

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: 10 June 2025

Application Ref: AFA047-01

Authorised use

Industrial use of chromium trioxide in conversion coating and passivation of circular and rectangular connectors in order to meet the requirements of international standards and special requirements of industries subject to harsh environments.

UK REACH authorisation number:

Authorisation number	Authorisation Holder
UKREACH/25/13/00	Tyco Electronics UK Limited

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.

¹ References to Regulation (EC) No 1907/2006, referred to in this decision as UK REACH, are to the assimilated law available online at <u>https://www.legislation.gov.uk/eur/2006/1907/contents</u>.

- Tyco Electronics UK Limited (the 'Authorisation Holder') with company registration number 00550926, whose registered address is at Faraday Road, Dorcan, Swindon, Wiltshire, SN3 5HH, submitted an application for authorisation to use chromium trioxide under EU REACH on 22 February 2016 (the 'Original Application'). On 15 June 2018, the Authorisation Holder was granted authorisation under EU REACH (the 'Original Authorisation').² The Authorisation Holder performs the use themselves at a single site.
- In accordance with Article 127F of UK REACH, on 31 December 2020, 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 21 March 2023, the Authorisation Holder submitted a review report (the 'Review Report') to the Health and Safety Executive (the 'Agency'), for the industrial use of chromium trioxide in conversion coating and passivation of circular and rectangular connectors in order to meet the requirements of international standards and special requirements of industries subject to harsh environments. The expiry date for the use of chromium trioxide under the Original Authorisation was 21 September 2024.³
- On 24 October 2024, the Agency sent its opinion (the 'Opinion') for this Application 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.
- In accordance with Article 60(4) of UK REACH, authorisation is granted to the Authorisation Holder as set out under the authorisation number UKREACH/25/13/00 for the following use:
 - a. UKREACH/25/13/00: Industrial use of chromium trioxide in conversion coating and passivation of circular and rectangular connectors in order to meet the requirements of international standards and special requirements of industries subject to harsh environments.
- The review period referred to in Article 60(9)(e) of UK REACH is set at 7 years. The authorisation will cease to be valid on 21 September 2031

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.

unless a review report is submitted in accordance with Article 61(1) of UK REACH by 21 March 2030.

- 4. The authorisation is subject to the following conditions (as well as the requirement in Article 60(10) of UK REACH, which stipulates that the authorisation holder must ensure exposure is reduced to as low a level as is technically and practically possible):
 - a. The authorisation holder 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 specified at sub-paragraph 4.b. below.
 - b. By 10 June 2026, the authorisation holder must review its OCs and RMMs and apply improved measures to reduce exposure of workers to Cr(VI), during routine and non-routine activities, in line with the authorisation holder's obligations under the Control of Substances Hazardous to Health Regulations 2002 (COSHH). Specifically:
 - The authorisation holder must review, and provide the gloves suitable for, any processes involving hand immersion in the liquid containing Cr(VI), and use dermal protection that is appropriate for each task that prevents exposure to Cr(VI);
 - (ii) The authorisation holder must arrange face-fit testing on each employee that is required to wear Respiratory Protective Equipment (RPE). Fit testing must be carried out by an accredited provider.⁵ Alternatively, the authorisation holder can instead choose to issue a Powered Air Purifying Respirator (PAPR) to each person that needs to use RPE. If PAPRs are issued, the authorisation holder must instigate a programme of monthly thorough examinations and tests of each PAPR. This programme must be carried out by a competent person;
 - (iii) The authorisation holder must document the requirements of paragraph 4.b. in its standard operating procedures and training materials.
- 5. The following monitoring arrangements must be applied:
 - a. The authorisation holder must undertake a minimum of three measurements per year of personal exposures to Cr(VI) where there is

⁴ This is a reference to the chemical safety report submitted by the Authorisation Holder on 21 March 2023 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 It is recommended that the competent provider has been certified under the Fit-2-Fit scheme – see also HSE guidance note INDG479 (rev 1) <u>https://www.hse.gov.uk/pubns/indg479.htm</u>.

potential inhalation exposure to Cr(VI) that is supported by appropriate contextual information for the work activities being undertaken during each monitoring period. In addition, air sampling surveys that are considered representative of full-shift exposures must be undertaken by a professionally qualified occupational hygienist⁶ at least once per year. In every case, these exposure measurements (and any reports on them) must:

- (i) be based on the methodology specified in BS ISO 16740:2005;⁷
- (ii) include personal inhalation exposure sampling measured on the lapel, and on the outside of any respiratory protection equipment that may be worn;
- be representative of the range of tasks with possible exposure to Cr(VI) and of the total number of workers that are potentially exposed.
- b. Where the 90th percentile of personal exposure to Cr(VI) for workers undertaking passivation activities exceeds the benchmark of 5 μg/m³ as an 8-hour time-weighted average (the 'Exposure Benchmark'), the authorisation holder must review and modify any relevant RMMs, such that the 90th percentile exposures are then reduced below the Exposure Benchmark.
- c. Where the RMMs have been modified to reduce exposures in paragraph 5.b., the authorisation holder must undertake personal monitoring surveys at least four times per year using the methodology that is given in BS ISO 16740:2005 until they have obtained a minimum of 10 personal exposure data points, from which the new 90th percentile of the worker's personal exposure to Cr(VI) after the change in the RMMs shall be determined.
- d. Once these 10 data points show that the new 90th percentile of the workers personal exposure to Cr(VI) has been reduced below the Exposure Benchmark, the authorisation holder shall nonetheless continue to carry out the monitoring arrangements for this particular job role as set out in paragraph 5.a.

⁶ A professionally qualified occupational hygienist refers to professionals who are entitled to put LFOH after their name or professionals of verified equivalent qualifications and status.

 $^{^7}$ BS ISO 16740:2005 specifies a method for the determination of the time-weighted average mass concentration of hexavalent chromium in workplace air. This international standard is applicable to the personal sampling of the inhalable fraction of airborne particles, as defined in ISO 7708, and to static (area) sampling. The analytical method is applicable to the determination of masses of 0.01 µg to 10 µg of hexavalent chromium per sample, without dilution.

- e. The results of the measurements referred to in paragraphs 5.a. to 5.d. must be documented by the authorisation holder, including the relevant contextual information, and made available upon request to the Agency.
- 6. The Agency has set out recommendations for the authorisation holder in section 10 of its Opinion, should a review report be submitted in accordance with Article 61(1) of UK REACH. These recommendations are not conditions of authorisation or conditions for any review report, except those that are already required by virtue of compliance with Article 61(1) of UK REACH.

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 and Article 61 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

- In its Opinion, the Agency concluded that it is not possible to determine a derived no-effect level (DNEL) 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.
- 10. 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.
- 11. 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

12. In accordance with the intrinsic properties referred to in Annex XIV of UK REACH, chromium trioxide presents a risk to human health due to its carcinogenic and mutagenic properties.

Workers

- 13. In its Opinion, the Agency concluded that the risk associated with worker exposure to chromium trioxide has been minimised to an appropriate and effective level. However, the Agency considered that there is some uncertainty due to the reliance on modelled data and lack of appropriate personal air monitoring data. The initial data submitted for personal air monitoring was presented as total chromium, therefore, the Agency could not use the data for an estimation of Cr(VI) exposure. Subsequent air monitoring data was supplied, and the samples were analysed using NIOSH 7605.⁸
- 14. Based on the air sampling data provided by the Authorisation Holder, the Agency highlighted in its opinion that it has confidence that the concentration of Cr(VI) in personal air samples is significantly below the Exposure Benchmark. However, the Agency recommended monitoring arrangements to ensure its preferred analytical methodology is used to measure personal exposure data as it is more sensitive than NIOSH 7605. The Authorisation Holder provided the Agency with 13 biological monitoring results as part of their application. The Agency noted that it was unclear if all of the biological monitoring data supplied were from individuals carrying out Cr(VI) treatment activities. The Agency noted that the biological monitoring results indicate that RMMs are appropriate and effective in limiting risk by all routes of exposure to Cr(VI) substances.
- 15. In section 10 of its Opinion, the Agency set out recommendations for the Authorisation Holder. There are two recommendations that I believe would be more suitable as conditions to ensure that proper practice is being followed in compliance with the Authorisation Holder's obligations under the Control of Substances Hazardous to Health Regulations 2002 (COSHH). As such, I have included these recommendations as conditions, as outlined in paragraph 4. I consider these appropriate to ensure good industrial practice is being followed and to provide assurance that the OCs and RMMs will continue to be effective at minimising exposure to Cr(VI).
- 16. The Agency assessed that the monetised human health impacts to workers could be up to £2,700 over the 7-year review period. This accounts for 12 directly exposed workers across a single site in GB.
- 17. Having evaluated the assessment of the OCs and RMMs in the Agency's Opinion, I believe that the monitoring arrangement outlined in paragraph 5 will provide assurances that the RMMs will remain appropriate and effective at minimising the exposures to Cr(VI). I agree with the Agency that such ongoing

⁸ NIOSH 7605 specifies a method used for air sampling analysis; <u>https://www.cdc.gov/niosh/docs/2003-154/pdfs/7024.pdf</u>.

monitoring represents good industrial practice, and the data collected will facilitate the evaluation of risks in any future review report.

18. Having evaluated the Agency's assessment, I agree with the Agency that the OCs and RMMs described in the Opinion are appropriate and effective in limiting the risk to workers provided they are adhered to. I agree with the Agency that the inclusion of conditions of authorisation and monitoring arrangements will help to minimise any remaining uncertainties and ensure that the OCs and RMMs remain appropriate and effective throughout the review period.

Humans via the environment

- 19. For human exposure to chromium trioxide via the environment, the Agency concluded that the OCs and RMMs are appropriate and effective at limiting releases to the environment. However, in the Opinion the Agency did express concerns regarding some uncertainty about the accuracy of the monitoring data and the proportion of Cr(VI) in the total chromium measured. Although, release factors and emissions to air and water are low and below the best available techniques emission benchmarks, which indicates the effectiveness of the measures, the Authorisation Holder did not use an accredited laboratory, although recognised methods were applied. The data was reported as total chromium, which introduces further uncertainty regarding the proportion of Cr(VI) in the measurements. However, the monitoring data resulting from the Original Authorisation has allowed the Agency to make an assessment on OCs and RMMs throughout the review period.
- 20. In its Opinion, the Agency assessed that the monetised human health impacts via the environment to the local population could be up to £98,000 over the 7-year review period. This accounts for an estimated local population of up to 7,623 people across a single site in GB.
- 21. Having evaluated the Agency's assessment, I agree with the Agency that the OCs and RMMs described in the Review Report are appropriate and effective in limiting the risk to humans via the environment, provided they are adhered to.

Socio-economic analysis

22. 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, avoided relocation costs, and the avoided social costs of unemployment if authorisation was not granted. The Agency estimated this to be at least £15.2 million over 7 years.

23. Having evaluated the Agency's assessment, I agree with its conclusions on the socio-economic benefits.

Conclusion on whether the benefits outweigh the risk

- 24. In its Opinion, the Agency concluded that the Authorisation Holder has demonstrated that the estimated monetised socio-economic benefits of granting an authorisation (at least £15.2 million over 7 years) are higher than the estimated monetised risk to human health (up to £101,000 over 7 years).
- 25. I consider that the Authorisation Holder has shown that the socio-economic benefits of granting authorisation outweigh the risk to human health because of:
 - a. the likely benefits in respect of avoided profit loss due to ceasing the use applied for, avoided relocation costs, and the avoided social cost of unemployment;
 - b. the assessed risk from the use of chromium trioxide.

Alternatives

- 26. In its Opinion, the Agency 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 Authorisation Holder by the expiry date of the of the Original Authorisation. There were no comments submitted by interested third parties in the consultation indicating that there are alternatives available that are technically and economically feasible.
- 27. The Authorisation Holder uses chromium trioxide in conversion coating and passivation of circular and rectangular connectors in order to meet the requirements of international standards and special requirements of industries subject to harsh environments. The Authorisation Holder has set out key functionalities that any alternatives need to have for their purposes. These include, corrosion resistance, conductivity, thickness of coating, thread lubricity, improved adhesion of subsequent coatings such as paint, temperature resistance and vibration resistance.
- 28. The Authorisation Holder shortlisted four potential alternatives in the Original Application. Alternatives 1 and 2 from the Original Application were not applicable for the GB based operations covered in this Review Report. Alternatives 3 and 4 were subjected to several tests giving poor results mainly due to the passivation film having poor adhesion and scratching off which leads to poor electrical continuity. Therefore, the Authorisation Holder did not move forward with the substitution plan included in the Original Authorisation. The Authorisation Holder instead shortlisted three new alternatives to chromium trioxide in this Review Report which met the specific requirements

for customers developing zinc alloy plating and black passivates. However, none of these alternatives were considered viable as they did not meet the electrical conductivity requirement. Therefore, they are deemed unsuitable by the Authorisation Holder.

29. Having evaluated the Agency's assessment, I agree with the conclusion that there were 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 being technically feasible.

Review period

- 30. In its Opinion, the Agency recommended that the review period referred to in Article 60(9)(e) of UK REACH should be set at 7 years.
- 31. In the Original Application submitted under EU REACH, an outline substitution plan was provided which gave a timeline of 8 to 15 years for research into alternatives, industrialisation, implementation, and time for testing by the different end users of the connectors. The Agency concluded that the Authorisation Holder is still in the research phase of the substitution plan from the Original Application and concluded that the Authorisation Holder has shown their commitment to continued research and development in the future.
- 32. The Agency accepted that none of the alternatives considered were deemed to be technically feasible. Therefore, the Agency concluded that the absence of a new substitution plan is understandable. The Agency believes that it would have been possible to devise a hypothetical substitution plan in the event of a suitable alternative being developed, however, the experience to date indicates that any such estimated timescales would be vague and subject to change. The lack of a substitution plan is therefore not a significant concern for the Agency.
- 33. The Authorisation Holder requested a 7-year review period to align with an authorisation for formulation, not covered within this Review Report. In its Opinion, the Agency concluded that the requested 7-year time-period is realistic when considering that the proposed alternatives are not currently technically feasible. The Agency evaluated the Authorisation Holder's proposition to align with a separate authorisation on formulation and agree that would take a minimum of 7 years for the substitution of chromium trioxide for the use applied for in this review report.
- 34. Having evaluated the Agency's assessment, I agree with the Agency's conclusions on these points and its proposal for a 7-year review period.

Conclusion

- 35. 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 were no suitable alternative substances or technologies available.
- 36. The Scottish Ministers and the Welsh Ministers have given their consent to this decision in accordance with the requirements of UK REACH.
- 37. In accordance with the provisions of Article 61(1), the Original Authorisation is amended and replaced with this decision, effective from 10 June 2025.

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