Department for Environment Food & Rural Affairs

Authorisation Decision

by Marc Casale Deputy Director, Chemicals, Pesticides and Hazardous Waste (DEFRA) Parliamentary Under Secretary of State

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

Decision date: 5 September 2024

Application Ref: AfA031-01

UK REACH authorisation No.:

Authorisation number	Authorisation holder	Authorised use
UKREACH/24/14/0 [sodium dichromate] UKREACH/24/14/1 [potassium dichromate]	Brenntag UK Ltd	Use of sodium dichromate and potassium dichromate in chemical conversion coating in the aerospace and defence industry and its supply chains.
UKREACH/24/14/2 [chromium trioxide] UKREACH/24/14/3 [dichromium tris(chromate)]	Wesco Aircraft EMEA Ltd	Use of chromium trioxide and dichromium tris(chromate) in chemical conversion coating in the aerospace and defence industry and its supply chains.

Preliminary Matters

- Chromium trioxide, sodium dichromate, potassium dichromate and dichromium tris(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, these Substances are subject to the authorisation requirement referred to in Article 56(1) of UK REACH.

- Chromium trioxide and dichromium tris(chromate) were included in Annex XIV due to their intrinsic carcinogenic and mutagenic properties (Article 57(a) and Article 57(b) of UK REACH).

- Sodium dichromate and potassium dichromate were included in Annex XIV due to their intrinsic carcinogenic and mutagenic properties (Article 57(a) and Article 57(b) of UK REACH) and their reproductive toxicity (Article 57(c) of UK REACH).

- Hexavalent chromium (Cr(VI)) is the form of chromium in chromium trioxide, sodium dichromate, potassium dichromate, and dichromium tris(chromate) to which the hazardous properties of each of these Substances are attributed.

- Brenntag UK Ltd, of Alpha House, Lawnswood Business Park, Redvers Close, Leeds, England LS16 6QY was granted authorisation for the use of sodium dichromate on 14 April 2020 and potassium dichromate on 8 April 2020 under EU REACH,[2] and Wesco Aircraft EMEA Ltd, of 50 Longbridge Lane, Allenton, Derby, DE24 8UJ was granted authorisation for the use of chromium trioxide on 22 October 2019 and dichromium tris(chromate) on 8 April 2020 under the EU REACH (together 'the Authorisation Holders' and 'the Original Authorisations' respectively). The Authorisation Holders are importers of sodium dichromate and members of the Aerospace and Defence Chromates Reauthorisation Consortium (ADCR).

- In accordance with Article 127F of UK REACH, the Original Authorisations had the relevant connection with Great Britain (GB) as the Authorisation Holders are established in GB. Therefore, the Original Authorisations continued to have effect in GB under UK REACH from 1 January 2021.

- On 22 December 2022, the Authorisation Holders submitted the review report (the 'Review Report') to the Health and Safety Executive (the 'Agency') in compliance with the requirement under Article 61(1) to submit this at least 18 months before the expiry date of the Original Authorisations. The expiry date for the use of sodium dichromate, potassium dichromate and chromium trioxide is 21

[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).

September 2024, and the expiry date for dichromium tris(chromate) is 22 January 2026.[3]

- The Review Report is for the use of chromium trioxide, sodium dichromate, potassium dichromate, and dichromium tris(chromate) in chemical conversion coating in the aerospace and defence industry and its supply chains. Chemical conversion coating is a chemical process that introduces a chemical coating or changes the surface of the substrate to improve the substrate 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.

Decision

1. This decision is addressed to the Authorisation Holders.

2. In accordance with Article 60(4) of UK REACH, authorisation is granted to the Authorisation Holders as set out under the following authorisation numbers for the following use:

   a. UKREACH/24/14/0 and UKREACH/24/14/1 for the use of sodium dichromate and potassium dichromate in chemical conversion coating in the aerospace and defence industry and its supply chains.

   b. UKREACH/24/14/2 and UKREACH/24/14/3 for the use of chromium trioxide and dichromium tris(chromate) in chemical conversion coating 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 21 September 2036 unless a review report is submitted in accordance with Article 61(1) of UK REACH by 21 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.[4]

[3] 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 Authorisation Holders submits a review report at least 18 months before the expiry of the time-limited review period.

[4] This is a reference to the chemical safety report submitted by the Authorisation Holders on 22 December 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).

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 61 and 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 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's Opinion

Reasons

9. In its Opinion, the Agency confirmed that reference derived no-effect levels (DNEL) have been calculated for the reproductive toxicity of sodium dichromate and potassium dichromate.[5] In its exposure assessment, the Agency concluded that the Authorisation Holders 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 Review Report 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.

[5] 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 4 Dec 15), the DNEL for sodium dichromate was calculated by the Authorisation Holder to be 43 µg/m^3 (for exposure via inhalation), and 43 µg/kg body weight/day (for dermal exposure).

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 dichromate and potassium dichromate may also be toxic for reproduction when their use is not adequately controlled.

14. In its Opinion, the Agency noted that the Authorisation Holders had provided a limited data set for downstream user sites in 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 Authorisation Holders.

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.[6]

16. 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 $\mu g/m^3$ 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 dichromate and potassium dichromate. Furthermore, the Agency noted 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, but that the OCs and RMMs described in the Review Report 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 £2.46 million over the 12-year review period. This accounts for 2,160 directly exposed workers across 80 sites in GB.

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

[6] 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.

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 Authorisation Holders, to use for GB sites.

20. In its Opinion, the Agency concluded that, based on a worst-case scenario, the Authorisation Holders' 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.

21. The Agency assessed the monetised human health impacts to humans via the environment to be up to £678,000 over the 12-year review period. This accounts for an estimated general population of 106,563 people across 80 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 Review Report 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 the Review Report was conducted by ADCR on behalf of the Authorisation Holders. 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 Review Report.

24. 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 £377 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 Authorisation Holders have demonstrated that the socio-economic benefits of granting authorisation (at least £377 million over 12 years) are higher than the risk to human health (up to £3.2 million over 12 years).

28. I consider that the Authorisation Holders 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 sodium dichromate, potassium dichromate, chromium trioxide and dichromium tris(chromate)

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 Authorisation Holders by the expiry date of the Original Authorisations.

30. The downstream users use the applied for Substances for chemical conversion coating of various components (e.g. cockpit frames, gearboxes, fuel pumps, propellers) with specific technical performance requirements that correspond with each individual component. In the Review Report, the Authorisation Holders submitted 78 distinct substitution plans focussing on six stages, and details on their approach to attempting to substitute the applied for Substances and the alternatives they are currently pursuing.

31. The Authorisation Holders provided a detailed overview of the substitution process within the aerospace and defence industry, highlighting that substitution of the Substances will be highly interconnected to other workstreams and it may not be possible for the substitution of conversion coatings to occur in isolation. The Agency noted that the Authorisation Holders provided a good overview of the status reported in the original CTAC (2015) applications and the progress that members have reported since. The Agency concluded that the Authorisation Holders' information relating to the potential alternatives was sourced from a wide variety of resources and the Agency was satisfied that the Authorisation Holders have identified an appropriate list of the most suitable alternatives.

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 Original Authorisations, and I consider that the Authorisation Holders 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 Review Report, the Authorisation Holders state that that there are uncertainties surrounding the expected progression of the substitution plans due to unforeseen technical failures and certification of any successful alternative and requested a 12-year review period. The Authorisation Holders estimated that 91% of substitution plans will be in place within 12 years, however, it is not likely that all the substitution plans for the Substances will be in place within that time due to on-going legacy requirements for in-service aircraft.

35. In its Opinion, the Agency concluded that the Authorisation Holders' substitution plans are credible for the review period requested and consistent between the analysis of alternatives and the socioeconomic analysis. The Agency concluded that the 12-year time-period is realistic when considering that the proposed alternatives are not currently technically feasible. The Agency evaluated the Authorisation Holders' substitution plans, along with the detailed answers to questions, and agree that it would take a minimum of 12 years for the substitution of the Substances in chemical conversion coating to listed alternatives, and possibly longer for some components.

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.

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

Marc Casale

Deputy Director, Chemicals, Pesticides and Hazardous Waste

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