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: AfA028-01

UK REACH authorisation No.:

Authorisation number	Authorisation holder	Authorised use
UKREACH/24/11/0	Boeing Distribution (UK) Inc.	Use of chromium trioxide in anodising in the aerospace and defence industry and its supply chains.
UKREACH/24/11/01	Henkel Ltd	
UKREACH/24/11/02	MacDermid Performance Solutions UK Ltd	
UKREACH/24/11/03	Wesco Aircraft EMEA Ltd	

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.
- 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. Boeing Distribution (UK) Inc. of 25 Victoria Street, Westminster, SW1H 0EX

  b. Henkel Ltd, of Wood Lane End, Hemel Hampstead, HP2 4RQ

  c. MacDermid Performance Solutions UK Ltd, of Unit 2 Genesis Business Park, Albert Drive, Sheerwater, Woking, Surrey, GU21 5RW

  d. Wesco Aircraft EMEA Ltd, of 50 Longbridge Lane, Allenton, Derby, DE24 8UJ,

  (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 10 January 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 anodising in the aerospace and defence industry, and its supply chains. Anodising is an electrolytic oxidation process where the surface of a metal is converted into an oxide which has desirable functional properties.
- On 5 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.

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

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/2024/11/0 for the use of chromium trioxide in anodising in the aerospace and defence industry and its supply chains
    b. UKREACH/2024/11/1 for the use of chromium trioxide in anodising in the aerospace and defence industry and its supply chains
    c. UKREACH/2024/11/2 for the use of chromium trioxide in anodising in the aerospace and defence industry and its supply chains
    d. UKREACH/2024/11/3 for the use of chromium trioxide in anodising 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]
5. The authorisation is not subject to any monitoring arrangements.
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.

[3] This is a reference to the chemical safety report submitted by the Applicants on 10 January 2023 as part of the Application. The risk management measures, and the operational conditions are described in sections 9 (exposure assessment) and 10 (risk characterisation related to combined exposure).

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, 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 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

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

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, in its Opinion, the Agency concluded that biomonitoring data demonstrates that worker exposure is well controlled and provided good evidence that the OCs and RMMs at each site 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 £818,000 over the 12-year review period. This accounts for 660 directly exposed workers across 30 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 concluded that, based on the worst-case scenario, the Applicants' estimates of human exposure via the environment are likely to be reasonable overall. The absence of site-specific data for most GB sites led to a degree of uncertainty, however, the Agency considered that the OCs and RMMs are likely to be appropriate and effective in limiting the risk to humans via the environment.

20. The Agency assessed the monetised health impacts on humans via the environment to be up to £892,000 over the 12-year review period. This accounts for an estimated general population of 39,961 people across 30 sites in GB.

21. Having evaluated the Agency's assessment, I agree with the Agency's conclusions that the OCs and RMMs described in the Application are likely to be appropriate and effective in limiting the risk to humans via the environment.

Socio-economic analysis

22. 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 authorisation for one use would trigger other costs associated with a refused authorisation in other uses. However, to provide a conservative estimate of the benefits of continued

use, the Agency only included the estimated costs directly related to the use applied for in this Application.

23. 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 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 £44.4 million over 12 years.

24. 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.

25. 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

26. In its Opinion, the Agency concluded that the Applicants have demonstrated that the socio-economic benefits of granting authorisation (at least £44.4 million over 12 years) are higher than the risk to human health (up to £1.7 million over 12 years).

27. I consider that the Applicants have shown that the socio-economic benefits of granting the 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 assessed risks from the use of chromium trioxide

Alternatives

28. 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).

29. The downstream users of the Applicants use chromium trioxide for anodising of various components with technical performance requirements. The use applied for may be interdependent, as any single surface treatment use may not be stand-alone but one part of an entire surface treatment process system. In the

Application, the Applicants submitted 47 distinct substitution plans, and details on their approach in attempting to substitute chromium trioxide and the five shortlisted alternatives they are currently pursuing. The Applicants do not consider that these alternatives currently equate to feasible substitution candidates for the purposes of the aerospace and defence sector. The Applicants also conducted reviews of literature, patents, and global collaboration projects. Due to the varying specific technical requirements of the components, the Applicants highlighted that it may not be possible for a single alternative to be used for all components, therefore multiple alternatives are required. The Agency agreed with this reasoning.

30. In its Opinion, the Agency noted that there has been little significant progress reported by the surface treatment industry suggesting promising alternatives which meet up to the superior performance levels of chromium trioxide. As such, the Agency noted that the Applicants' analysis focused on previous relative applications for authorisation to the European Chemicals Agency under EU REACH and thought that the Applicants made reasonable estimates in trying to establish the possible future for the shortlisted alternatives. In its Opinion, the Agency concluded that the Applicants have provided a detailed assessment of the alternatives which includes adequate explanation of why there were no suitable alternatives currently available.

31. 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

32. 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.

33. In the Application, the Applicants proposed a 12-year review period due to the uncertainty and the high complexity of the substitution, as demonstrated in their substitution plans. In its Opinion, 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 socioeconomic analysis. The Applicants noted that key technical performance issues still remain where some potential alternatives show inadequate corrosion protection, fatigue strength, and inconsistent performance, and that while an estimated 94% of substitution plans will be in place within 12 years, it is not likely that all of the substitution plans for chromium trioxide will be in place within that time.

34. In its Opinion, the Agency concluded that this 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 Applicants' detailed answers to questions, and agreed that it would take a minimum of 12 years for the substitution of chromium trioxide.

35. 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

36. 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.

37. 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