Department for Environment Food & Rural Affairs

Authorisation Decision
by Robbie Moore MP
Parliamentary Under Secretary of State
On behalf of the Secretary of State for Environment, Food and Rural Affairs
Decision date: 12 March 2024

Application Ref: AFA006-01

UK REACH authorisation number: UKREACH/24/01/0

Authorisation holder: ENTEK International Limited

Authorised use

Use of trichloroethylene as an extraction solvent for removal of process oil and formation of the porous structure in polyethylene-based separators used in lead-acid batteries.

Preliminary Matters

Trichloroethylene (TCE) is listed in Annex XIV to EUR 2006/1907 concerning the registration, evaluation, authorisation and restriction of chemicals ('UK REACH').[1] As such, TCE is subject to the authorisation requirement referred to in Article 56(1) of that Regulation.

TCE was included in Annex XIV because of its carcinogenicity (Article 57(a) category 1B, 'may cause cancer').

ENTEK International Limited, of Mylord Crescent, Camperdown Industrial Estate, Killingworth, Newcastle upon Tyne, NE12 5XG ('the Authorisation Holder') was granted authorisation for this use of TCE on 20 February 2018 under the EU REACH Regulation ('the Original Authorisation').

On 19 October 2021, the Authorisation Holder submitted a review report to the Health and Safety Executive ('the Agency'), 18 months before the Original Authorisation expiry date of 21 April 2023.[2]

[1] References to EUR 2006/1907, 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.
[2] Under Article 61(1), authorisations granted in accordance with Article 60 shall be regarded as valid until the Secretary of State decides to amend or withdraw the authorisation in the context of a review, provided that the holder of the authorisation submits a review report at least 18 months before the expiry of the time-limited review period.

On 27 April 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 Authorisation Holder.

2. An authorisation is granted to the Authorisation Holder in accordance with Article 60(4) of UK REACH for the following use of TCE:

    a. as an extraction solvent for removal of process oil and formation of the porous structure in polyethylene-based separators used in lead-acid batteries.

3. The review period referred to in Article 60(9)(e) of UK REACH is set at twelve years. The authorisation will cease to be valid on 21 April 2035 unless the Authorisation Holder has submitted a review report in accordance with Article 61(1) by 21 October 2033.

4. The authorisation is 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,[3] subject to the conditions specified at sub-paragraph b below.

    b. The Authorisation Holder must review its OCs and RMMs and apply improved measures to these, to reduce inhalation exposures to TCE for personnel working where the trichloroethylene solvent extraction processes for lines 1/2 and 7/8 are undertaken (within the 'main enclosures') during routine and non-routine activities. Specifically:

        (a) By 12 June 2024, the Authorisation Holder must put in place measures to manage the amount of time that workers spend within the main enclosures and manage repeated entries to the enclosure throughout workers' shifts;

        (b) By 12 June 2024 and until 4.b.(c) is implemented, the Authorisation Holder must implement mandatory use of higher APF air powered full-facepiece respirators fitted with TH3 head-tops for all entries into the main enclosure; with powered respirators meeting EN 12941 fitted during breakdowns; and

[3] This is a reference to the chemical safety report submitted by ENTEK International Limited on 8 March 2022 as part of the review report. The risk management measures and operational conditions are described in sections 9 (exposure assessment) and 10 (risk characterisation related to combined exposure).

(c) By 12 September 2025 the Authorisation Holder must implement mandatory use of full facepiece breathing apparatus (in demand mode) supplied with appropriate quality breathing air.

c. The Authorisation Holder must implement the OCs and RMMs stated in paragraphs 4.b.(a), 4.b.(b) and 4.b.(c) unless it devises, designs and implements alternative OCs and RMMs that are at least as appropriate and effective at controlling the exposures to TCE.

5. The following monitoring arrangements must be applied:

a. The Authorisation Holder must take occupational exposure measurements supported by contextual information of the work activities undertaken during the monitoring period. Sampling must be done at least annually and with a sampling strategy that is directed by expert advice.

b. Until the measures described in paragraph 4.b.(c) are operational, or until an alternative that is at least as appropriate and effective is in place (4.c.), the Authorisation Holder must ensure maintenance engineers working inside enclosures during line breakdowns use personal photo-ionisation detector monitors. Other employees working inside the enclosure during line breakdowns must also undertake appropriate personal exposure monitoring.

c. Once the measures described in paragraph 4.b.(c) are operational, the Authorisation Holder must undertake surveys to test that the air being supplied to breathing apparatus equipment meets the standards in EN 12021, and that every user is supplied with at least the minimum quantity of breathing quality air that the breathing apparatus manufacturer stipulates, when the maximum number of users are plugged into the air supply system.[4] These measurements must be taken at least once every three months, with no more than three months between measurements while the authorised use takes place.

d. Subject to gaining appropriate consent from employees, the Authorisation Holder must implement its voluntary biological monitoring programme for trichloroacetic acid (TCA) in urine samples for both production and maintenance personnel. Anonymised results for each individual in the biological monitoring programme should be submitted to the Agency on an annual basis, and upon request, for the duration of the authorisation.

e. The Authorisation Holder must use the data collected from the monitoring arrangements specified in 5.a., 5.b. and 5.c., as well as any available data from 5.d. to review the effectiveness of the RMMs and OCs and take appropriate action in order to ensure compliance with its obligations.

[4] It is not essential to test every plug-in point separately during any particular quarterly survey of the breathing air supply systems. However, the testing regime should be devised to provide assurance that the test results are representative of every plug-in point.

f. If the Authorisation Holder chooses to implement alternative OCs and RMMs that are at least as appropriate and effective at controlling the exposures to TCE (4.c.), then personal air monitoring must be used to demonstrate this, as well as any available data from the Authorisation Holder's voluntary biological monitoring programme.

6. By 12 November 2025, the Authorisation Holder must provide an update report to the Agency based on the above conditions and monitoring arrangements, demonstrating that inhalation exposures to TCE during non-routine work within the main enclosures is being reduced in an appropriate and effective way. This report must include:

   a. Personal air sampling from at least 5 separate line breakdown events, including the monitoring data from whichever monitoring survey relating to 5.a. and 5.b. yielded the highest measured TCE exposures;[5]

   b. Detailed descriptions (including photographs) of the revised RMMs and OCs that have been installed; and

   c. Subject to gaining appropriate consent from employees, results from the Authorisation Holder's voluntary biological monitoring programme for Trichloroacetic acid (TCA) in urine.

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

   a. Representative personal exposure monitoring data (that directly measures the non-respiratory protective equipment (RPE) adjusted airborne levels of TCE) for a range of routine and non-routine situations to capture a worst-case exposure to significant levels of TCE; and

   b. The data collected as a result of the monitoring in 5.a., 5.b., 5.c., as well as any available data from 5.d. (and 5.f. if relevant), and document any actions taken as a result of collecting these data. This should also be made available on request to the Agency.

[5] If there are too few breakdown events for 5 monitoring surveys to be undertaken, then an interim report should be submitted based on the available information. A full report should be submitted once the monitoring data from the minimum of 5 surveys (and therefore at least 10 personal sample data points) are available.

Background

8. This decision is made under Articles 61 and 60(4) of UK REACH and having obtained the consent of Scottish and Welsh Ministers.

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

   a. The review report 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

10. The Agency concluded that it was not possible to determine a derived no effect level (DNEL) for the carcinogenic properties of TCE.

11. 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.

12. 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 TCE and if there are no suitable alternative substances or technologies.

Risk to human health

13. TCE presents a risk to human health due to its carcinogenic properties.

14. In its Opinion, the Agency concluded that provided the OCs and RMMs described in the review report are adhered to, they would limit the risk resulting from inhalation exposures in the case of all but one of the exposure groups. The Agency concluded that the environmental OCs and RMMs are appropriate in limiting the risk to the general population living in the vicinity of the site, and that human exposure via TCE releases to water or the finished products are expected to be negligible.

15. The Authorisation Holder did not assess direct dermal exposure as part of the exposure monitoring strategy, as it assumed that the potential for dermal exposure to workers was negligible because of the very limited physical contact with the polyethylene separators and the low levels of TCE present in the separator. When forming its Opinion, the Agency questioned this assumption and the appropriateness of the types of gloves being worn by workers where exposures were more likely, for example in the case of spillages. The Authorisation Holder has confirmed to the Agency that it has already implemented the use of more heavy-duty gloves for workers. The Agency concluded that the upgraded gloves offer better protection from

exposure to TCE, and that the biological monitoring (5.d.) will be effective to confirm that respiratory and dermal protection is effective in real-world situations.

16. In its assessment, the Agency identified a specific scenario during which the risk from inhalation exposures in one exposure group, specifically for individuals entering and working inside the main enclosures for protracted routine and non-routine activities (breakdowns), were not appropriately covered in the Authorisation Holder's review report. Furthermore, the Agency did not agree that the respiratory protective equipment currently being used provides adequate respiratory protection for all potential exposures. This matters as those needing to enter the main enclosures during a breakdown would be exposed to significantly higher concentrations. Additionally, no directly measured personal sampling data during a line breakdown was available to demonstrate exposure levels.

17. Due to the reasons above, the Agency concluded that the OCs and RMMs described in the review report are not appropriate and effective in limiting the risk. The Agency therefore proposed additional conditions and monitoring arrangements.

18. Due to the uncertainties relating to the lack of exposure data, the Agency calculated its own theoretical extreme worst-case exposure estimates to assess exposure risk for workers involved within the main enclosures. However, the Agency did not consider its exposure estimates to be a likely representation of the real-world exposures.

19. Based on the Agency's extreme worst-case exposure estimates, the Agency concluded that the risk of continued use based on the RMMs and OCs presented in the review report could theoretically result in two additional statistical cancer cases over 40 years with a monetised value of £0.31 million to £1.05 million over 12 years. This allows a direct comparison of the monetised risk and benefits.

20. Due to the Agency concluding that the OCs and RMMs described in the review report are not appropriate and effective in limiting the risk, the Agency proposed conditions. The conditions are expected to reduce the risk significantly[6] within 18 months of re-authorisation. The Agency's recommended monitoring arrangements outlined in paragraph 5 will corroborate the effectiveness of the Authorisation Holder's RMMs and OCs and confirm whether they are appropriate and effective in limiting the risk.

21. Having evaluated the Agency's assessment, I agree that whilst the extreme worst-case exposure estimate (used to assess whether the benefits outweigh the risk) is not considered to be a likely representation of the real-world exposures and therefore risk, there is nonetheless still a potential risk to those workers inside the main enclosures. Therefore, I agree with Agency's recommended conditions and recommended monitoring arrangements and

[6] For example, the use of breathing apparatus in demand mode would reduce exposures to TCE by 100 times.

agree that these will result in OCs and RMMs that are appropriate and effective in limiting the risk for all exposed groups, at the earliest opportunity.

Socio-economic analysis

22. The Agency concluded that the Authorisation Holder's socio-economic analysis is based on a suitable general methodological approach and that the non-use scenario is plausible and credible, establishing the likely general situation for the Authorisation Holder in the event of not being granted an authorisation. The socio-economic benefits of granting the authorisation were calculated by the Agency to be at least £58 million over 12 years. This figure accounts for avoided profit losses, avoided relocation and closure costs, and avoided social costs of unemployment.

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

Conclusion on whether the benefits outweigh the risk

24. The Agency Opinion concluded that the Authorisation Holder's assessment provides a robust conclusion that benefits outweigh the risk for the applied for use scenario associated with the granting of an authorisation.

25. In its Opinion, the Agency concluded that the Authorisation Holder has clearly demonstrated, on the basis of a quantitative assessment, that economic and social impacts outweigh the health impacts by a considerable margin. This conclusion is based on the risk calculated on the Agency's extreme worst-case exposure estimates.

26. I consider that the Authorisation Holder has shown that the socio-economic benefits of granting authorisation outweigh the risk to human health because of:

    a. The likely quantitative benefits in respect of avoided profit losses, avoided relocation and closure costs, and avoided social costs of unemployment; and

    b. Even in the worst-case scenario, the potential risk of continued use to one exposure group is likely to be low compared to the balance of socio-economic benefit, based on the monetised comparison used.

27. Even in the worst-case scenario, whereby the risk of exposure to TCE could result in two additional statistical cancer cases over 40 years (and as monetised in paragraph 19), the benefits of authorisation outweigh the risk by orders of magnitude. Nevertheless, I consider it proportionate to include suitable conditions and monitoring arrangements in order to address the appropriateness and effectiveness of the RMMs and OCs.

Alternatives

28. 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 were safer and technically and economically feasible for the Authorisation Holder by the expiry date of the current authorisation decision.

29. The Authorisation Holder has identified a shortlist of potential alternative replacement solvents and a most promising alternative technology. The Agency agreed that the Authorisation Holder's justifications regarding the technical and economic feasibility were well founded, logical and cogent. The Agency concluded that the changes required to switch from TCE to alternative solvents are extensive and would not be able to be completed before the expiry date of the current authorisation. The Agency agreed that none of the alternatives would be technically or economically feasible before the expiry date of the current authorisation, including the most promising alternative technology, as it is in its primitive stages and is still under research and development.

30. Having evaluated the Agency's assessment, I agree with that conclusion and consider that the Authorisation Holder 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

31. 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.

32. The Authorisation Holder provided a substitution plan for the most suitable alternative which contained detailed cost breakdowns. The Authorisation Holder requested a minimum of a 12-year review period, based on an assumption that testing would be successful. At the time of writing its Opinion, the Agency noted that the Authorisation Holder had so far met their milestones and the timeline remained valid. The Agency concluded that ENTEK has convincingly demonstrated that it has a plan in place for substitution, and recognised that, due to its infancy, there are uncertainties around the timeline of the substitution plan and therefore the Agency accepted that it may take longer than 12 years to implement the full plan.

33. I agree with the Agency's conclusions on these points and its recommendation for a 12-year review period and agree with the Agency's recommendations for any future review report.

Conclusion

34. For the reasons set out above I conclude that the socio-economic benefits outweigh the risk to human health for the use of TCE referred to in paragraph 2 and that there are no suitable alternative substances or technologies.

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

36. In accordance with the provisions of Article 61(1), the Original Authorisation is amended and replaced with this decision, effective from the decision date referenced above.

Robbie Moore MP

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