Department for Environment Food & Rural Affairs

Authorisation Decision

By Marc Casale, Deputy Director, Chemicals, Pesticides and Hazardous Waste (DEFRA)

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

Decision date: 5 September 2024

Application Ref: AfA035-01

UK REACH authorisation No.:

Authorisation number	Authorisation holder	Authorised use
UKREACH/24/17/0 UKREACH/24/17/1 UKREACH/24/17/2 UKREACH/24/17/3	Boeing Distribution (UK) Inc. Wesco Aircraft EMEA Ltd MacDermid Performance Solutions UK Ltd Henkel Ltd	Pre-treatments using chromium trioxide in aerospace and defence industry and its supply chains.

Preliminary Matters

- Chromium trioxide is 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, chromium trioxide is 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.

- Chromium trioxide was included in Annex XIV due to its intrinsic carcinogenic and mutagenic properties (Article 57(a) and Article 57(b) of UK REACH).
- Hexavalent chromium (Cr(VI)) is the form of chromium in chromium trioxide to which the hazardous properties are attributed.
- The application is made by:
    a. Wesco Aircraft EMEA Ltd, of 50 Longbridge Lane, Allenton, Derby, DE24 8UJ
    b. Boeing Distribution (UK) Inc. of 25 Victoria Street, Westminster, SW1H 0EX
    c. Henkel Ltd, of Wood Lane End, Hemel Hampstead, HP2 4RQ
    d. MacDermid Performance Solutions UK Ltd, of Unit 2 Genesis Business Park, Albert Drive, Sheerwater, Woking, Surrey, GU21 5RW

    (together, the 'Applicants') who are importers of chromium trioxide. The Applicants are members of the Aerospace and Defence Chromates Reauthorisation Consortium ('ADCR').
- As a result of the conditions of Article 127H of UK REACH having been met, the use of chromium trioxide authorised under EU REACH[2] can continue until 21 September 2024.
- On 7 March 2023, the Applicants submitted an application for authorisation (the 'Application') to the Health and Safety Executive (the 'Agency') for the use of chromium trioxide in pre-treatments in the aerospace and defence industry and its supply chains. Pre-treatment processes (including deoxidising, desmutting, and pickling/etching) prepare surface substrates of components for subsequent main treatments.
- On 21 March 2024, 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 Applicants.
2. In accordance with Article 60(4) of UK REACH, authorisation is granted to the Applicants as set out under the following authorisation numbers for the following use:
    a. UKREACH/2024/17/0 for the use of chromium trioxide in pre-treatments in the aerospace and defence industry and its supply chains
    b. UKREACH/2024/17/1 for the use of chromium trioxide in pre-treatments in the aerospace and defence industry and its supply chains

[2] EU REACH refers to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

c. UKREACH/2024/17/2 for the use of chromium trioxide in pre-treatments in the aerospace and defence industry and its supply chains

d. UKREACH/2024/17/3 for the use of chromium trioxide in pre-treatments in the aerospace and defence industry and its supply chains

3. The review period referred to in Article 60(9)(e) of UK REACH is set at 12 years. The authorisation will cease to be valid on 5 September 2036 unless a review report is submitted in accordance with Article 61(1) of UK REACH by 5 March 2035.

4. The authorisation is 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):

   a. The authorisation holders and the downstream users must adhere to the operational conditions (OCs) and risk management measures (RMMs) described in the chemical safety report referred to in Article 62(4)(d) of UK REACH,[3] subject to the monitoring arrangement specified at subparagraph 5.d. below.

5. The authorisation is subject to monitoring arrangements. The authorisation holders must request written confirmation from each downstream user that it will:

   a. undertake measurements of the concentrations of total chromium and Cr(VI) released to air (from the stack) and wastewater (from final discharge point to the foul sewer) for each site where the authorised use takes place. The frequency of measurements must be taken in accordance with what is stated in any environmental permits where the authorised use takes place. Measurements must be representative of any operating conditions. Sufficient measurements must be taken to demonstrate the data is robust and representative of emissions arising from the authorised use

   b. check measurements taken as a result of the monitoring in subparagraph 5.a. against any emission limit values and most up-to-date Best Available Techniques standards

   c. use an accredited laboratory for the analysis of total chromium and Cr(VI). The laboratory must use an analytical method capable of adequately characterising chromium and Cr(VI) at an appropriate limit of detection

   d. use the monitoring data to review the effectiveness of the OCs and RMMs and take appropriate action to ensure compliance with their obligations

[3] This is a reference to the chemical safety report submitted by the Applicants on 7 March 2023 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).

e. make available to the Agency on request the data collected as a result of the monitoring in subparagraph 5.a., as well as any actions taken as a result of collecting the data.

6. The Agency has set out recommendations for the authorisation holders and the downstream users in section 10 of its Opinion, should the authorisation holders submit a review report in accordance with Article 61(1) of UK REACH. These recommendations are not conditions of authorisation or conditions for any review report.

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 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's Opinion

Reasons

9. In its Opinion, the Agency concluded that it is not possible to determine a derived no-effect level for the carcinogenic and mutagenic properties of chromium trioxide. Therefore, for chromium trioxide, it is not possible to determine a threshold in accordance with section 6.4 of Annex I of UK REACH.

10. Therefore, and in accordance with Article 60(3)(a) of UK REACH, this means that Article 60(2) of UK REACH does not apply to the Application and authorisation may only be granted on the basis of Article 60(4) of UK REACH.

11. 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 chromium trioxide and if there are no suitable alternative substances or technologies.

Risk to human health

12. In accordance with the criteria set out in Annex XIII of UK REACH, chromium trioxide presents a risk to human health due to its carcinogenic and mutagenic properties.

13. In its Opinion, the Agency noted that the Applicants had provided a limited data set for downstream user sites in Great Britain (GB). Therefore, in order to assess the risk to human health (both to workers and to humans via the environment), the Agency used the exposure data and descriptions of the OCs and RMMs at

downstream user sites from both the European Economic Area (EEA) and GB, as provided by the Applicants.

Workers

14. In its Opinion, the Agency concluded that the risk associated with worker exposure to chromium trioxide has been minimised to an appropriate and effective level. The Agency considered that the OCs and RMMs employed by the sites in GB were broadly consistent with those in the EEA. To allow for a robust assessment for risk to workers, the Agency used the 90th percentile values from the combined EEA and GB data set to reflect a worst-case exposure scenario.[4]

15. In its Opinion, the Agency concluded that for inhalation exposure to workers, based on the 90th percentile, the Applicants have demonstrated that personal exposure data for each worker contributing scenario was less than the Agency benchmark of 5 µg/m^3 as an 8-hour time weighted average. Furthermore, the Agency noted that biomonitoring data further supported the conclusion that the OCs and RMMs at downstream user sites in GB were likely to be appropriate and effective at controlling exposures from all routes to workers. Therefore, whilst the Agency concluded that the limited GB data set creates some uncertainty, the OCs and RMMs described in the Application are likely to be appropriate and effective in limiting the risk to workers, provided they are adhered to.

16. The Agency assessed the monetised human health impacts to workers to be up to £598,000 over the 12-year review period. This accounts for 360 directly exposed workers across 20 sites in GB.

17. Having evaluated the Agency's assessment, I agree with its conclusion that the OCs and RMMs described in the Application are likely to be appropriate and effective in limiting the risk to workers provided they are adhered to.

Humans via the environment

18. For human exposure to chromium trioxide via the environment, the Agency noted that the limited GB data set results in some uncertainty when extrapolating emission figures across all sites in GB. Therefore, to reflect a worst-case scenario in its assessment of risk, the Agency adopted a highly conservative approach in selecting which emission values from the combined GB and EEA data set, provided by the Applicants, to use for GB sites.

19. In its Opinion, the Agency considered that, based on the worst-case scenario, the Applicant's estimates of human exposure via the environment are likely to be reasonable overall. Therefore, the Agency concluded that the OCs and RMMs are likely to be appropriate in limiting the risk to humans via the environment, provided they are adhered to.

[4] In its Opinion, the Agency noted that the worst-case exposures are highly conservative and not typical or expected but allow for a robust conclusion on whether the benefits outweigh risks.

20. However, the Agency was unable to conclude definitively that the OCs and RMMs described in the Application are effective in limiting the risk to humans via the environment. This was due to uncertainty in the representativeness and reliability of emission data and exposure estimates across GB sites. Furthermore, the combined environmental emissions data from the GB and EEA sites to water and air demonstrated elevated exposure levels, suggesting that the OCs and RMMs could be amended to become more effective. The paucity of GB data combined with the elevated exposure levels, suggests that it is possible that an emission scenario could arise at one or more GB sites which might pose an increased level of risk to humans via the environment. Therefore, to reduce the existing uncertainty around the effectiveness of RMMs and the potential for human exposure via the environment, the Agency recommended monitoring arrangements.

21. In its Opinion, the Agency concluded that these monitoring arrangements will ensure that evidence is available to demonstrate that emissions of Cr(VI) to air and water, and therefore risk, are being effectively controlled at GB sites. Furthermore, the Agency explained that the data collected from the monitoring arrangements can be used by the Applicants and downstream users to review the effectiveness of the OCs and RMMs and enable them to take appropriate action to ensure compliance with their obligations.

22. The Agency assessed the monetised health impacts to humans via the environment to be up to £698,000 over the 12-year review period. This accounts for an estimated general population of 26,641 people across 20 sites in GB.

23. Having evaluated the Agency's assessment, I agree with the Agency that, as it could not conclude fully on the effectiveness of the OCs and RMMs in limiting the risk to humans via the environment, monitoring arrangements are appropriate. I agree with the Agency that monitoring arrangements will reduce the uncertainty around the effectiveness of OCs and RMMs and will enable downstream users to take appropriate action to improve their OCs and RMMs where required.

Socio-economic analysis

24. The socio-economic analysis for the Application was conducted by ADCR on behalf of the Applicants. ADCR also completed the socio-economic analyses for other applications for a range of connected uses. The refusal of one use would trigger other costs associated with a refused authorisation in other uses. However, to provide a conservative estimate of benefits of continued use, the Agency only included the estimated costs directly related to the use applied for in the Application.

25. In its Opinion, the Agency assessed the socio-economic benefits arising from the applied for use and the socio-economic implications of a refusal to authorise. The socio-economic benefits of authorisation are based on the avoided profit losses

and the avoided social costs of unemployment if authorisation was not granted. The Agency estimated this to be at least £14.7 million over 12 years.

26. This estimate is further considered to be conservative as additional socio-economic benefits of granting authorisation have been assessed qualitatively by the Agency but have not been monetised. These consist of avoided negative impacts on airlines, air passengers, customers, cargo, and avoided negative impacts on emergency services, military forces' operational capacity and mission readiness associated with service disruption.

27. 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

28. In its Opinion, the Agency concluded that the Applicants have demonstrated that the socio-economic benefits of granting authorisation (at least £14.7 million over 12 years) are higher than the risk to human health (up to £1.3 million over 12 years).

29. I consider that the Applicants have 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 and the avoided social costs of unemployment

    b. the likely qualitative benefits in respect of avoided negative impacts on airlines, air passengers, customers, cargo, and avoided negative impacts on emergency services, military forces' operational capacity, mission readiness associated with service disruption

    c. the likely assessed risk from the use of chromium trioxide

Alternatives

30. In its Opinion, the Agency concluded that there are no available alternative substances or technologies with the same function and a similar level of performance that will be technically and economically feasible for the Applicants by the expiry date of the authorised use under EU REACH (21 September 2024).

31. The downstream users of the Applicants use chromium trioxide for the pre-treatment of various components (cockpit frames, gearboxes, fuel pumps, gun barrels, ancillaries and propellers) with specific technical performance requirements that correspond to each individual component. In their Application, the Applicants submitted 24 distinct substitution plans focussing on seven stages. These plans detailed the Applicants' approach to attempting to find substitutes for chromium trioxide and the seven shortlisted alternatives they are currently pursuing. The Applicants also highlighted emerging technologies found in relevant literature and patent searches along with current global collaboration

projects. The Applicants do not consider that these alternatives currently equate to feasible substitution candidates for the purposes of the aerospace and defence sector and that the different set of requirements for an array of components means that a 'one-size fits all' approach for substitution is unable to be taken. The Agency noted that the Applicants' analysis focused on previous relevant applications for authorisation to the European Chemicals Agency under EU REACH which represented decades of research and investment into alternatives to pre-treatments.

32. In its Opinion, the Agency accepts that finding and implementing alternatives across the whole aerospace and defence sector is challenging and that there is currently no drop-in replacement available for all uses of Cr(VI) in pre-treatments. The Agency concluded that the Applicants have provided a thorough assessment of the alternatives with extensive detail surrounding the seven shortlisted alternatives for further research, and it is satisfied that the Applicants have successfully identified an appropriate list of the most suitable alternatives.

33. Having evaluated the Agency's assessment, I agree with the conclusion that there will be no available alternatives by the expiry date of the authorised use under EU REACH and consider that the Applicants have discharged their burden of proof in demonstrating the absence of suitable current 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 being technically feasible.

Review period

34. 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.

35. In the Application, the Applicants proposed a 12-year review period due to the complexity of substitution, as demonstrated in their substitution plans. The Agency concluded that the Applicants' substitution plans are credible for the review period requested and are consistent between the analysis of alternatives and the socio-economic analysis. While the Applicants expect that 83% of substitutions may occur within 12 years, there is uncertainty surrounding this due to the potential for unforeseen technical failures. The Agency was satisfied that it is unlikely that substitution would be achieved for all plans within 12 years due to the technical, economic and regulatory challenges described in the application.

36. In its Opinion, the Agency concluded that a 12-year time-period is realistic when considering that not all the current proposed alternatives are technically feasible. The Agency evaluated the Applicants' substitution plans, along with the detailed answers to the Agency's questions, and agree that it would take a minimum of 12 years for the substitution of chromium trioxide in pre-treatments to listed alternatives, and possibly longer for some components.

37. Having evaluated the Agency's assessment, I agree with the Agency's conclusions on these points and its proposal for a 12-year review period.

Conclusion

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

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

Marc Casale

Deputy Director, Chemicals, Pesticides and Hazardous Waste

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