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: AFA045-01, AFA045-02

**UK REACH authorisation No.:**

| Authorisation number | Authorisation holder | Authorised use |
|---|---|---|
| UKREACH/24/22/0 | Indestructible Paint Limited | Use of chromium trioxide in the formulation of mixtures intended for supply to authorised downstream users to use these formulations as part of coatings to protect industrial gas turbines and related industrial equipment and components. |
| UKREACH/24/22/1 | Indestructible Paint Limited | Treatment of components used in industrial gas turbines and associated components using slurry coating products containing chromium trioxide to enhance corrosion resistance, chemical resistance, high temperature oxidation resistance, adhesion to components which produce a smooth finish and enhance the technical performance of turbines. |

## 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 Indestructible Paint Limited, 16-25 Pentos Drive, Sparkhill, Birmingham, B11 3TA (the 'Applicant') a formulator of chromium trioxide and supplier of chromium trioxide containing products.
- As a result of the conditions of Article 127H of UK REACH having been met, the uses of chromium trioxide authorised under EU REACH[2] can continue until 21 September 2024.
- On 7 March 2023, the Applicant submitted an application for authorisation (the 'Application') to the Health and Safety Executive (the 'Agency'), for two uses:
    a. Use 1: Use of chromium trioxide in the formulation of mixtures intended for supply to authorised downstream users to use these formulations as part of coatings to protect industrial gas turbines and related industrial equipment and components
    b. Use 2: Treatment of components used in industrial gas turbines and associated components using slurry coating products containing chromium trioxide to enhance corrosion resistance, chemical resistance, high temperature oxidation resistance, adhesion to components which produce a smooth finish and enhance the technical performance of turbines
- On 12 April 2024, the Agency sent its opinions for Use 1 and Use 2 (the 'Opinion for Use 1' and 'Opinion for Use 2' respectively, together the 'Opinions') to the Secretary of State for Environment, Food and Rural Affairs, and Scottish and Welsh Ministers.

## Decision

1. This decision is addressed to the Applicant.
2. In accordance with Article 60(4) of UK REACH, authorisation is granted to the Applicant as set out under the following authorisation numbers for the following uses:

[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).

a. UKREACH/24/22/1 (Use 1): Use of chromium trioxide in the formulation of mixtures intended for supply to authorised downstream users to use these formulations as part of coatings to protect industrial gas turbines and related industrial equipment and components.

b. UKREACH/24/22/2 (Use 2): Treatment of components used in industrial gas turbines and associated components using slurry coating products containing chromium trioxide to enhance corrosion resistance, chemical resistance, high temperature oxidation resistance, adhesion to components which produce a smooth finish and enhance the technical performance of turbines.

3. The review period referred to in Article 60(9)(e) of UK REACH is set at 12 years for both uses. The authorisation for either use will cease to be valid on 5 September 2036 unless a review report is submitted for each use 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 holder and the downstream users must adhere to the operational conditions (OCs) and risk management measures (RMMs) described in the chemical safety reports referred to in Article 62(4)(d) of UK REACH,[3] subject to the monitoring arrangement specified at paragraph 7 below.

5. UKREACH/24/22/2 (Use 2) is not subject to any conditions or monitoring arrangements in addition to those set out in paragraph 4.a.

6. UKREACH/24/22/1 (Use 1) is subject to the following conditions, in addition to the condition in paragraph 4.a.[4]:

   a. By 5 December 2025, the authorisation holder must ensure they have effective engineering control measures that reduce the personal Cr(VI) inhalation exposures of the operators to no more than 5 µg/m³ for the duration of the weighing out and mixing activities in Worker Contributing Scenario (WCS) 1, without taking into account the effectiveness of any respiratory protective equipment (RPE) that may be worn.

   b. In order to meet the condition set out in paragraph 6.a. above, the authorisation holder must do the following (or use an alternative engineering

[3] This is a reference to the chemical safety reports dated February 2023 submitted by the Applicant on 7 March 2023 for each use, 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).

[4] The Agency provided additional notes for these conditions, set out in Section 8.1 of the Agency Opinion.

means of controlling Cr(VI) exposures to achieve an equivalent outcome to that set out in paragraph 6.a. above):

a) 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) 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 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 mixing 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 as referenced in paragraph 7, that demonstrate that the exposure criterion specified in paragraph 7.b. is being met in practice.

7. UKREACH/24/22/1 (Use 1) is also subject to the following monitoring arrangements:

a. The authorisation holder must undertake measurements of personal exposures to Cr(VI) for WCS1. These shall be supported by appropriate contextual information regarding descriptions of each specific work task being undertaken. Air sampling surveys must be undertaken at least annually. In every case, these exposure measurements must:

a) be based on the methodology specified in BS ISO 16740:2005 (to detect exposures below 1 µg/m³, and preferably down to 0.1 µg/m³)

b) include personal inhalation exposure sampling measured on the lapel, and on the outside of any RPE 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) collect enough personal exposure data so that estimates of the geometric mean (GM) and the geometric standard deviation (GSD) for the exposure

distribution for each job role can be determined. To achieve this, a minimum of 3 personal exposure data points must be collected for each job role, with a total of 10 personal exposure data points collected within the corresponding similarly exposed group where practicable, to determine reliable estimates of the GM and GSD by 21 December 2025. Once the authorisation holder has obtained a minimum of 10 personal exposure data points for any particular job role where significant inhalation exposure to Cr(VI) is liable to occur, the minimum frequency for further air monitoring for that particular job role can be reduced to annual surveys, provided that the measured personal exposures are below the benchmark defined in paragraph 7.b.

b. Where the 90th percentile of the operator's personal exposure to Cr(VI) measured using the methodology that is given in BS ISO 16740:2005 exceeds the Agency's benchmark of 5 μg/m³ as an 8 hour time-weighted average (TWA), the RMMs must be modified such that the 90th percentile exposures is then reduced below 5 μg/m³ as an 8-hour TWA. Any local exhaust ventilation (LEV) shall be subject to performance monitoring carried out regularly along with regular maintenance of the LEV system and associated abatement technology.

8. For each use, the Agency has set out recommendations for the authorisation holder and, for Use 2, the downstream users in section 10 of its Opinions, 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

9. This decision is made under Article 60(4) of UK REACH and having obtained the consent of Scottish and Welsh Ministers.

10. 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 Opinions

## Reasons

11. In its Opinions, 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.

12. 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.

13. 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**

15. 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.

**Workers**

16. In its Opinion for Use 1, the Agency noted that there were some uncertainties regarding the appropriateness and effectiveness of the RMMs. Specifically, the RMMs for WCS1 were judged by the Agency to be effective at reducing exposure, but as they relied heavily on RPE, were not likely to be appropriate. There was also a level of uncertainty regarding the effectiveness of the LEV system used for Task 2 in WCS1 to reduce Cr(VI) exposure to workers.

17. Despite these uncertainties, the Agency concluded in its Opinion for Use 1 that the Applicant has most of the necessary OCs and RMMs in place that should minimise the exposures of employees to Cr(VI) to an appropriate and effective level, with the exception of WCS1. The Agency also concluded that, based on the 90th percentile, personal inhalation exposure data for WCS1 had the potential to be over the Agency benchmark of 5 µg/$m^3$ as an 8-hour TWA.

18. For Use 1, the Applicant also provided biomonitoring data. The Agency noted in its Opinion for Use 1 that the majority of biomonitoring data from workers were at or below the UK biological monitoring guidance value (BMGV) for chromium trioxide with the exception of one value, which was deemed spurious upon a retest.

19. For Use 1**,** due to the Agency judging the Applicant to have an overreliance on RPE as a means of reducing worker exposure, the design of the LEV system not being fully effective, and the potential for the Agency's benchmark of 5 µg/$m^3$ as an 8-hour TWA to be exceeded, the Agency proposed additional conditions and monitoring arrangements. In its Opinion for Use 1, the Agency concluded that the proposed additional conditions and monitoring arrangements are expected to improve the effectiveness of the RMMs for WCS1 by limiting the generation of inhalable dust associated with the applied for use. Monitoring arrangements were also recommended by the Agency in order to determine the performance of the

RMMs following this improvement. I agree with the Agency's proposed monitoring arrangements and conditions.

20. In its Opinion for Use 2, the Agency noted that the Applicant had provided insufficient inhalation data from Great Britain (GB) for downstream user sites in GB. Therefore, in order to assess the risk to human health to workers, the Agency used the 90th percentile of the exposure data as well as the descriptions of the OCs and RMMs at downstream user sites from both the European Economic Area (EEA) and GB, as provided by the Applicant.

21. For Use 2, the Agency noted that the supplied questionnaire data for GB sites did not allow for a full evaluation of the RMMs that were in place, leading to uncertainties regarding the effectiveness of the OCs and RMMs in place due to the low level of detail in the information provided from the questionnaires from GB sites. Therefore, the Agency elected to rely on the 90th percentile of the combined EEA and GB data sets to allow for a more robust exposure assessment.

22. In its Opinion for Use 2**,** the Agency used the methodology set out in paragraph 17 to conclude that it is likely the downstream users have most of the necessary key OCs and RMMs in place that should minimise the exposures of employees to Cr(VI) to an appropriate and effective level, and so generally minimise the risk based on the information provided within the Application.

23. For Use 2, the Agency concluded that the Applicant has demonstrated that the 90th percentile of personal inhalation exposures for each WCS is less than 5 $\mu g/m^3$ as an 8-hour TWA.

24. For Use 2, the Applicant also provided biomonitoring data. The majority of biomonitoring data from workers were at or below the BMGV with the exception of four results, for which appropriate measures have been taken and those exceedances have been rectified. Therefore, the Agency concluded that confidence in the inhalation and dermal worker exposure assessments is further enhanced by the GB biological monitoring data.

25. In its Opinions for each use, the Agency noted that the Application included all relevant tasks and routes of exposure as well as endpoints and worker populations in the cancer risk assessment and that there are no significant uncertainties in the characterisation of risk.

26. For each use, the Agency assessed the monetised human health impacts to workers. For Use 1, the Agency assessed the monetised human health impacts to workers to be up to £2,000 over the 12-year review period. This accounts for <10 workers at 1 site in GB. For Use 2, the Agency assessed the monetised human health impacts to workers to be up to £282,000 over the 12-year review period. This accounts for 180 directly exposed workers at 22 sites across GB.

27. 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, and the proposed monitoring arrangements and conditions, for each use, and agree that these will improve the effectiveness of the RMMs for WCS1.

**Humans via the environment**

28. In its Opinion for Use 1, the Agency noted that the Applicant had provided exposure assessment data taken from 2021 and that it is therefore difficult to say how reflective of normal operating conditions the environmental emission values given are. Therefore, in order to assess the exposure of humans to chromium trioxide via the environment, the Agency took forward the highest reported concentration of Cr(VI) into its exposure assessment, and hence considered the data provided by the Applicant regarding human exposure to chromium trioxide via the environment to be reasonable.

29. Despite these uncertainties, in its Opinion for Use 1, the Agency was able to use this judgement to conclude that the described OCs and RMMs are appropriate and effective in limiting the risks to humans via the environment.

30. In its Opinion for Use 2, the Agency noted that the Applicant had provided a limited GB data set, which led to a degree of uncertainty regarding the representativeness, reliability, and variability of the monitoring data set for humans via the environment. The Applicant therefore included data from 11 sites from the aerospace industry and 5 sites in the EEA in its exposure assessment. Therefore, in order to assess the exposure of humans to chromium trioxide via the environment, the Agency used the maximum values for air in its risk characterisation and calculation of the SEA.

31. For Use 2, the Agency acknowledged that, despite the uncertainty regarding the representativeness of the monitoring data, the amounts of Cr(VI) released are not expected to be high across the remaining GB sites based on the maximum emissions data presented by the Applicant. The Agency therefore concluded that the OCs and RMMs are likely to be appropriate and effective for controlling environmental releases where implemented.

32. For each use, the Agency assessed the monetised health impacts to humans via the environment. For Use 1, the Agency assessed the monetised human health impacts to humans via the environment to be up to £2,000 over the 12-year review period. This accounts for an estimated general population of <50,000 people at one site in GB. For Use 2, the Agency assessed the monetised human health impacts to humans via the environment to be up to £1.43 million over the 12-year review period. This accounts for an estimated general population of 226,320 people across 22 sites in GB.

33. Having evaluated the Agency's assessment, I agree with its conclusions that the OCs and RMMs described in the Application are appropriate and effective in limiting the risk to humans via the environment (for Use 1), and likely to be appropriate and effective in limiting the risk to humans via the environment (for Use 2).

**Socio-economic analysis**

34. The Agency concluded in its Opinions that for each use the Applicant's socio-economic analysis is considered proportionate, and that the evidence in the Application is sufficient for the Agency to reach a definitive conclusion.

35. The Agency's Opinions 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. This is estimated by the Agency to be up to £5 million for Use 1 over 12 years, and at least £35.7 million for Use 2 over 12 years.

36. This is a conversative estimate, as, for each use, likely additional socio-economic benefits of granting authorisation have been assessed qualitatively by the Agency but have not been monetised. For Use 1, these consist of avoided societal producer surplus losses, additional avoided social costs of unemployment and unquantified benefits of continued use for downstream users performing surface treatment. For Use 2, these consist of avoided societal producer surplus losses, additional avoided social costs of unemployment, and avoided negative impacts on the other parts of the supply chain on the industrial gas turbine sector, and on other sectors.

37. Having evaluated the Agency's assessment, I agree with its conclusions on the quantitative and qualitative benefits for each use.

**Conclusion on whether the benefits outweigh the risk**

38. In its Opinion for Use 1, the Agency concluded that the Applicant has demonstrated that the socio-economic benefits of granting authorisation (up to £5 million) are higher than the risk to human health (up to £4,000).

39. In its Opinion for Use 2, the Agency concluded that the Applicant has demonstrated that the socio-economic benefits of granting authorisation (at least £35.7 million) are higher than the risk to human health (up to £1.7 million).

40. I consider that the Applicant has shown that the socio-economic benefits of granting authorisation for each use outweigh the risk to human health because of:

    a. the likely benefits in respect of avoided profit losses, and avoided social costs of unemployment for each use

b. the likely risks from the applied for uses of chromium trioxide

c. the assessed risk from the use of chromium trioxide

**Alternatives**

41. The Agency agreed with the Applicant that the analysis of alternatives for Use 1 is not relevant as chromium trioxide does not provide any specific function at the formulation stage, and therefore was not necessary for Use 1. Use 1 is entirely dependent on the subsequent demands of Use 2. Therefore, no alternative would be used for Use 1 until an alternative is provided for Use 2. Any alternatives identified for Use 2 would therefore be adopted in Use 1.

42. For each use, the Agency concluded in its Opinions 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 Applicant and the downstream users by the expiry date of the authorised use under EU REACH (21 September 2024).

43. For Use 2, the Opinion stated that the timescales proposed by the Applicant are optimistic but credible and clear for their substitution plans. Both the Applicant and the Agency also acknowledged that there may be delays to the substitution plans due to unforeseen technical failures. The Applicant is monitoring the developments of alternatives in the sector and if one is identified they will move to validate it for their uses.

44. For Use 2, the Applicant gave details of several alternatives that are being assessed, the current positions of those potential alternatives in their validation process, and expressed their confidence that substitution will be achievable by 2036. The Agency acknowledged the progression of the potential alternatives in the validation process and felt it unnecessary to request further information relating to the testing status of those alternatives.

45. Having evaluated the Agency's assessment, I agree with its conclusion 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 Applicant before the expiry date of the authorised use under EU REACH, and consider that the Applicant has discharged their burden of proof in demonstrating the absence of suitable 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**

46. In its Opinions, the Agency recommended the review period referred to in Article 60(9)(e) of UK REACH should be set at 12 years for each use. In reaching its conclusion, the Agency noted:

    a. Use 1 is entirely dependent on the subsequent use demand and substitution plans for slurry coating (Use 2) and so the review period for Use 1 should be the same as that awarded for Use 2.

    b. For Use 2:

        a) the substitution timescales are optimistic, but credible and consistent with the analysis of alternatives and socio-economic analysis

        b) given the challenges described in the Application, the Agency is satisfied that the downstream users covered by the Application will not be able to substitute chromium trioxide for a suitable alternative in all current slurry coating formulations within 12 years and agrees that a long review period is credible in this respect for this use

        c) by the expiry date of the authorised use under EU REACH, there will be no technically and economically feasible alternatives.

47. 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

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

49. 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*