



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: 28 May 2025

### Application Ref: AFA048-01

### 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).<sup>1</sup> 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 the Surface Engineering Association Chromium Trioxide Authorisation Consortium (SEA), on behalf of:
  - a. Cannock Chemicals Limited (the 'Applicant'), with company registration number 01643201, whose registered address is North Street Industrial Estate, Bridgtown, Cannock, Staffs, WS11 0AZ.
- On 21 March 2023, the Applicant submitted an application for authorisation (the 'Application') to the Health and Safety Executive (the 'Agency') for the use of chromium trioxide for the formulation of surface treatment process solutions, specifically producing chromic acid from chromium trioxide by the addition of water.

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<sup>1</sup> 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>

- On 15 August 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 Applicant.
2. Pursuant to Article 60(4) of UK REACH, the Applicant is refused authorisation for the following use of chromium trioxide:
  - a. for the formulation of surface treatment process solutions, specifically producing chromic acid from chromium trioxide by the addition of water (the ‘Applied for Use’).

## Background

3. This decision is made pursuant to Article 60(4) of UK REACH and having obtained the consent of Scottish and Welsh Ministers.
4. 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); and
  - c. the Agency’s Opinion.

## Reasons

5. In its Opinion, the Agency concluded that it is not possible to determine a derived no-effect level for the carcinogenic and mutagenic properties of chromium trioxide.<sup>2</sup> Therefore, for chromium trioxide, it is not possible to determine a threshold below which exposure can be considered safe in accordance with section 6.4 of Annex I of UK REACH.
6. 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.
7. 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

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<sup>2</sup> The cancer risk is estimated according to the Committee for Risk Assessment (RAC) reference dose-response relationships for Cr(VI) carcinogenicity ([RAC/27/2013/06 Rev.1](#)). As a genotoxic mode of action (mutagenicity) is thought to be at least partially responsible for the carcinogenicity of Cr(VI), these relationships also account for the intrinsic property mutagenicity.

environment arising from the Applied for Use of chromium trioxide and if there are no suitable alternative substances or technologies.

## **Risk to human health**

8. Chromium trioxide presents a risk to human health due to its carcinogenic and mutagenic properties.

## **Humans via the environment**

9. In its Opinion, the Agency noted four potential routes of exposure by which chromium trioxide could be released to the environment – air, water, soil and waste.
10. In its Opinion, the Agency concluded that adequate containment of the mixer operation is not provided, nor is any local exhaust ventilation (LEV) provided for the activity. Since the mixing operation is located outside under a canopy, the fugitive emissions that are released will be dispersed by wind, and therefore an unknown proportion of the fugitive emissions that may reach beyond the boundary of the Applicant's site could expose members of the local population. Furthermore, there is uncertainty surrounding these fugitive emissions and the exposure of the local population due to the lack of emissions monitoring data provided by the Applicant. As a result, the Agency considered that the risk to humans via the environment was unacceptable due to the fugitive releases from the chromic acid mixing activity. The Agency noted that the operational conditions (OCs) and risk management measures (RMMs) are not appropriate and effective in limiting the risks for this activity.
11. The Agency assessed the monetised human health impacts via the environment to be up to £2.244 million. This accounts for an estimated exposed general population of 6,833 surrounding one site in GB.
12. The Agency indicated that a more refined modelling of the risk by using less conservative figures and assumptions would lead to a materially lower risk than calculated. However, the Agency also noted that additional data would be required to carry out a more refined risk assessment to substantiate a lower risk existing.
13. I have used the above calculation in paragraph 11 of monetised health risks via the environment for the purposes of this decision as it is based on the data submitted by the Applicant and the existence of a lower risk has not been substantiated by the Applicant.

## **Workers**

14. The human health risk to directly exposed workers is the risk of developing lung cancer through the inhalation of Cr(VI) during work activities. The Agency

assessed the monetised human health impacts to workers to be up to £51,000. This accounts for four directly exposed workers across one site in GB and is based on the appropriateness and effectiveness of the risk management measures proposed by the Applicant. Having evaluated the Agency's assessment, I agree with this calculation, and have used this calculation for the purposes of this decision.

15. In its Opinion, the Agency noted limitations in the data supplied by the Applicant regarding the potential risk to workers, which lead to uncertainties regarding the levels of fugitive airborne releases during the chromic acid mixing activity. A static sample air monitoring result from a position close to the mixer confirmed that the airborne concentration of Cr(VI) was  $9.6 \mu\text{g}/\text{m}^3$  during the 4-hour mixing operation. Although only a single measurement result is available, the Agency concluded in its Opinion that a significant level of airborne fugitive releases is likely to occur during the chromic acid mixing activity. This could lead to significant inhalation exposure levels for the operator who is carrying out the loading of the mixer. The Agency therefore concluded in its Opinion that, for this task, the current RMMs are neither appropriate nor effective enough to control the risk.
16. In addition, in its Opinion, the Agency highlighted concerns regarding the transfer of the chromic acid solutions from large storage vessels into smaller containers. There is no automated engineering control of the transfer, and the current process is wholly reliant on manual intervention by the operator. The Agency noted that any failure of the pipework, due to the highly corrosive nature of the chromic acid solution, could result in a significant spillage, or the accidental spraying of personnel by highly corrosive chromic acid. Therefore, the Agency concluded in its Opinion that the current OCs and RMMs for this task are not appropriate and effective.
17. In its Opinion, the Agency concluded that the Applicant has a proportion of the necessary OCs and RMMs in place that should reduce the exposures of employees to Cr(VI) to an appropriate and effective level, but not all those necessary to minimise the risk. Having evaluated the Agency's assessment, I agree with its conclusion that the OCs and RMMs described in the Application are not sufficient to minimise the risk to workers.

## **Socio-economic analysis**

18. 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 monetised 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 £500,000 over 12 years.

19. In its Opinion, the Agency assessed the socio-economic risks of granting an authorisation. The present value of the total monetised excess cancer risks over the 12-year review period is estimated to be £2.3 million, combining the risks to the two main exposure groups (directly exposed workers and humans via the environment).
20. The monetised risks (estimated to be £2.3 million) are greater than the monetised benefits (estimated to be £500,000).
21. In addition to the monetised benefits, a number of qualitative benefits were considered by the Agency in its Opinion. These included costs related to the potential loss of related business, disposal costs (described by the Applicant as minimal in response to clarification questions from the Agency) and costs related to the disruption to the Applicant's supply chain.
22. Having considered these qualitative benefits, I am of the view that there is significant uncertainty as to the relevance of these costs, the likelihood of these costs occurring and the scale of any such costs involved because:
- a. the Applicant did not reference a potential loss of related business in its Application and submit sufficient applicable supporting information to substantiate a materially significant loss of business;
  - b. the Applicant did not submit sufficient supporting information with respect to disposal costs to substantiate materially significant costs; and
  - c. the Applicant did not submit sufficient supporting information on the actions the supply chain would take and on the significance of any cost implications if the Application for authorisation was refused.
23. Having evaluated the Agency's assessment, including taking into account relevant qualitative benefits, I have therefore concluded that it has not been shown that the benefits of authorisation outweigh the risks. This is because:
- a. the monetised benefits do not outweigh the monetised risks;
  - b. the qualitative benefits are not supported by sufficient information to substantiate a material likelihood of arising; and
  - c. the qualitative benefits are not supported by sufficient information to substantiate a material impact.
24. Only the benefits applicable to the Applied for Use and the Application submitted to the Agency have been taken into account.

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

25. I consider that the Applicant has not shown that the socio-economic benefits outweigh the risk to the environment or human health given that the monetised benefits (estimated to be £500,000) do not outweigh the monetised risks (estimated to be £2.3 million).

26. I have concluded that the qualitative benefits when considered with the monetised benefits do not materially affect the socio-economic analysis so as to show that the benefits of authorisation outweigh the risks.

## **Alternatives**

27. While all aspects of the Application were considered, as the Applicant failed to fulfil the condition laid down in Article 60(4) of Regulation (EC) No 1907/2006 that it is shown that the socio-economic benefits outweigh the risk to human health or the environment from the Applied for Use, it is not necessary to set out if the Applicant has fulfilled the other condition, namely that there were no alternatives with the same function and a similar level of performance that would have been technically and economically feasible to the Applicant.

## **Conclusion**

28. For the reasons set out above I conclude that the socio-economic benefits do not outweigh the risk to the environment or human health.

29. An authorisation is refused in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the Applied for Use.

30. The Scottish Ministers and the Welsh Ministers have given their consent to this decision in accordance with Articles 4A and 64(8) 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*