Department for Environment Food & Rural Affairs

Authorisation Decision
by Rebecca Pow MP
Parliamentary Under Secretary of State
On behalf of the Secretary of State for Environment, Food and Rural Affairs
Decision date: 14 July 2023

Application Ref: AFA007-01
UK REACH authorisation No.:

Authorisation number	Authorisation holder	Authorised use
UKREACH/23/02/0 [4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated] UKREACH/23/02/1 [4-Nonylphenol, branched and linear, ethoxylated]	IDEXX Laboratories Limited	Use of 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated and use of 4-Nonylphenol, branched and linear, ethoxylated 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

Preliminary matters

- 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 EUR 2006/1907 concerning the registration, evaluation, authorisation and restriction of chemicals ('UK REACH')[1]. As such, 4-tert-OPnEO and 4-NPnEO are subject to the authorisation requirement referred to in Article 56(1) of that Regulation.
- 4-tert-OPnEO and 4-NPnEO were included in Annex XIV because there is scientific evidence of probable serious effects to the environment from their endocrine-disrupting properties when they degrade.
- The application is made by: IDEXX Laboratories Limited of Grange House, Sandbeck Way, Wetherby, West Yorkshire, LS22 7DN ('the Applicant').

[1] References to EUR 2006/1907, referred to in this decision as UK REACH, are to the retained version of Regulation (EC) No 1907/2006, as amended. The retained version of that Regulation is available online at https://www.legislation.gov.uk/eur/2006/1907/contents.

- On 12 November 2021, the Applicant submitted an application for authorisation ('the Application') to the Health and Safety Executive ('the Agency') for the use of 4-tert-OPnEO and 4-NPnEO in in-vitro diagnostic (IVD) veterinary products (SNAP tests and ELISA Plate tests). The technical function of 4-tert-OPnEO and 4-NPnEO is as an ingredient in a variety of solutions used for the tests.
- Article 127GA applied to this application. The sunset date for 4-tert-OPnEO and 4-NPnEO for this use was therefore 30 June 2022.
- On 19 December 2022, the Agency sent its opinion ('the Agency Opinion') to the Secretary of State for Environment, Food and Rural Affairs, and Scottish and Welsh Ministers.

Decision

1. This Decision is addressed to the Applicant.

2. Authorisations are granted in accordance with Article 60(4) of UK REACH for the following use of 4-tert-OPnEO and 4-NPnEO:

    a. In IVD 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.

3. The review period referred to in Article 60(9)(e) of UK REACH is set at twelve years from the sunset date for authorisations UKREACH/23/02/0 and UKREACH/23/02/1. Those authorisations will cease to be valid on 30 June 2034 unless the authorisation holder has submitted a review report in accordance with Article 61(1) by 30 December 2032.

4. The authorisations are subject to the following conditions (as well as the requirement in Article 60(10) of UK REACH to ensure exposure is reduced to as low a level as is technically and practically possible):

    a. The authorisation holder and its downstream users must adhere to the risk management measures ('RMMs') and operational conditions ('OCs') described in the chemical safety report referred to in Article 62(4)(d) of UK REACH[2].

5. In the event that a review report is submitted in accordance with Article 61(1) it should include:

    a. a new representative survey of the authorisation holder's downstream users including details of their disposal procedures for solid and liquid waste containing 4-tert-OPnEO and/or 4-NPnEO with regard to national

[2] This is a reference to the chemical safety report submitted by IDEXX Laboratories Limited on 12 November 2021 as part of the Application. The risk management measures and operational conditions are described in sections 9 (exposure assessment) and 10 (risk characterisation related to combined exposure).

and local regulations. This survey must be conducted within three years of submission of any review report.

6. The authorisations are not subject to any monitoring arrangements.

Background

7. This decision is made under Article 60(4) of UK REACH and having obtained the consent of Scottish and Welsh Ministers.

8. In making this decision, I have taken into account:

   a. The Application.

   b. The elements referred to in Article 60(4)(a) to (d) of UK REACH, and the aspects referred to in Article 60(5).

   c. The Agency Opinion.

Reasons

9. In the Application, the Applicant did not derive predicted no-effect concentrations (PNECs). Therefore, the Agency concluded that for the purposes of the assessment of this application it was not possible to determine PNECs for the endocrine disrupting properties of 4-tert-OPnEO or 4-NPnEO for the environment.

10. In accordance with Article 60(3)(a) of UK REACH, this means that Article 60(2) of that Regulation does not apply to this application. Article 60(2) does not apply to substances for which it is not possible to determine a threshold in accordance with Section 6.4 of Annex I. Therefore, an authorisation may only be granted on the basis of Article 60(4) of that Regulation.

11. An authorisation may only be granted under Article 60(4) of UK REACH if it is shown that the socio-economic benefits outweigh the risk to human health or the environment and there are no suitable alternative substances or technologies. A suitable alternative should be safer, available, and technically and economically feasible.

Risk to the environment

12. In its opinion, the Agency concluded that the Applicant is not able to demonstrate that 100% compliance with appropriate waste disposal would be achieved through the OC and RMMs applied by the downstream users. Therefore, the Agency did not accept the Applicant's modelled estimate of zero emissions from its more than 1,000 downstream users. At the request of the Agency, the Applicant provided a worst-case estimate of emissions which would result in approximately 130kg of emissions of 4-tert-OPnEO and 4-NPnEO to the environment, across more than 1,000 downstream users over 12 years. This was based on a worst-case assumption where the entirety of the substances used by downstream users is released to water. The Agency

concluded that the use applied for will be unlikely to result in anywhere near the worst-case estimate of emissions.

13. 4-tert-OPnEO and 4-NPnEO present a risk to aquatic life when they degrade in water. When degraded, they can adversely affect the endocrine systems of aquatic organisms. I note that this risk cannot be excluded even at low levels.

14. In its opinion, the Agency compared the surface water predicted environment concentrations from the worst-case environmental emissions provided by the Applicant for 4-tert-OP and 4-NP[3] with the environmental quality standards proposed for ethinylestradiol, another endocrine disruptor with the same estrogenic mode of action. On the basis of this comparison, the Agency concluded that the worst-case emissions in the use applied for would not result in discernible environmental impacts on wildlife in the receiving surface waters in relation to endocrine disruption.

15. The Agency also concluded that the Applicant has demonstrated how it instructs downstream users to carry out adequate disposal of the 4-tert-OPnEO and 4-NPnEO-containing wastes. The Agency Opinion concluded that the OCs and RMMs, although not establishing 100% compliance, have been shown to be appropriate and effective at limiting the risk and that the Applicant has demonstrated that exposure to the environment has been reduced to as low a level as is technically and practically possible. Therefore, the Agency did not propose any additional conditions or monitoring arrangements.

16. Having evaluated the Agency's assessment, I agree with its conclusion that the use applied for will have no discernible environmental impacts in relation to endocrine disruption.

Socio-economic analysis

17. The agency opinion concluded that the applicant's socioeconomic analysis is considered proportionate, and the evidence in the application sufficient for the Agency to reach a definitive conclusion.

18. In its opinion, the Agency concluded that the Applicant has demonstrated that the socioeconomic benefits of granting the authorisation are over ten million pounds. This figure accounts for avoided social costs of unemployment only.

19. The Agency concluded that many major benefits of continued use are not monetised. These qualitative benefits consist of:

    a. avoided losses to end-users of tests, from costs including equipment replacement and test revalidation

    b. avoided issues with lower accuracy disease testing, which could lead to increases in Transboundary Animal Diseases. This in turn could lead to:

[3] 4-tert-OP and 4-NP are formed when 4-tert-OPnEO and 4-NPnEO degrade in the environment.

(a) avoided negative impacts on animal care

(b) avoided negative impacts on animal productivity

(c) avoided market disruptions and trade restrictions

(d) avoided impacts on human health and the public health system

20. Having evaluated the Agency's assessment, I agree with its conclusions on the quantitative and qualitative benefits.

Conclusion on whether the benefits outweigh the risk

21. I consider that the Applicant has shown that the socio-economic benefits of granting authorisation outweigh the risk to the environment because of:

a. The likely quantitative benefits in respect of avoided job losses;

b. The likely qualitative benefits in respect of avoided negative impacts on end-users of tests, animal health, markets and trade, and human health; and

c. The likelihood of low emissions in Great Britain and no discernible environmental impacts in relation to endocrine disruption.

Alternatives

22. The Agency concluded in its opinion that currently there were no available alternative substances or technologies with the same function and a similar level of performance that were safer and technically and economically feasible for the Applicant by the sunset date.

23. The Applicant has identified a shortlist of potential alternatives for feasibility testing. The agency agreed with the applicant's assessment that none of the potential alternatives are currently able to successfully address a key performance requirement relating to the test's sensitivity and specificity. Therefore, whilst shortlisted alternatives are considered economically feasible, they are not currently technically feasible.

24. Having evaluated the Agency's assessment, I agree with that conclusion and consider that the Applicant has discharged their burden of proof in demonstrating the absence of suitable alternatives. In reaching this conclusion, I have considered the Agency's assessment of the technical and economic feasibility of alternative substances already on the market.

Review period

25. In its opinion, the Agency recommended the review period referred to in Article 60(9)(e) of UK REACH should be set at 12 years.

26. The Applicant provided a substitution plan stating that the substitution of 4-tert-OPnEO and 4-NPnEO from all of its SNAP and ELISA test products will take 18 – 23 years to complete. This time frame takes into account research

and development, verification and validation, stability testing and regulatory approval. The Applicant requested a 12-year review period: the Applicant anticipates that it will apply for a review of the authorisation to complete its substitution efforts. The Agency concluded that the substitution plan is credible for the review period requested and is consistent with the analysis of alternatives and the socio-economic analysis.

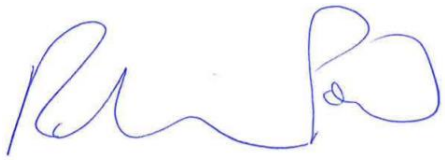
27. I agree with the Agency's conclusions on these points and its recommendation for a 12-year review period.

28. As the Applicant is likely to submit a review report, I conclude that this should include the results of a new representative survey of the Applicant's downstream users. This will confirm, at the time of any review, the continued effectiveness of the Applicant's OCs and RMMs and demonstrate how downstream users are disposing of solid and liquid waste containing 4-tert-OPnEO and/or 4-NPnEO in accordance with national and local regulations. In turn, this will support any future assessment by the Agency at the time of any review.

Conclusion

29. For the reasons set out above I conclude that the socio-economic benefits outweigh the risk to the environment for the use of 4-tert-OPnEO and 4-NPnEO referred to in paragraph 2 and that there are no suitable alternative substances or technologies.

30. The Scottish Ministers and the Welsh Ministers have given their consent to this decision in accordance with Articles 4A and 64(8) of UK REACH.



Rebecca Pow MP

On behalf of the Secretary of State for Environment, Food and Rural Affairs