with respect to those substances under paragraph 4 of that Article.

(5) RAC noted that 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 and 2, RAC concluded that the risk management measures and operational conditions described in the application are not appropriate and effective in limiting the risk to the environment. RAC noted that, although all solid waste is collected for incineration, wastewater containing 4-tert-OPnEO from washing of reusable equipment and of the coating machine dispersing system and tubing is discharged untreated in the municipal sewer system. However, RAC also acknowledged that the applicant is planning to install an on-site wastewater treatment plant with oxidation treatment and that the contaminated wastewater has been collected and incinerated as a short-term solution since the end of 2020. Therefore, RAC recommended conditions and a monitoring programme, with the aim of reducing to a minimum releases into the environment and to ensure the effectiveness of the risk management measures and operational conditions. In particular, RAC recommended that the applicant should ensure that all emissions of the substances into the environment are subject to adequate treatment as the release into the municipal sewer system or to surface waters is not considered as adequate treatment. Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendation.

(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 in limiting the risk to the environment. RAC noted that there is no requirement for downstream users to collect solid and liquid waste for adequate treatment and that there are uncertainties concerning the treatment of that waste by the downstream users concerned. Therefore, RAC recommended as a condition the collection of all solid waste and wastewater for adequate treatment, with the aim of reducing to a minimum releases into the environment, specifying that release to the sewer system or to surface waters is not considered as adequate treatment. Having evaluated RAC's assessment, the Commission agrees with its 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 applicants' assessment of the socio-economic benefits and of the risk to the environment associated with the continued use of the substances. Taking into account SEAC's assessment, the lack of scientific knowledge at present to quantify or monetise the risk to the environment associated with the uses of the substances, the combined estimated remaining emissions from all

[3] https://echa.europa.eu/documents/10162/a5e17b34-2eaa-0d6a-1a3b-86e135b08e80
https://echa.europa.eu/documents/10162/432a3c7d-c4d0-b53d-5d2c-a1e3b6f997ac
https://echa.europa.eu/documents/10162/4864704c-8f19-66d6-846f-3a6f0570dfe2

sites in the order of hundreds of kilograms of 4-tert-OPnEO and tens of kilograms of 4-NPnEO per year , the combined estimated benefits due to avoided loss of profits and jobs at minimum in the order of tens of millions of euro over the entire review period, the estimated cost of avoiding the remaining releases of the substances in the order of hundreds of thousands of euro per kilogram, and the qualitatively assessed additional socio-economic benefits of the uses on animal health due to the availability of test kits to detect infectious diseases in cattle, sheep, cervid and poultry herds, as well as any distributional impact, the Commission concludes that the applicants have demonstrated that the socio-economic benefits of the continued uses of the substances 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 uses 1 and 3, SEAC concluded that there were no suitable alternative substances or technologies available for the applicants by the sunset date. The Commission, having evaluated SEAC's assessment and all relevant information available, notes that the identified alternatives still need to undergo extensive testing to verify whether they allow the functionality required, in terms of their capacity to prevent the non-specific binding of unwanted macromolecules, in order to obtain regulatory approvals for the test kits. Therefore, the Commission 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) In its opinion on use 2, SEAC concluded that there were no suitable alternative substances or technologies available for the applicant before the sunset date. SEAC noted that there is no function *per se* provided by the substance in the use applied for, since use 2 covers the use of 4-tert-OPnEO for formulation of mixtures intended exclusively for uses 1 and 3, thus the function of the substance is not relevant in this case. Therefore, due to the interlink with uses 1 and 3, SEAC concluded that the assessment of alternatives for use 2 should rely on the one concerning uses 1 and 3. The Commission, having evaluated SEAC's assessment, agrees with that conclusion.

(12) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the three uses of 4-tert-OPnEO and the one use of 4-NPnEO described in the application, provided that the risk management measures and operational conditions described in the chemical safety report as well as the conditions set out in this Decision are fully applied.

(13) 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 the existence of 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 emission information be generated.

(14) In its opinions, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set at 12 years for all uses. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments, and, in particular, the socio-economic benefits, the emissions, the lack of suitable alternatives within a shorter timeline, the time needed for field testing, in particular for low prevalence diseases, as well as the time needed to update the regulatory licensing and marketing authorisations.

(15) 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 holders 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.

(16) 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 to the substance 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[4]. 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[5], 92/85/EEC[6], 94/33/EC[7] and 98/24/EC, or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

(17) 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[8] or Directive 2010/75/EU of the European Parliament and of the Council[9], 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

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4 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).

5 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).

6 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).

7 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).

8 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).

9 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).

Council[10] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[11]. 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.

(18) 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,

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) and Nonylphenol, branched and linear, ethoxylated (4-NPnEO):

Authorisation number	Authorisation holder	Authorised use
REACH/22/43/0	Idexx Montpellier SAS	4-tert-OPnEO as detergent in the technical manufacturing of in vitro diagnostic veterinary ELISA Plate tests (plate coating) to prevent the non-specific binding of unwanted macromolecules
REACH/22/43/1	Idexx Montpellier SAS	Formulation of 4-tert-OPnEO in the manufacture of sample diluents and standard solutions used in in vitro diagnostic veterinary ELISA Plate tests used for the detection of infectious diseases in livestock and poultry

[10] 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).

[11] 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).

REACH/22/43/2 REACH/22/43/3	Idexx Montpellier SAS Idexx B.V.	4-tert-OPnEO in in vitro diagnostic veterinary products (SNAP tests and ELISA Plate tests) as an ingredient in the wash solutions, sample diluents, control solutions, conjugate solutions, SNAP wash solutions, tissue soaking buffers and detection solutions
REACH/22/43/4 REACH/22/43/5	Idexx Montpellier SAS Idexx B.V.	4-NPnEO in in vitro diagnostic veterinary products (SNAP tests and ELISA Plate tests) as an ingredient in the wash solutions, sample diluents, control solutions, conjugate solutions, SNAP wash solutions, tissue soaking buffers and detection solutions

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[12], and to the conditions set out in this Decision.

Article 2

1. The authorisation bearing numbers REACH/22/43/0 and REACH/22/43/1 shall be subject to the conditions set out in paragraphs 2 to 7.
2. The authorisation holder shall collect 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.
3. The authorisation holder shall carry out for the first time by 26 October 2023 and afterwards when new information becomes available, a study on the feasibility of implementing an appropriate treatment of wastewater and act in accordance with the outcome of that assessment.

[12] https://ec.europa.eu/docsroom/documents/47941

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

   (a) 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;

   (b) 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;

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

5. The authorisation holder shall carry out a mass balance analysis. This analysis shall be carried out annually and include:

   (a) details of the calculations carried out;

   (b) the assumptions made, if any;

   (c) corresponding release values.

6. The authorisation holder shall use the information gathered in accordance with paragraphs 4 and 5 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.

7. The authorisation holder shall document and keep the information obtained in accordance with paragraphs 3 to 5, as well as the outcome and conclusions of the review and of any action taken in accordance with paragraph 6. The authorisation holder shall submit that information, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 3

The authorisation bearing numbers REACH/22/43/2 to REACH/22/43/5 shall be subject to the following condition: the authorisation holders and their downstream users shall collect all solid waste and wastewater contaminated with 4-tert-OPnEO or 4-NPnEO for adequate treatment. The treatment shall minimise releases 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 4

1. The review period shall expire on 4 January 2033.

2. The authorisation shall cease to be valid on 4 January 2033 with regard to an authorised use if the review report for that use has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 4 July 2031.

Article 5

Where the authorisation holders submit a review report, it shall include the following:

(a) as regards the authorisation bearing numbers REACH/22/43/0 and REACH/22/43/1, the information in accordance with Article 2(7);

(b) as regards the authorisation bearing numbers REACH/22/43/2 to REACH/22/43/5, a representative survey concerning the downstream users' methods of collection and treatment in accordance with the condition referred to in Article 3.

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) Idexx Montpellier SAS, 326, rue de la Galera, 34090 Montpellier, France ;

(2) Idexx B.V., Scorpius 60 Building F, 2132 LR Hoofddorp, Netherlands.

Done at Brussels, 26.10.2022

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION