Department for Environment Food & Rural Affairs

Authorisation Decision
by Jo Churchill MP
Parliamentary Under Secretary of State
On behalf of the Secretary of State for Environment, Food and Rural Affairs
Decision date: 31 January 2022

Application Ref: ID 0186-04; 0186-05; 0186-06; 0186-07; 0186-08

UK REACH authorisation No.:

Authorisation number	Authorisation holder	Authorised use
UKREACH/22/03/0	Beckman Coulter UK Ltd.	Downstream, clinical use of 4-tert-OPnEO-containing laboratory products that require registration, licensing, approval and monitoring by country-based health authorities, designed for use in dedicated clinical chemistry, immunology, haematology and flow cytometry laboratory instruments and assays (use 3 in the Original Application).
UKREACH/22/03/1	Beckman Coulter UK Ltd.	Downstream, clinical use of 4-NPnEO-containing laboratory products that require registration, licensing, approval and monitoring by country-based health authorities, designed for use in dedicated clinical chemistry, immunology, haematology and flow cytometry laboratory instruments and assays (use 3 in the Original Application).
UKREACH/22/03/2	Beckman Coulter UK Ltd.	Downstream, non-clinical use of 4-tert-OPnEO-containing laboratory products designed for use in flow cytometry, genomics and particle characterization laboratory instruments and assays for quality control and research and development (use 4 in the Original Application).
UKREACH/22/03/3	Beckman Coulter UK Ltd.	Downstream, non-clinical use of 4-NPnEO-containing laboratory products designed for use in flow cytometry, genomics and particle characterization laboratory instruments and assays for quality control and research and development (use 4 in the Original Application).
UKREACH/22/03/4	Beckman Coulter UK Ltd.	4-tert-OPnEO-containing laboratory products which are being phased out from the market due to obsolescence or next generation formulations (use 5 in the Original Application).

Preliminary Matters

- 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated and 4-Nonylphenol, branched and linear, ethoxylated ('4-tert-OPnEO' and '4-NPnEO,' respectively) are listed in Annex 14 to EUR 2006/1907 concerning the registration, evaluation, authorisation and restriction of chemicals (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 to Regulation (EC) No 1907/2006[2] 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 Beckman Coulter UK Ltd of Oakley Court, Kingsmead Business Park, London Road, High Wycombe, Buckinghamshire, United Kingdom, HP11 1JU ('the Applicant').
- On 13 June 2019, the Applicant made an application for authorisation ('the Original Application') to the European Chemicals Agency (ECHA) for:
    a. Downstream, clinical use of 4-tert-OPnEO and 4-NPnEO-containing laboratory products that require registration, licensing, approval, and monitoring by country-based health authorities. These products are designed for use in dedicated clinical chemistry, immunology, haematology and flow cytometry laboratory instruments and assays (use 3).
    b. Downstream, non-clinical use of 4-tert-OPnEO and 4-NPnEO-containing laboratory products designed for use in flow cytometry, genomics and particle characterization laboratory instruments and assays for quality control and research and development (use 4).
    c. The use of 4-tert-OPnEO-containing laboratory products which are being phased out from the market due to obsolescence or next generation formulations (use 5).
- On 10 December 2020, ECHA sent the Consolidated Opinions of the Committee for Risk Assessment (RAC) and Committee for Socio-Economic Analysis (SEAC) (the 'RAC Opinions' and the 'SEAC Opinions', respectively) to the European Commission.
- On 16 February 2021, the Applicant notified the Secretary of State of the Original Application in accordance with Article 127G of EUR 2006/1907.

[1] References to "EUR 2006/1907" 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
[2] References to "Regulation (EC) No 1907/2006" are to that Regulation as it has effect in EU law.

- The Original Application related to the use of 4-tert-OPnEO and 4-NPnEO at 5000-10,000 sites in the European Union, Norway, Iceland and Lichtenstein. In further information provided by the Applicants, they reported that over one hundred of these sites are located within Great Britain, though a significant number of these show very low usage, suggesting that they are not routine users of these products.
- In reaching this decision I have considered the likely emissions to the environment and the likely socio-economic benefits in respect of Great Britain.

Decision

1. This decision is addressed to the Applicant.

2. Authorisations are granted in accordance with Article 60(4) of EUR 2006/1907 for the following uses of 4-tert-OPnEO and 4-NPnEO[3] as set out in the table above titled 'UK REACH authorisation No.':

    a. Use 3: Downstream, clinical use of 4-tert-OPnEO and 4-NPnEO-containing laboratory products that require registration, licensing, approval and monitoring by country-based health authorities, designed for use in dedicated clinical chemistry, immunology, haematology and flow cytometry laboratory instruments and assays.

    b. Use 4: Downstream, non-clinical use of 4-tert-OPnEO and 4-NPnEO-containing laboratory products designed for use in flow cytometry, genomics and particle characterisation laboratory instruments and assays for quality control and research and development.

    c. Use 5: 4-tert-OPnEO-containing laboratory products which are being phased out from the market due to obsolescence or next generation formulations.

3. The review period referred to in Article 60(9)(e) of EUR 2006/1907 is set at 12 years for authorisations UKREACH/22/03/0 and UKREACH/22/03/1 (use 3). Those authorisations will cease to be valid from 5 January 2033 unless the authorisation holder submits a review report in accordance with article 61(1) of EUR 2006/1907 by 4 July 2031.

4. The review period referred to in Article 60(9)(e) of EUR 2006/1907 is set at 7 years for authorisations UKREACH/22/03/2 and UKREACH/22/03/3 (use 4). Those authorisations will cease to be valid from 5 January 2028 unless the authorisation holder submits a review report in accordance with article 61(1) of EUR 2006/1907 by 4 July 2026.

5. The review period referred to in Article 60(9)(e) of EUR 2006/1907 is set at 5 years for authorisation UKREACH/22/03/4 (use 5). That authorisation will

[3] The Original Application was for 5 uses. However, uses 1 and 2 are not relevant to this decision notice as they take place exclusively within the European Union.

cease to be valid from 5 January 2026 unless the authorisation holder submits a review report in accordance with article 61(1) of EUR 2006/1907 by 4 July 2024.

6. The authorisations are subject to the following conditions (as well as the requirement in Article 60(10) of EUR 2006/1907 to ensure exposure is reduced to as low a level as is technically and practically possible):

   a. For all uses:

      i. The authorisation holder must adhere to the risk management measures and operational conditions described in the chemical safety report referred to in Article 62(4)(d) of EUR 2006/1907[4].

   b. For UKREACH/22/03/0 and UKREACH/22/03/1 (use 3):

      i. All solid waste containing 4-tert-OPnEO and/or 4-NPnEO must be collected for incineration.

      ii. The collection of liquid waste containing 4-tert-OPnEO and/or 4-NPnEO for incineration must be continued at sites where it is already implemented.

      iii. The Applicant must implement the substitution plan for use 3[5] and the reformulation strategy for Great Britain[6].

   c. For UKREACH/22/03/2 and UKREACH/22/03/3 (use 4):

      i. The collection of solid and liquid waste containing 4-tert-OPnEO and/or 4-NPnEO for incineration must be continued at sites where it is already implemented.

      ii. The Applicant must implement the substitution plan for use 4[7].

   d. For UKREACH/22/03/4 (use 5):

      i. The collection of solid and liquid waste containing 4-tert-OPnEO for incineration must be continued at sites where it is already implemented.

      ii. The Applicant must implement the substitution plan for use 5[8].

[4] This is a reference to the updated chemical safety report dated 14 October 2020. The risk management measures and operational conditions are described in sections 9.3 to 9.5 (p. 84-101).
[5] The substitution plan for use 3 is set out in section 5.3.1.9 (Substitution timeline for use 3 (p. 68-72)) of the updated Analysis of Alternatives and Socio-Economic Analysis dated 14 October 2020.
[6] The reformulation strategy for Great Britain is set out on page 3 of the document titled 'Response to Correspondence Regarding Beckman Coulter's NPnEO and OPnEO's Authorisation Application' dated 30 March 2021.
[7] The substitution plan for use 4 is set out in section 5.3.1.10 (Substitution timeline for use 4 (p. 72-73)) of the updated Analysis of Alternatives and Socio-Economic Analysis dated 14 October 2020.
[8] The substitution plan for use 5 is set out in section 5.3.1.11 (Substitution timeline for use 5 (p. 73-74)) of the updated Analysis of Alternatives and Socio-Economic Analysis dated 14 October 2020.

7. In the event a review report is submitted in accordance with article 61(1) of EUR 2006/1907, for UKREACH/22/03/0 and/or UKREACH/22/03/1 (use 3), it should include the following information:

    a. a new representative survey of the Applicant's downstream users recording how they are disposing of solid and liquid waste containing 4-tert-OPnEO and/or 4-NPnEO.

8. This authorisation is not subject to any monitoring arrangements.

Background

9. This decision is made under Article 64(8) of EUR 2006/1907.

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

    a. The Original Application.

    b. The elements referred to in Article 60(4)(a) to (d) of EUR 2006/1907, and the aspects referred to in Article 60(5).

    c. The RAC Opinion and the SEAC Opinion for each use.

    d. The Applicant's written argumentation submitted in accordance with Article 64(5) of Regulation (EC) No 1907/2006.

    e. Further information provided by the Applicant relating to the relevance of the Original Application data to Great Britain, and to the impact on emissions of the Applicant's development of a diagnostic SARS COV-2 antigen assay to help combat COVID-19.

Reasons

11. In the Original Application, the Applicant did not derive predicted no-effect concentrations (PNECs). The Applicant therefore treated 4-tert-OPnEO and 4-NPnEO as substances for which it is not possible to determine a threshold for the purposes of Article 60(3)(a) of Regulation (EC) No 1907/2006. The RAC Opinions concluded that for the purposes of the assessment of this application, it was not possible to determine PNECs for the endocrine disrupting properties for the environment of 4-tert-OPnEO or 4-NPnEO in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006.

12. In accordance with Article 60(3)(a) of EUR 2006/1907, this means that Article 60(2) of that Regulation does not apply. 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 1. Therefore, an authorisation may only be granted under Article 60(4) of that Regulation.

13. An authorisation may only be granted under Article 60(4) of EUR 2006/1907 if it is shown that the socio-economic benefits outweigh the risks 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.

Risks to the environment and conditions for use 3

RAC's assessment of risks and conditions for use 3

14. RAC sent its draft opinion on use 3 to the Applicant on 11 June 2020 (the 'draft RAC Opinion for use 3'). The draft RAC Opinion for use 3 concluded that the Applicant had not demonstrated that releases to environmental compartments (air, water, soil) have been prevented or minimised as far as technically and practically possible.

15. In reaching this conclusion, RAC noted the results of a survey ('the first survey') of how downstream users across the European Union treat solid and liquid waste containing 4-tert-OPnEO and/or 4-NPnEO ('contaminated solid waste' and 'contaminated liquid waste' respectively, together 'contaminated waste').

16. This survey showed that over half of respondents drain contaminated liquid waste into the sewer system. It also showed that the majority of respondents collect contaminated solid waste for incineration. However, the Applicant only received responses from a small minority of its customers.

17. The draft RAC Opinion for use 3 proposed a condition that all contaminated waste should be collected for adequate treatment (the 'draft use 3 waste condition').

18. In response to the draft use 3 waste condition, the Applicant stated that collecting all contaminated liquid waste for adequate treatment would not be feasible due to:

    a. the very high financial costs of having to install the necessary infrastructure and equipment at hospitals to capture and appropriately handle very large quantities of liquid waste;

    b. the delays in testing and diagnosis whilst collection systems are installed, causing negative impacts on health sector efficiency and risks to patient heath; and

    c. the high financial costs and subsequent carbon emissions from incinerating very large quantities of wastewater.

19. The Applicant also submitted a reformulation strategy for use 3 (the 'original reformulation strategy') which showed the expected reduction in emissions resulting from the implementation of the substitution plan for use 3. This involves substituting products with the highest emissions first. The Applicant also conducted another survey of their downstream users in five key markets, including the UK ('the second survey'). This survey showed that all respondents collect all contaminated solid waste for incineration, and 25-50% collect contaminated liquid waste for incineration.

20. SEAC concluded that the Applicant's reasons for not incinerating all contaminated liquid waste were credible. Therefore, the draft use 3 waste condition was amended in respect of contaminated liquid waste. The final

RAC Opinion for use 3 recommended a condition that the collection of contaminated liquid waste for adequate treatment should continue at the sites where it is already implemented.

21. In amending the draft use 3 waste condition, RAC took into consideration the original reformulation strategy which would enable the Applicant to achieve a significant reduction of emissions to the environment at a very early stage. The final RAC Opinion for use 3 recommended a condition that the applicant should follow the substitution plan for use 3 and the original reformulation strategy, which will result in zero emissions of 4-tert-OPnEO and 4-NPnEO by 2032.

22. The Applicant did not object to the draft use 3 waste condition in respect of contaminated solid waste. RAC therefore retained the recommendation that all contaminated solid waste in respect of use 3 should be collected for adequate treatment in their final opinion. RAC stated that the treatment shall minimise releases to environmental compartments as far as technically and practically possible.

23. RAC concluded that the proposed additional conditions on the treatment of contaminated solid and liquid waste described in paragraphs 20 - 22 are expected to result in the risks being limited in an appropriate and effective way.

Further information and conditions for use 3 in Great Britain

24. In response to my request for further information in respect of Great Britain, the Applicant stated that downstream users for use 3 in Great Britain account for less than 2% of the downstream users considered in the Original Application and that emissions of 4-tert-OPnEO and 4-NPnEO in Great Britain account for less than 10% of those referred to in the Original Application.

25. The Applicant also provided their reformulation strategy for Great Britain in respect of use 3 (‘the reformulation strategy for Great Britain’). This was consistent with the original reformulation strategy in showing significant reductions of emissions to the environment at an early stage for both chemicals.

26. I agree with RAC’s proposed condition that all contaminated solid waste should be collected for adequate treatment. I consider that specifying that this waste must be incinerated will provide certainty to the Applicant and its downstream users about the treatment method that should be applied. I conclude that this condition will result in a low risk to the environment from solid waste for use 3.

27. I also agree with RAC’s proposed condition that the collection and treatment of contaminated liquid waste should be continued at sites where it is already implemented. As with the condition for contaminated solid waste, I consider that specifying incineration as the treatment method will provide certainty to the applicant and its downstream users. In reaching this conclusion, I note the

impracticalities for clinical downstream users of collecting large amounts of contaminated liquid waste.

28. I also agree with RAC's proposed condition that the Applicant should implement the substitution plan for use 3 and their reformulation strategy. I consider their analysis to be relevant to the reformulation strategy for Great Britain. In making this conclusion, I recognise the significant impact their implementation will have on reducing emissions to the environment at an early stage in Great Britain.

29. I consider that these conditions for use 3 will result in the risks being limited in an appropriate and effective way for Great Britain.

Conclusions on the risks for use 3

30. When degraded in water, 4-tert-OPnEO and 4-NPnEO can adversely affect the endocrine systems of aquatic organisms. I note that these risks cannot be excluded even at low levels.

31. However, I conclude that the risk is low because:

    a. all contaminated solid waste, and some contaminated liquid waste, will continue to be collected for incineration; and

    b. the substitution plan for use 3 and the reformulation strategy for Great Britain will lead to significant reductions of emissions to the environment at an early stage for both chemicals, with their use ceasing by the end of the review period.

Monitoring arrangements for use 3

32. RAC did not propose any monitoring arrangements for use 3 and I agree that no monitoring arrangements are required for this use in Great Britain.

<u>Socio-economic analysis for use 3</u>

33. The SEAC Opinion for use 3 concluded that SEAC has no substantial reservations on the quantitative and qualitative elements of the Applicant's assessment of the socio-economic benefits and the risks to the environment associated with the continued use of 4-tert-OPnEO and 4-NPnEO.

34. In the Original Application, the Applicant stated that not granting authorisation could lead to delays in the diagnosis of critical conditions and increase mortality in the affected disease groups. SEAC agreed that disruption in the supply of tests to the health sector could have negative impacts for a significant number of patients as well as having a negative impact on the efficiency of the health care sector. SEAC also concluded that not granting authorisation for this use would put health care providers under severe economic pressure to find new suppliers of tests.

35. SEAC concluded for use 3 that the quantified estimated benefits due to avoided profit losses and job losses are in the range of tens of millions of

euros to hundreds of millions of euros over a 12-year assessment period. However, SEAC concluded that the main impacts of non-authorisation for this application would be on patient health and the health care system. SEAC also concluded that this was the Applicant's strongest argument for the authorisation to be granted. As these impacts were not quantified, SEAC considered that the Applicant had underestimated the benefits.

36. In respect of the emissions for use 3, SEAC calculated cost-effectiveness ratios by adopting a worst-case approach. SEAC took the year with the highest expected emissions and applied this for every year of the requested 12-year review period. It was also based on the assumption that all contaminated waste is released as liquid waste into wastewater. This does not take account of the fact that not all of the waste is liquid. It also does not take account of the results of the first and second surveys. The first survey suggested the majority of contaminated solid waste is incinerated and the second survey suggested all contaminated solid waste is incinerated. Both surveys suggested some contaminated liquid waste is incinerated.

37. SEAC acknowledged that the original reformulation strategy will result in a significant reduction of emissions to the environment at a very early stage. However, SEAC only included the year with the highest emissions in its cost-effectiveness ratios, which also leads to an overestimation of the emissions and quantified risks.

38. SEAC recognised that additional emissions relating to COVID-19 tests developed by the Applicant were included in the total emissions for 4-tert-OPnEO, but neither the Applicant nor SEAC included the related benefits in the cost-effectiveness calculations. Including these emissions without including the associated benefits further overestimates the scale of the risks as compared to the benefits. The ratios also do not take account of the other significant qualitative benefits to health care and patients referred to above.

39. The points discussed in paragraphs 35 - 38 above mean that the cost-effectiveness ratios are likely to overestimate the risks and underestimate the benefits.

40. In response to my request for further information on the Applicant's contributions to the healthcare sector in Great Britain, the Applicant stated that over 150 million tests containing 4-tert-OPnEO and 4-NPnEO are carried out annually in Great Britain. They also stated that a restriction on the supply of diagnostic testing products would require hospitals in Great Britain to spend significant amounts of time and money trying to find new suppliers and, potentially, purchasing new equipment to meet their specifications.

<u>Conclusion on whether the benefits outweigh the risks for use 3</u>

41. I consider that the Applicant has shown that the socio-economic benefits of use 3 outweigh the risks to the environment because:

a. there are likely to be benefits in terms of avoided profit losses and job losses;

b. there are likely to be significant benefits to the health sector and patients, including in respect of Covid-19 testing;

c. there are likely to be some emissions of 4-tert-OPnEO and 4-NPnEO relating to the disposal of contaminated liquid waste, but these will be limited in an appropriate and effective way through the conditions for use 3, and the risks from them are likely to be low; and

d. the substitution plan for use 3 and the reformulation strategy for Great Britain are likely to lead to significant early reductions in the use of 4-tert-OPnEO and 4-NPnEO, with their use ceasing by the end of the review period.

Alternatives for use 3

42. The SEAC Opinion for use 3 concluded that there are no available alternative substances or technologies with the same function and a similar level of performance that are safer and technically and economically feasible for the Applicant by the sunset date.

43. The Applicant has assessed different alternatives from the family of alkyl ethoxylates such as TERGITOL TM and from the family of Polysorbates such as Tween®. The Applicant stated that their research has not identified an alternative that delivers the required functionalities currently provided by 4-tert-OPnEO and 4-NPnEO.

44. SEAC agreed that these findings are relevant to the Applicant's conclusion on the availability of suitable alternatives. SEAC also considered the Applicant's search methodology for shortlisting alternatives to be adequate and comprehensive. Furthermore, SEAC concluded that even if an alternative was to become technically feasible, its successful implementation across the entire range of products would require the requested review period.

45. Having evaluated SEAC's assessment, I agree with its conclusions and consider that the Applicant has discharged its burden of proof in demonstrating the absence of suitable alternatives. In reaching this conclusion I have considered SEAC's assessment of the technical feasibility of alternative substances already on the market and I consider this to be applicable to Great Britain.

Review period for use 3

46. The SEAC Opinion for use 3 recommended that the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 should be set at 12 years.

47. This was based on the Applicant's substitution plan for use 3, which says that it will take twelve years to phase out both 4-tert-OPnEO and 4-NPnEO in the clinical downstream use of in-vitro diagnostic products.

48. SEAC found the substitution plan for use 3 presented by the Applicant to be credible, with well described phases and timelines for completion. SEAC therefore recommended that the review period should be 12 years as provided for in the substitution plan for use 3.

49. I agree with SEAC's recommendation that the review period should be set at 12 years. I also agree with SEAC's assessment and conclusions, and consider them to be relevant to Great Britain, that:

    a. the substitution plan and timelines proposed by the Applicant are credible;

    b. the Applicant is already engaged in a substitution programme, prioritising the substitution of the products containing the highest concentrations of 4-tert-OPnEO and 4-NPnEO first, to minimise emissions;

    c. the Applicant is due to have stopped using 4-tert-OPnEO and 4-NPnEO by the end of the review period; and

    d. even if an alternative was to become technically feasible, its successful implementation would require the requested review period.

50. RAC stated that in the event a review report is submitted for use 3, the authorisation holder should include a new representative survey of its downstream users. I agree with this conclusion and consider that this should include information regarding how downstream users in Great Britain are disposing of solid and liquid waste containing 4-tert-OPnEO and/or 4-NPnEO.

51. This survey will allow the UK REACH Agency (the Health and Safety Executive) to understand how contaminated liquid and solid waste is being treated at the time of any review.

<u>Risks to the environment and conditions for uses 4 and 5</u>

RAC's assessment of risks and conditions for uses 4 and 5

52. The RAC Opinions for uses 4 and 5 concluded that the Applicant has not demonstrated that releases to environmental compartments have been prevented or minimised as far as technically and practically possible. In reaching this conclusion, RAC noted the results from the first survey referred to above in respect of use 3.

53. There were fewer responses to the first survey in respect of use 4 than use 3, so the outcome was less conclusive. Due to the low number of responses to the first survey for use 5, the Applicant assumed that these downstream users would have similar responses to those for uses 3 and 4 as the only difference between the uses is that the products under use 5 will be discontinued.

54. As with use 3, the first survey showed that the majority of respondents collect contaminated solid waste for incineration and drain contaminated liquid waste into the sewer system.

55. The RAC Opinion for use 4 noted the low quantities of 4-tert-OPnEO and 4-NPnEO used and therefore the low releases to the environment. RAC also noted that implementing additional measures to collect all contaminated waste would likely take a significant amount of time and effort. RAC noted that it would likely take longer to implement these measures than the substitution of 4-tert-OPnEO and 4-NPnEO for use 4, or the discontinuation of relevant products for use 5.

56. Therefore, RAC concluded that a condition requiring all downstream users to collect all contaminated waste for adequate treatment should not be imposed. Instead, RAC recommended a condition in respect of uses 4 and 5 that sites should continue to collect contaminated waste for adequate treatment where they already do so.

57. In addition, RAC noted SEAC's view that the Applicant's ongoing and planned substitution activities for use 4 are well-described and appropriate to achieving substitution within the review period applied for. Products containing the highest concentrations of 4-tert-OPnEO and 4-NPnEO will be substituted first to minimise emissions early on and will result in zero emissions of 4-tert-OPnEO and 4-NPnEO by the end of 2027.

58. Therefore, RAC recommended a condition in respect of use 4 that the Applicant should follow the substitution plan for use 4. This would lead to the full substitution of 4-tert-OPnEO and 4-NPnEO by 2027.

59. The RAC Opinion for use 5 noted SEAC's view that the Applicant's plan to completely phase out the use of the affected products is credible. This will result in zero emissions of 4-tert-OPnEO by the end of 2025.

60. RAC recommended a condition in respect of use 5 that the Applicant shall follow the substitution plan for use 5 to cease the use of 4-tert-OPnEO by the end of 2025.

61. The RAC Opinions for uses 4 and 5 concluded that the proposed additional conditions are expected to result in the risks being limited in an appropriate and effective way.

Conditions for uses 4 and 5 in Great Britain

62. I agree with RAC's conclusions on the conditions for uses 4 and 5 and consider them to be relevant to Great Britain. Sites should continue to collect contaminated waste for incineration where they already do so, which will result in the risks being limited in an appropriate and effective way. I agree that it is disproportionate to require downstream users to incinerate all contaminated waste due to the time and resources required to implement the additional risk management measures. The Applicant's plans to substitute 4-tert-OPnEO and 4-NPnEO for use 4, and cease use of 4-tert-OPnEO for use 5, will further minimise emissions during the respective review periods.

Conclusions on the risks for uses 4 and 5

63. With fewer sites expected in Great Britain for all uses than in the Original Application, I expect the emissions in Great Britain for uses 4 and 5 would be lower than those given in the Original Application.

64. When degraded in water, 4-tert-OPnEO and 4-NPnEO can adversely affect the endocrine systems of aquatic organisms. I note that these risks cannot be excluded even at low levels.

65. However, I conclude that the risk is low in respect of uses 4 and 5 because:

    a. of the low levels of emissions for uses 4 and 5;

    b. some contaminated solid and liquid waste will continue to be collected for incineration; and

    c. the substitution plans for uses 4 and 5 will mean that the use of 4-tert-OPnEO and 4-NPnEO will reduce over the course of the respective review periods and cease by the end of them.

Monitoring arrangements for uses 4 and 5

66. RAC did not propose any monitoring arrangements for uses 4 and 5 and I agree that no monitoring arrangements are required for these uses in Great Britain.

<u>Socio-economic analysis for uses 4 and 5</u>

67. The SEAC Opinions for uses 4 and 5 concluded that SEAC has no substantial reservations on the quantitative and qualitative elements of the Applicant's assessment of the socio-economic benefits and the risks to the environment associated with the continued use of 4-tert-OPnEO and 4-NPnEO for use 4, and 4-tert-OPnEO for use 5.

68. SEAC concluded, as it did with use 3, that non-authorisation could lead to disruption in the supply of medical tests, with negative impacts for a significant number of patients and the efficiency of the health care sector.

69. For uses 4 and 5, the Applicant was unable to quantify benefits beyond lost profits in the Original Application. For use 4, SEAC concluded that not granting the authorisation could result in lost profits in the range of hundreds of thousands of euros to one million euros per year. For use 5, SEAC concluded that not granting the authorisation could result in lost profits also in the range of hundreds of thousands of euros to one million euros per year. SEAC also concluded that some job losses are likely for both uses but they were not quantified.

70. I requested further information from the Applicant on the quantified impacts in respect of Great Britain. The Applicant stated that in a non-use scenario for use 4, the clinical trial equipment used by research laboratories would be affected. This equipment is not normally changed mid-trial due to the

introduction of uncertainty to the trial results. In the non-use scenario for use 4, research laboratories would need to try to find alternative suppliers and may need to purchase new equipment costing £10,000 - £150,000 per analyser to meet their specifications. This may also lead to the results of trials being delayed.

71. Use 5 covers products and associated testing equipment in both clinical and non-clinical settings. I therefore conclude that the costs and delays caused by having to prematurely replace equipment are also relevant in respect of use 5.

72. As with use 3, SEAC concluded that the main benefit of authorisation for uses 4 and 5 is the qualitative impact on the health sector. The Applicant stated that not granting authorisation for these uses would risk disruption to medical tests and increased mortality. SEAC agreed that a disruption to testing could have negative impacts for a significant number of patients and have a negative impact on the efficiency of the health care sector. Due to these having not been quantified, SEAC considered that the Applicant had underestimated the benefits for uses 4 and 5.

73. I agree with SEAC's conclusion that not granting authorisation for uses 4 and 5 could have negative impacts for a significant number of patients and have a negative impact on the efficiency of the health care sector. I also consider this to be relevant to Great Britain.

74. As with use 3, SEAC calculated a cost-effectiveness ratio for uses 4 and 5. SEAC again used the year with the highest expected emissions. This level of emissions was used to calculate the ratio for every year of each requested review period. It was also based on the assumption that all contaminated waste is released as liquid waste into wastewater. As with use 3, this does not take account of the fact that not all of the waste is liquid. This also does not take account of the first survey which suggested that the majority of downstream users already collect contaminated solid waste, and some downstream users already collect contaminated liquid waste, for incineration.

75. Furthermore, SEAC did not take account of any reductions that would be achieved by the substitution plans for uses 4 and 5. The ratios also do not take account of the significant qualitative benefits to health care and patients.

76. This means that, as with use 3, the cost-effectiveness ratios likely overestimate the risks and underestimate the benefits.

<u>Conclusion on whether the benefits outweigh the risks for uses 4 and 5</u>

77. I consider that the Applicant has shown that the socio-economic benefits of uses 4 and 5 outweigh the risks to the environment because:

    a. there are likely to be benefits in terms of avoided profit losses and job losses;

    b. there are likely to be benefits in terms of avoided additional costs for clinical trials;

c. there are likely to be significant benefits to the health sector and patients;

d. there are likely to be some emissions of 4-tert-OPnEO and 4-NPnEO, but these will be limited in an appropriate and effective way through the conditions for uses 4 and 5, and the risks from them are likely to be low; and

e. the substitution plans for uses 4 and 5 are likely to lead to reductions in emissions of 4-tert-OPnEO and 4-NPnEO, with the use ceasing by the end of the respective review periods.

Alternatives for uses 4 and 5

78. The SEAC Opinion for uses 4 and 5 concluded that there are no available alternative substances or technologies with the same function and a similar level of performance that are safer and technically and economically feasible for the Applicant by the sunset date.

79. SEAC found both substitution plans presented by the Applicant to be credible, with well described phases and timelines for substitution in respect of use 4. For uses 4 and 5, SEAC also found credible the Applicant's claim that, even if an alternative was to become technically feasible, its successful implementation across the entire range of products would require the whole of the requested review periods.

80. Having evaluated SEAC's assessment, I agree with its conclusions and consider that the Applicant has discharged its burden of proof in demonstrating the absence of suitable alternatives. In reaching this conclusion, I have considered SEAC's assessment of the technical feasibility of alternative substances already on the market and I consider this to be applicable to Great Britain.

Review period for uses 4 and 5

81. The SEAC Opinion for uses 4 and 5 recommended the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 should be set at:

a. Seven years for use 4.

b. Five years for use 5.

82. This was based on the Applicant's substitution plans. In respect of use 4, SEAC found the Applicant's substitution plan to be credible with well described phases and timelines for completion and concluded that it supports the seven-year review period.

83. Use 5 is for a separate group of laboratory products which will be removed from the market by the end of 2025. These will be replaced by products that do not contain 4-tert-OPnEO. For use 5, SEAC found it plausible that substitution for such a short period of time would not be proportionate, even in the unlikely case that an alternative was to become technically feasible. SEAC therefore recommended a five-year review period.

84. I agree with SEAC's recommendations for uses 4 and 5. I also agree with SEAC's assessment and conclusions, and consider them to be relevant to Great Britain, that:

a. the substitution plans and timelines proposed by the Applicant to either substitute (use 4) or discontinue use (use 5) are credible;

b. the Applicant is already engaged in a substitution programme for use 4, prioritising the substitution of the products containing the highest concentrations of 4-tert-OPnEO and 4-NPnEO first, to minimise emissions;

c. the programme to discontinue use of 4-tert-OPnEO for use 5 is underway;

d. the Applicant is due to have stopped using 4-tert-OPnEO and 4-NPnEO in respect of uses 4 and 5 by the end of the respective review periods; and

e. even if an alternative was to become technically feasible, its successful implementation would require the requested review periods for uses 4 and 5.

Conclusion

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

86. Scottish and Welsh Ministers have given their consent to this decision in accordance with Articles 4A and 64(8) of EUR 2006/1907.

Jo Churchill MP
On behalf of the Secretary of State for Environment, Food and Rural Affairs.