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: AfA039-01

UK REACH authorisation No.:

Authorisation number	Authorisation holder	Authorised use
UKREACH/24/19/0 [chromium trioxide] UKREACH/24/19/1 [chromium trioxide] UKREACH/24/19/2 [chromium trioxide]	Wesco Aircraft EMEA Ltd MacDermid Performance Solutions UK Ltd Henkel Ltd	Use of chromium trioxide in anodise sealing in the aerospace and defence industry and its supply chains.
UKREACH/24/19/3 [chromium trioxide] UKREACH/24/19/4 [sodium chromate]	Boeing Distribution (UK) Inc	Use of chromium trioxide and sodium chromate in anodise sealing in the aerospace and defence industry and its supply chains.

Preliminary Matters

- Chromium trioxide and sodium chromate (together, the 'Substances') are listed in Annex XIV to assimilated Regulation (EC) No 1907/2006 concerning the

registration, evaluation, authorisation and restriction of chemicals (UK REACH).[1] As such, both the Substances are 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).
- Sodium chromate was included in Annex XIV due to its intrinsic carcinogenic and mutagenic properties (Article 57(a) and Article 57(b) of UK REACH) and its reproductive toxicity (Article 57(c) of UK REACH).
- Hexavalent chromium (Cr(VI)) is the form of chromium in chromium trioxide and sodium chromate to which the hazardous properties of each of the Substances 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. MacDermid Performance Solutions UK Ltd, of Unit 2 Genesis Business Park, Albert Drive, Sheerwater, Woking, Surrey, GU21 5RW

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

  (together, the 'Applicants') who are importers of the Substances. 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 the Substances 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 the Substances in anodise sealing in the aerospace and defence industry and its supply chains. Anodise sealing is typically the final step within the anodising process. It is a chemical process which is carried out in surface treatment.
- 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/24/19/0, UKREACH/24/19/1, and UKREACH/24/19/2 for the use of chromium trioxide in anodise sealing in the aerospace and defence industry and its supply chains

    b. UKREACH/24/19/3 and UKREACH/24/19/4 for the use of chromium trioxide and sodium chromate in anodise sealing 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.

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

    a. the Application submitted to the Agency

[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).

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 confirmed that a reference derived no-effect level (DNEL) has been calculated for the reproductive toxicity of sodium chromate.[4] In its assessment of exposures, the Agency concluded that the Applicants have demonstrated that exposures to workers across all worker contributing scenarios (WCS) as well as exposures to humans via the environment, are below the DNEL.

10. However, in its Opinion, the Agency concluded that it is not possible to determine a DNEL for the carcinogenic and mutagenic properties of the Substances. Therefore, it is not possible to determine a threshold for the Substances in accordance with section 6.4 of Annex I of UK REACH.

11. 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.

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

Risk to human health

13. In accordance with the criteria set out in Annex XIII of UK REACH, the Substances present a risk to human health due to their carcinogenic and mutagenic properties. Sodium chromate may also be toxic for reproduction when its use is not adequately controlled.

14. 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.

[4] The DNEL is the minimum level of exposure to a substance required for its toxicity to take effect. In accordance with the ECHA risk assessment committee guidance on DNEL determination (RAC/35/2015/09 dated 04 Dec 15), the DNEL for sodium chromate was calculated by the Applicants to be 43 µg/m^3 (for exposure via inhalation), and 43 µg/kg body weight/day (for dermal exposure).

Workers

15. In its Opinion, the Agency concluded that the risk associated with worker exposure to the Substances 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.[5]

16. In its Opinion, the Agency noted that for inhalation exposure to workers, based on the 90th percentile, personal exposure data for each WCS was less than the Agency benchmark of 5 µg/m^3 as an 8-hour time weighted average. The Agency also concluded that dermal exposures across each WCS are less than the DNEL for reproductive toxicity of sodium chromate. Furthermore, the Agency concluded that biomonitoring data provided good evidence that the OCs and RMMs at each site in GB were likely to be appropriate and effective at controlling exposures to the Substances 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.

17. The Agency assessed the monetised human health impacts to workers to be up to £959,000 over the 12-year review period. This accounts for 805 directly exposed workers across 35 sites in GB.

18. 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

19. For human exposure to the Substances 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.

20. In its Opinion, the Agency concluded that, based on a 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 many 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.

[5] 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.

21. The Agency assessed the monetised health impacts to humans via the environment to be up to £116,000 over a 12-year period. This accounts for an estimated general population of 46,621 people across 35 sites in GB.

22. 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

23. The socio-economic analysis for this 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.

24. In its Opinion, the Agency assessed both the socio-economic benefits arising from the applied for uses 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 £35.7 million over 12 years.

25. 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.

26. 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

27. In its Opinion, the Agency concluded that the Applicants have demonstrated that the socio-economic benefits of granting authorisation (at least £35.7 million over 12 years) are higher than the risk to human health (up to £1.1 million over 12 years).

28. 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 risks from the use of the Substances

Alternatives

29. 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).

30. The downstream users of the Applicants use chromium trioxide and sodium chromate for anodise sealing of various components (e.g. cockpit frames, gearboxes, fuel pumps, propellers) with specific technical performance requirements that correspond with each individual component. In the Application, the Applicants submitted 34 distinct substitution plans and details on their approach to attempting to substitute chromium trioxide and sodium chromate and progress on alternatives they are currently pursuing. The Applicants noted the relationship with, and dependency on, other surface treatment processes. The Applicants highlighted the extensive periods which would be required for qualifications and necessary regulatory approvals which means even if a suitable alternative was identified in the coming year, it could then take up to 15 years to implement. However, the Applicants claimed that, in some cases, substitution will be achievable in four to eight years and not all substitutions are predicted to take the full 12 years.

31. The Agency noted that the Applicants' analysis of alternatives is detailed and includes adequate explanation of why no suitable alternatives are currently available. The Agency understood that anodise sealing is not a standalone process and whilst there is uncertainty for other surface treatment processes, the route to substitution for anodising will remain less clear. The Agency concluded that the time-period requested is realistic given that none of the proposed alternatives are currently technically feasible in fulfilling the universal role of Cr(VI) in aerospace and defence applications.

32. 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 currently being technically feasible.

Review period

33. 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.

34. In the Application, the Applicants proposed a 12-year review period due to the uncertainty and the high complexity of the substitution, alongside the likelihood that a longer review period would be needed in the cases of legacy parts. The Applicants explained how the uncertainty surrounding the alternatives meant that the timeline was based on past experience of, for example, how long qualification and certification usually takes and that none of the proposed alternatives can be implemented for all components within 12 years.

35. 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 socio-economic analysis. The Agency concluded that the argument surrounding the legacy parts was well justified and that the requested time-period is realistic given that none of the proposed alternatives are currently technically feasible in fulfilling the universal role of Cr(VI) in aerospace and defence applications. The Agency noted that, given that the Applicants' substitution time scales are optimistic and based on an assumption that no setbacks are encountered, the timescales for substitution could be longer, and concluded that it would be disproportionate to recommend a shorter review period.

36. 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

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

38. 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