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: AfA030-01

UK REACH authorisation No.:

Authorisation number	Authorisation holder	Authorised use
UKREACH/24/13/0	Brenntag UK Ltd	Use of sodium dichromate for the passivation of stainless-steel in the aerospace and defence industry and supply chains.

Preliminary Matters

- Sodium dichromate 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, sodium dichromate is subject to the authorisation requirement referred to in Article 56(1) of UK REACH.
- Sodium dichromate was included in Annex XIV due to its intrinsic carcinogenic and mutagenic properties (Article 57(a) and Article 57(b) of UK REACH) and because of its reproductive toxicity (Article 57(c) of UK REACH).
- Hexavalent chromium (Cr(VI)) is the form of chromium in sodium dichromate to which the hazardous properties of the sodium dichromate are attributed.

[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.

- 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 under EU REACH[2] (together the 'Authorisation Holder' and the 'Original Authorisation' respectively). The Authorisation Holder is an importer of sodium dichromate and a member of the Aerospace and Defence Chromates Reauthorisation Consortium (ADCR).

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

- On 22 December 2022, the Authorisation Holder submitted the Review Report (the 'Review Report') to the Health and Safety Executive (the 'Agency') in compliance with the requirements under Article 61(1) to submit this at least 18 months before the expiry date of the Original Authorisation on 21 September 2024.[3]

- The Review Report is for the use of sodium dichromate in the passivation of stainless-steel. Steel passivation is a chemical process that involves the removal of embedded iron/steel particles from the substrate, and the formation of a protective chromium oxide layer on the surface of the substrate.

- 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 Holder.

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

    a. UKREACH/24/13/0 for the use of sodium dichromate in the passivation of stainless-steel in the aerospace and defence industry and 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.

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

[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 holder of the authorisation submits a review report at least 18 months before the expiry of the time-limited review period.

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 holder and 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]

5. The authorisation is not subject to any monitoring arrangements.

6. The Agency has set out recommendations for the authorisation holder and the downstream users in section 10 of its Opinion, should the authorisation holder 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 a reference derived no-effect level (DNEL) has been calculated.[5] In its exposure assessment, the Agency concluded that the Authorisation Holder has demonstrated that exposures to workers across all worker-contributing scenarios (WCS), and exposures to humans via the environment, are both below the DNEL for the reproductive toxicity of sodium dichromate.

[4]This is a reference to the chemical safety report dated 22 December 2022 submitted by Brenntag UK Ltd 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 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).

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

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 sodium dichromate 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, sodium dichromate presents a risk to human health due to its carcinogenic and mutagenic properties. Sodium dichromate may also be toxic for reproduction when its use is not adequately controlled.

14. In its Opinion, the Agency noted that the Authorisation Holder 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 Authorisation Holder.

Workers

15. In its Opinion, the Agency concluded that the risk associated with worker exposure to sodium dichromate 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 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 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 sodium dichromate from all routes to workers. Therefore, the Agency concluded that the limited GB data set creates some uncertainty, but that the OCs and

[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 benefits outweigh risks.

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 £336,000 over the 12-year review period. This accounts for 340 directly exposed workers across 20 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 exposure to workers provided they are adhered to.

Humans via the environment

19. For human exposure to sodium dichromate 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 Holder, to use for GB sites.

20. In its Opinion, the Agency concluded that, based on a worst-case scenario, the Authorisation Holder's 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 £22,000 over the 12-year review period. This accounts for an estimated general population of 26,641 people across 20 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 this Review Report was conducted by ADCR on behalf of the Authorisation Holder. ADCR also completed the socio-economic analyses for other applications and review reports 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 £16.6 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 Holder has demonstrated that the socio-economic benefits of granting authorisation (at least £16.6 million over 12 years) are higher than the risk to human health (up to £0.359 million over 12 years).

28. I consider that the Authorisation Holder has 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 likely assessed risk from the use of sodium dichromate

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 Holder by the expiry date of the Original Authorisation (21 September 2024).

30. The downstream users of the Authorisation Holder use sodium dichromate for the passivation of stainless steel on various components (e.g. cockpit frames, gearboxes, fuel pumps, propellers), each with specific technical performance requirements. In the Review Report, the Authorisation Holder submitted 16 distinct substitution plans focussing on six stages as well as details on its approach in attempting to substitute sodium dichromate in steel passivation. The Authorisation Holder shortlisted six alternatives, all of which are to be taken forward for further research. The Authorisation Holder also conducted reviews of literature, patents and global collaboration projects. The Authorisation Holder noted that there is no current alternative available that would be applicable for all uses of steel passivation and that due to the varying specific technical

requirements of the components, 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

31. The Agency noted that the Authorisation Holder's analysis of alternatives focused on alternatives highlighted in the previous relevant applications for authorisation to the European Chemicals Agency under EU REACH which represented decades of research and investment into alternatives to sodium dichromate in steel passivation. In its Opinion, the Agency concluded that it was satisfied with the Authorisation Holder's response that the technologies are still at a laboratory scale and are not feasible on an industrial scale. The Agency was also satisfied that that the Authorisation Holder is moving towards alternatives where possible. The Agency concluded that the Authorisation Holder has successfully identified and provided a thorough assessment of the alternatives with extensive detail surrounding most suitable alternatives shortlisted for further research.

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 Authorisation and consider that the Authorisation Holder has discharged its 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 Holder requested a 12-year review period due to the complexity of substitution, as demonstrated in the substitution plans. The Agency concluded that the Authorisation Holder's substitution plans are credible for the review period requested and is consistent between the analysis of alternatives and the socioeconomic analysis. The Authorisation Holder noted that while some substitutions are being implemented in limited situations, key issues still remain. These include the availability of test alloys, and degradation and corrosion during the passivation process. The Authorisation Holder noted that it will take a minimum of 12 years before substitution leads to a significant reduction in Cr(VI) usage.

35. In its Opinion, The Agency evaluated the Authorisation Holder's substitution plans along with the Authorisation Holder's detailed answers to the Agency's questions about the substitution plans. The Agency concluded that the 12-year time-period is realistic when considering that the proposed alternatives are not currently technically feasible and agree that it would take a minimum of 12 years for the substitution of sodium dichromate in steel passivation to listed alternatives, and possibly longer for some alternatives.

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 sodium dichromate 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 Authorisation is 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