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: AfA033-01

UK REACH authorisation No.:

Authorisation number	Authorisation holder	Authorised use
UKREACH/24/16/0 [chromium trioxide] UKREACH/24/16/1 [chromium trioxide] UKREACH/24/16/2 [chromium trioxide]	Boeing Distribution (UK) Inc Indestructible Paint Ltd MacDermid Performance Solutions UK Ltd	Formulation of mixtures with soluble chromium trioxide for use in aerospace and defence industry and its supply chains for surface treatments.
UKREACH/24/16/3 [chromium trioxide] UKREACH/24/16/4 [sodium dichromate]	Wesco Aircraft EMEA Ltd	Formulation of mixtures with soluble chromium trioxide and sodium dichromate for use in aerospace and defence industry and its supply chains for surface treatments.

Preliminary Matters

- Chromium trioxide and sodium dichromate (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, 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 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 its reproductive toxicity (Article 57(c) of UK REACH).

- Hexavalent chromium (Cr(VI)) is the form of chromium in chromium trioxide and sodium dichromate to which the hazardous properties of the Substances are attributed.

- The application is made by:

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

  b. Indestructible Paints Ltd, 25 Pentos Drive, Sparkhill, Birmingham, B11 3TA

  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 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 the formulation of mixtures for use in the aerospace and defence industry and its supply chains for surface treatments.

[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).

- On 27 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/24/16/0, UKREACH/24/16/1 and UKREACH/24/16/2 for the formulation of mixtures with soluble chromium trioxide for use in the aerospace and defence industry and its supply chains for surface treatments

   b. UKREACH/24/16/3 and UKREACH/24/16/4 for the formulation of mixtures with soluble chromium trioxide and sodium dichromate for use in the aerospace and defence industry and its supply chains for surface treatments

3. The review period as required by 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 conditions (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[3] 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] subject to the conditions set out in paragraph 4.b. and the monitoring arrangements set out in paragraph 5.

   b. By 5 December 2025, each GB site undertaking formulation must install engineering control measures to reduce the personal Cr(VI) inhalation exposures to no more than 5 µg/m^3 for the duration of the weighing out activity for Worker Contributing Scenario (WCS), without taking into account the effectiveness of any respiratory protective equipment (RPE) that may be worn. In order to meet this condition, the authorisation holders must install the

[3] Article 56(2) states that a downstream user may use a substance which fulfils the relevant criteria provided that the use is in accordance with the conditions of an authorisation granted to an actor up the supply chain for that use.
[4] 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).

following equipment (or use an alternative engineering means of controlling Cr(VI) exposures to achieve an equivalent outcome):

(a) the authorisation holders must put the whole of the weighing equipment inside a suitably sized laminar downflow booth, with a fixed vertical screen between the weigh-scale and the operator that is weighing out either the chromium trioxide flake or powder

(b) in addition to the downflow booth, the authorisation holders must install a vacuum transfer system for transferring the weighed quantity of solid chromate directly into the mixer as a closed vessel addition, to eliminate generation of dust from the addition of the Substances to the mixing vessel. The vacuum transfer unit should be bolted on to the lid of the mixer enclosure via a new aperture such that there is an air-tight and dust-tight seal formed between the vacuum transfer unit and the inside of the mixer. The vacuum transfer unit must incorporate a H14 HEPA filter on the air vent from the unit. The vacuum lance should be used to transfer the solid chromate powder or flake from its container directly into the mixer vessel

c. By 5 March 2026, the authorisation holder must provide an update report to the Agency based on the above conditions, demonstrating that the new OCs and RMMs have been implemented and are reducing the risk to workers. The update report must include:

(a) details of the revised RMMs, including photographs and commissioning data including performance test results of the new engineering control measures that have been installed

(b) personal air monitoring data using the methodology specified in BS ISO 16740:2005 on a minimum of at least 3 separate days, that demonstrate that the exposure criterion specified in paragraph 4.b. is being met in practice.

5. The authorisation is subject to the following monitoring arrangements:

a. The authorisation holders must undertake at least 10 GB personal inhalation exposure monitoring measurements for each similarly exposed group across all WCSs, which must:

(a) be based on the methodology specified in BS ISO 16740:2005 (to detect exposures below 1 µg/m^3, and preferably down to 0.1 µg/m^3)

(b) include personal inhalation exposure sampling measured within the 30cm breathing zone of the wearer, and with samplers positioned on the outside of any respiratory protective equipment that may be worn

(c) be representative of the range of tasks with possible exposure to Cr(VI) and of the total number of workers that are potentially exposed

(d) include gathering adequate contextual information for each sampling event sufficient to interpret and inform the results.

b. The authorisation holders must conduct personal inhalation exposure sampling at least annually, until a minimum of 10 personal samples are collected. Thereafter the monitoring frequency may be reduced if data review and evaluation support this.

c. The authorisation holders must continue to collect personal exposure monitoring data from GB sites as a matter of good occupational hygiene practice. Monitoring programs shall include all similar exposure groups with the potential for exposure, adequate contextual information to inform results, and sampling shall be conducted at least annually. The collated personal exposure monitoring data must be documented and made available on request to the Agency.

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 confirmed that a reference derived no-effect level (DNEL) has been calculated for the reproductive toxicity of sodium dichromate.[5] In its assessment of exposures, the Agency concluded that the Applicants have

[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 04 Dec 15), the DNEL for sodium dichromate 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).

demonstrated that exposures to workers across all WCSs 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 this Application and an 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 dichromate 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, 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

15. In its Opinion, the Agency concluded that the GB formulation sites have in place most of the necessary OCs and RMMs that should minimise the exposure risk to an appropriate and effective level, for workers. The Agency noted that there are concerns as to whether the RMMs are the most appropriate measures that could be implemented with respect to the principles of hierarchy of exposure control, as a high reliance upon personal protective equipment (PPE) exists for some tasks. Therefore, in its Opinion, the Agency proposed conditions and additional monitoring activities which are expected to better inform this conclusion and allow operations to be modified to further improve the robustness of the RMMs. For these reasons, I agree with the Agency's proposed conditions monitoring arrangements.

16. 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 sets as a worst-case exposure scenario.[6]

17. The Agency noted that the Applicants had adopted a conservative approach by regarding any exposure over two hours as an 8-hour time weighted average (TWA), which the Agency considered would mitigate uncertainties around different monitoring and analysis methods used in the sites' monitoring programs. The Agency concluded that for inhalation exposure to workers, based on the conservative approach, personal exposure data for each WCS was less than the Agency benchmark of 5 μg/m^3 as an 8-hour TWA.

18. The Agency also concluded that dermal exposures across each WCS are less than the DNEL for reproductive toxicity of sodium dichromate. Furthermore, the Agency concluded that the biomonitoring data supplied by the Applicants, and also by the two GB sites, generally help to bolster the conclusion that the exposures are well controlled if OCs and RMMs are being followed. There was a single result which exceeded the biological monitoring guidance values (BMGV) (10 μmol Cr/mol creatinine) however, this was found to be below the BMGV upon repeat and so deemed to be a false result.

19. The Agency assessed the monetised human health impacts to workers to be up to £27,000 over the 12-year review period. This accounts for 18 directly exposed workers across two sites in GB.

20. Having evaluated the Agency's assessment, I agree with its conclusion that the OCs and RMMs described in the Application are likely appropriate and effective in limiting the risk to workers provided they are adhered to. I agree that the monitoring arrangements discussed in paragraph 5, and the conditions in paragraph 4, will serve to further improve robustness of RMMs, in light of a high dependency on PPE for some tasks.

Humans via the environment

21. For exposure of humans to the Substances via the environment, the Agency used the highest emission values provided by the Applicants, from the larger of the two GB sites, as a worst-case scenario in their assessment of risk for both GB sites.

22. 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 Agency concluded that the absence of site-specific data for one of the GB sites results in minor uncertainties, 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.

[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.

23. The Agency assessed the monetised health impacts on humans via the environment to be less than £1,000 over the 12-year review period. This accounts for an estimated general population of 2,664 people across two sites in GB.

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

Socio-economic analysis

25. 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 this Application.

26. 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 for this use only, if authorisation was not granted. The Agency estimated this to be at least £1.4 million over 12 years.

27. 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.

28. 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

29. In its Opinion, the Agency concluded that the Applicants have demonstrated that the socio-economic benefits of granting authorisation (at least £1.4 million over 12 years) are higher than the risk to human health (up to £28,000 over 12 years).

30. 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 assessed risks from the use of the Substances

Alternatives

31. At the formulation stage, the Substances have no specific function, hence no analysis of alternatives was provided by the Applicants. The formulations will be used across a range of surface treatment processes in the aerospace and defence industry which are subject to other ADCR consortium applications for authorisation, and in which substitution activities are addressed. When substitution has occurred in these uses then there will be no requirement for the formulations.

32. The Agency agreed with this approach and confirmed in its Opinion that it considers that the Application includes all the necessary information specified in Article 62 (and therefore Article 62(4)(e)) of UK REACH, caveating that the assessment of alternatives is not relevant as the substance does not provide any specific function at the formulation stage, and an analysis of alternatives has been provided for the subsequent use of the formulations. Therefore, the Agency did not undertake an assessment of the analysis of alternatives for this use.

33. Having evaluated the Agency's assessment, I agree with the conclusion that an analysis of alternatives is not relevant to this particular use, for the reasons stated above. I agree with the Agency's approach of not undertaking an assessment of the analysis of alternatives for this use.

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. The Applicants have requested a 12-year review period. The Agency believes that this time period is realistic when considering that none of the proposed alternatives (for the subsequent surface treatment uses) are currently technically or economically feasible in fulfilling the universal role of Cr(VI) in aerospace and defence applications. The formulation use is entirely dependent on subsequent use demand by the aerospace and defence manufacturers/maintenance operators. As such, it will continue only if there is continued use of the formulations by these companies, mitigating the risk that formulation will continue longer than necessary given available alternatives. The Agency therefore recommends a 12-year review period for this use.

36. Having evaluated the Agency's assessment, I agree with the Agency's conclusions on these points and its recommendation 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 applied for use of chromium trioxide and sodium dichromate referred to in paragraph 2, and that an analysis of alternatives is not relevant to this particular use.

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