Department for Environment Food & Rural Affairs

Authorisation Decision

by Robbie Moore, Parliamentary Under Secretary of State

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

Decision date: 3 July 2024

Application Ref: AFA014-01

UK REACH authorisation Numbers:

Authorisation number	Authorisation holder	Authorised use
UKREACH/24/05/0 [4-(1,1,3,3 tetramethylbutyl) phenol, ethoxylated] UKREACH/24/05/1 [4-nonylphenol, branched and linear, ethoxylated]	Roche Diagnostics Limited	Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) and 4-nonylphenol, branched and linear, ethoxylated (4-NPnEO) in 10 *in-vitro* diagnostic (IVD) assays used for example in Clinical Chemistry (CC) and Drug Monitoring (DM) products.

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 assimilated regulation (EC) No 1907/2006 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 UK REACH.

[1] References to regulation (EC) No 1907/2006, referred to in this decision as UK REACH, are to the assimilated law available online at https://www.legislation.gov.uk/eur/2006/1907/contents.

- 4-tert-OPnEO and 4-NPnEO were included in Annex XIV because they meet the criteria set out in Article 57(f) of UK REACH. There is scientific evidence of probable serious effects to the environment from their endocrine-disrupting properties when they degrade into 4-tert-OP and 4-NP respectively.
- This application is made by: Roche Diagnostics Limited, Roche House, Charles Avenue, Burgess Hill, West Sussex, RH15 9RY ('the Applicant').
- Article 127GA of UK REACH applied to this application. The latest application date for 4-tert-OPnEO and 4-NPnEO for this use was therefore extended to 30 June 2022.[2] The sunset date for this use was 30 June 2022.
- On 19 May 2022, the Applicant submitted an application for authorisation ('the Application') to the Health and Safety Executive ('the Agency') for the professional use of 4-tert-OPnEO and 4-NPnEO as a surfactant in the use of IVD assays by downstream users at clinical sites across the UK including laboratories, hospitals and blood banks, to monitor human health and detect, cure, treat or prevent diseases (e.g., HIV tests, cancer screening, blood type identification).
- On 20 September 2023, the Agency sent its opinion (the '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 to the Applicant in accordance with Article 60(4) of UK REACH for the following use of 4-tert-OPnEO and 4-NPnEO:

    a. In 10 *in-vitro* diagnostic (IVD) assays used for example in Clinical Chemistry (CC) and Drug Monitoring (DM) products.

3. The review period referred to in Article 60(9)(e) of UK REACH is set at 5.5 years from the sunset date for authorisations UKREACH/24/05/0 and UKREACH/24/05/1. These authorisations will cease to be valid on 30 December 2027 unless the authorisation holder submits a review report in accordance with Article 61(1) by 30 June 2026.
4. The authorisations are subject to the following condition (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):

[2] This provided time for applicants to submit their application under UK REACH following the transition from EU REACH, where certain criteria were met.

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.[3]

5. The authorisations are not subject to any additional monitoring arrangements.

Background

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

7. In making this decision I have taken into account:

   a. The Application submitted to the Agency;

   b. The provisions of Article 60 of UK REACH, including the elements referred to in Article 60(4) and the requirements of Article 60(5);

   c. The Agency Opinion.

Reasons

8. 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.

9. In accordance with Article 60(3)(a) of UK REACH, this means that Article 60(2) of UK REACH 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, authorisations may only be granted on the basis of Article 60(4) of UK REACH.

10. 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 arising from the use of 4-tert-OPnEO and 4-NPnEO and if there are no suitable alternative substances or technologies.

[3] This is a reference to the chemical safety report submitted by Roche on 19 May 2022 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).

Risk to the environment

11. The Applicant chose to model emissions based on the assumption that all intermediate degradation products of 4-tert-OPnEO and 4-NPnEO may eventually transform into 4-tert-OP or 4-NP.

12. The Applicant expressed concentrations of all 4-tert-OPnEO and 4-NPnEO related compounds as 4-tert-OP and 4-NP equivalents respectively ('OP equivalent' and 'NP equivalent') which included all ethoxylate, carboxylic acids and alkylphenol compounds modelled along the 4-tert-OPnEO and 4-NPnEO degradation pathways. The Agency considered this modelling approach to be appropriate.

13. 4-tert-OP and 4-NP 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. The Applicant explained that approximately 20 to 110 million litres of liquid waste is generated per year across all downstream users. The vast majority of this liquid waste is wastewater generated by the use of IVD kits, which is released to sewer for treatment at the local sewage treatment plants (STPs) where it is discharged to surface water.

15. The Applicant gave modelled breakdowns of the worst-case scenario releases over the review period of 5.5 years across all downstream users. These were 44.8kg and 0.06kg maximum releases to surface water of OP equivalent and NP equivalent respectively, and 37.3kg and 0.17kg maximum releases to sludge via soil of OP equivalent and NP equivalent respectively. These amounts combine to an estimated worst-case scenario of 82.1kg of OP equivalent emissions to the environment and 0.23kg of NP equivalent emissions to the environment totalled over the 5.5-year review period. The Applicant also provided modelled subsequent environmental concentrations based on these releases.

16. The Agency concluded that using the Applicant's modelling approach is likely to lead to a significant overestimate of actual environmental concentrations of 4-tert-OP and 4-NP and is therefore highly conservative. Nonetheless, the Agency considers that the overall modelling approach is appropriate.

17. In its Opinion, the Agency assessed environmental risk by reference to a well-characterised endocrine disruptor with the same mode of action; ethinylestradiol (EE2), which is known to be more potent than the degradation products 4-tert-OP and 4-NP. On the basis of this comparison, the Agency concluded that the worst-case emissions in the use applied for is unlikely to cause discernible impacts on aquatic species through endocrine disruption.

18. The Applicant claimed that downstream users are unable to incinerate the large volume of liquid waste due to the impracticalities and cost of collection and

transportation. Additionally, the Applicant explained that it could not find a commercially available alternative that would completely degrade 4-tert-OPnEO and 4-NPnEO for all kinds of IVD waste compositions.

19. In its Opinion, the Agency agreed with the Applicant's explanation and therefore concluded that the Applicant has demonstrated that the OCs and RMMs currently in place are appropriate and effective at limiting 4-tert-OPnEO and 4-NPnEO emissions to the environment. The Agency also concluded that implementation of RMMs in addition to those that the Applicant currently has in place would not be practical or reasonable given the proposed substitution plan, the proposed review period for the use and the substitutions already implemented. Therefore, the Agency did not propose any conditions or monitoring arrangements.

20. 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 and that no additional conditions or monitoring arrangements are appropriate for the use applied for.

Socio-economic analysis

21. The Agency Opinion concluded that the Applicant's socio-economic analysis is considered proportionate, and that the evidence in the Application is sufficient for the Agency to reach a definitive conclusion.

22. In its Opinion, the Agency assessed both the socio-economic benefits arising from the applied for use and the socio-economic implications of a refusal to authorise. The Agency concluded that the Applicant has demonstrated that the socio-economic benefits of granting the authorisation are greater than £10 million. This figure accounts for avoided reductions in healthcare provision (lower bound).

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

    a. Avoided social cost of unemployment;

    b. Avoided costs to downstream users; and

    c. Additional reduction in healthcare provision not quantified.

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

Conclusion on whether the benefits outweigh the risks

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

    a. The likely quantitative benefits, in respect to avoided reduction in healthcare provision;

b. The likely significant qualitative benefits in respect of avoided costs to downstream users and avoided social cost of unemployment; and

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

Alternatives

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

27. In its Opinion, the Agency noted the Applicant's extensive search for alternative surfactants, resulting in a list of 39 substances which all underwent feasibility testing and hazard assessments, for all products. The Agency agreed with the Applicant's assessment that there were no alternatives available prior to the sunset date due to the complexity of the substitution process, regulations on IVD production and possible extensive validation phases.

28. 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. The Agency did not evaluate the risk of alternatives due to the alternatives not currently being technically feasible.

Review period

29. In its Opinion, the Agency recommended the review period referred to in Article 60(9)(e) of UK REACH should be set at 5.5 years (as requested by the Applicant).

30. The Applicant provided a substitution plan stating that the substitution process began in 2016-2017 and will be completed by the end of 2027. This time frame takes into account the estimated time of substitution, the shelf life of existing products and a transition period required for a new analyser to be developed, as well as technical and regulatory risks. 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.

31. I agree with the Agency's conclusions on these points and its recommendations for a 5.5-year review period.

Conclusion

32. 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.

33. The Scottish Ministers and the Welsh Ministers have given their consent to this decision in accordance with the requirements of UK REACH.

Robbie Moore

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