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## Authorisation Decision

by Robbie Moore, Parliamentary Under Secretary of State

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

Decision date: 3 July 2024

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## Application Ref: AFA022-01

UK REACH authorisation No.:

Authorisation number	Authorisation holder	Authorised use
UKREACH/24/02/0	TCL Manufacturing Ltd (trading as Perrin & Rowe)	Industrial use of chromium trioxide for functional chrome plating with decorative character for sanitary applications

## 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 is included in Annex XIV due to its intrinsic carcinogenic and mutagenic properties (Article 57(a) and Article 57(b)).
- Hexavalent chromium ('Cr(VI)') is the form of chromium in chromium trioxide.
- The Application is made by TCL Manufacturing Ltd (trade name 'Perrin and Rowe'), Shaw Road, Bushbury, Wolverhampton, WV10 9LB ('the Applicant').

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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>.

- Article 127GA of UK REACH applied to this application. The latest application date for chromium trioxide for this use was therefore extended to 30 June 2022.<sup>2</sup> The sunset date for this use was 30 June 2022.
- On 29 June 2022, the Applicant submitted an application for authorisation ('the Application') to the Health and Safety Executive ('the Agency') for the industrial use of chromium trioxide for functional chrome plating with decorative character for sanitary applications.
- On 30 June 2023 the Agency sent its opinion ('the Agency 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. An authorisation is granted to the Applicant in accordance with Article 60(4) of UK REACH for the following use of chromium trioxide:
  - a. Industrial use of chromium trioxide for functional chrome plating with decorative character for sanitary applications.
3. The review period referred to in Article 60(9)(e) of UK REACH is set at 10 years from the sunset date. The authorisation will cease to be valid on 30 June 2032 unless the authorisation holder submits a review report in accordance with Article 61(1) by 30 December 2030.
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 must adhere to the risk management measures ('RMMs') and operational conditions ('OCs') described in the chemical safety report referred to in Article 62(4)(d) of UK REACH.<sup>3</sup>
5. The authorisation is not subject to any monitoring arrangements.
6. The Agency has set out recommendations for the authorisation holder in section 10 of the Agency Opinion, should the authorisation holder submit a review report

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<sup>2</sup> This provided time for applicants to submit their application under UK REACH following the transition from EU REACH, where certain criteria were met.

<sup>3</sup> This is a reference to the chemical safety report dated 28 June 2022 submitted by the Applicant as part of the Application. The RMMs and OCs are described in sections 9 (exposure assessment and related risk characterisation) and 10 (risk characterisation related to combined exposure).

in accordance with Article 61(1) of UK REACH. These recommendations are not conditions of authorisation or conditions for any future 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 Opinion.

## Reasons

9. In accordance with the criteria set out in Annex XIII of UK REACH, chromium trioxide is carcinogenic and mutagenic. In the Agency Opinion, the Agency confirmed that it is not possible to determine a derived no-effect level ('DNEL') for the carcinogenic properties of chromium trioxide and therefore chromium trioxide is a substance for which it is not possible to determine a threshold in accordance with Section 6.4 of Annex I of UK REACH. 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. Therefore, an authorisation may only be granted on the basis of Article 60(4) of UK REACH.
10. An 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

11. At the site, workers are directly exposed to Cr(VI) via inhalation when performing tasks described in the worker contributing scenarios<sup>4</sup> and this presents a cancer risk.<sup>5</sup> The Agency Opinion concluded that the Applicant has in place the necessary OCs and RMMs to minimise the exposures of employees to Cr(VI) to

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<sup>4</sup> These include tasks such as delivery of raw material, storage of raw material and operating the plating line. Depending on the task performed the exposure to Cr(VI) is between 0.00014µg and 0.86µg per m<sup>3</sup> over an 8-hour shift.

<sup>5</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](#)). The intrinsic property of mutagenicity is a genotoxic mode of action thought to be at least partially responsible for the carcinogenicity of Cr(VI), it is therefore accounted for by the cancer risk assessment.

as low a level as is technically and practically possible, provided that each RMM is applied correctly. Therefore, the Agency Opinion did not propose any additional conditions or monitoring arrangements.

12. The Agency assessed the monetised human health impacts directly exposed workers to be £6,800 to £9,400 over the 10-year review period.
13. Having evaluated the Agency's assessment, I agree with its conclusion that the RMMs and OCs as described in the Agency Opinion are appropriate and effective in limiting the risks to workers, provided they are adhered to.
14. The Agency Opinion concluded the RMMs and OCs are expected to prevent releases to environmental compartments (air, water, soil and waste sludge). The Agency considers that any residual emissions of chromium to air and water compartments are unlikely to result in discernible impacts to human health via environmental exposure. Waste sludge is collected in the wastewater treatment system and taken off site for disposal in intermediate bulk containers. The Agency did note that there may be some releases to the atmosphere, however, chromium trioxide has low volatility and the Applicant's investigative monitoring did not detect Cr(VI) in stack emissions.
15. The Agency assessed the monetised human health impacts of the surrounding population and indirectly exposed workers to be £200 to £300 over the 10-year review period.
16. Having evaluated the Agency's assessment, I agree with their conclusion that RMMs and OCs are expected to prevent releases to environmental compartments and that any residual emissions of chromium to air and water are unlikely to result in discernible impacts to human health via environmental exposure.

### **Socio-economic analysis**

17. The Agency Opinion concluded that the Applicant's socio-economic analysis is considered proportionate, and the evidence in the Application is sufficient for the Agency to reach a definitive conclusion.
18. The Agency Opinion assessed both the socio-economic benefits arising from the applied for use and the socio-economic implications of a refusal to authorise. The Agency Opinion concluded that the Applicant has demonstrated that the socio-economic benefits of granting authorisation are estimated to be £11.4 million to £22.7 million. This figure accounts for the avoided profit losses, unemployment costs and outsourcing costs which would have been incurred in the most likely non-use scenario where production of chrome-plated parts is outsourced to a third party (outside the UK and EU).

19. Having evaluated the Agency's assessment, I agree with its conclusions on the quantified benefits.

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

20. The Agency Opinion concluded that the Applicant has demonstrated that the socio-economic benefits of granting an authorisation (£11.4 million to £22.7 million) are higher than the risk to human health (£7,000 to £9,700).
21. I consider that the Applicant has shown that the socio-economic benefits significantly outweigh the risk to human health because of:
  - a. The likely benefits in respect of avoided profit losses, avoided social costs of unemployment and outsourcing cost; and
  - b. The likely risks from the applied for uses of chromium trioxide.

### **Alternatives**

22. The Agency Opinion concluded that there were no available alternative substances or technologies with the same function and a similar level of performance that were technically and economically feasible for the Applicant by the sunset date.
23. The Agency Opinion stated that the timescales proposed by the Applicant are theoretical and can be viewed as ambitious as substitution is anticipated to take a minimum of 10 years. Each stage of the substitution plan is well defined and has been produced in stages so that the progress can be monitored closely by the Applicant and quality controlled at various checkpoints. The Applicant has demonstrated a clear understanding of the complexities associated with the substitution and provided details of how they will commit time and resources to the research and development of alternatives.
24. Having evaluated the Agency's assessment, I agree with the conclusion that there were no available alternatives before the sunset date and consider that the Applicant has 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**

25. The Agency Opinion recommended that the review period referred to in Article 60(9)(e) of UK REACH should be set at 10 years from the sunset date.
26. The Applicant requested a review period of 10 years and the Agency concluded that the substitution plan is credible for the review period requested, however the substitution is likely to take longer than 10 years. Additionally, the substitution

plan is consistent with the analysis of alternatives and the socio-economic analysis.

27. I agree with the Agency's recommendation for a 10-year review period from the sunset date.

## **Conclusion**

28. For the reasons set out above, I conclude that the socio-economic benefits outweigh the risk to human health for the use of chromium trioxide referred to in paragraph 2 and that there are no suitable alternative substances or technologies.
29. The Scottish Ministers and the Welsh Ministers have given their consent to this decision in accordance with the requirements of UK REACH.



Robbie Moore

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