

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: 31 July 2024

Application Ref: AfA023-01 and AfA023-02

UK REACH authorisation No.:

Authorisation number	Authorisation holder	Authorised use
UKREACH/24/08/0 UKREACH/24/08/1	Borough Ltd. Quality Plated Products Ltd.	Use 1: Industrial use of chromium trioxide for the etch pre-treatment step for functional chromium plating with decorative character for automotive, sanitary, heating and other applications.
UKREACH/24/08/2 UKREACH/24/08/3 UKREACH/24/08/4 UKREACH/24/08/5	Aalberts Integrated Piping Systems Ltd. Borough Ltd. Quality Plated Products Ltd. Samuel Heath and Sons plc.	Use 2: Industrial use of chromium trioxide for functional chromium plating with decorative character for automotive, sanitary, heating and other 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). 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:
 - a. Aalberts Integrated Piping Systems Ltd ('Aalberts'), Belmont Works, St. Catherines Avenue, Doncaster, South Yorkshire, DN4 8DF (Use 2);
 - b. Borough Ltd ('Borough'), 65 Progress Road, Leigh-on-Sea, Essex SS9 5JT (Uses 1 & 2);
 - c. Quality Plated Products Ltd ('QPP'), Shady Lane, Great Barr, Birmingham, B44 9ER (Uses 1 & 2);
 - d. Samuel Heath and Sons plc ('Samuel Heath'), Cobden Works, Leopold Street, Birmingham, B12 0UJ (Use 2).

(together the 'Applicants') who are members of the CrO₃4UK Group.

- Article 127GA of UK REACH applied to this application. The latest application date for chromium trioxide for Use 1 and Use 2 was therefore extended to 30 June 2022.² The sunset date for this Use 1 and Use 2 was 30 June 2022.
- On 29 June 2022, the Applicants submitted an application for authorisation (the 'Application') to the Health and Safety Executive (the 'Agency') for two uses of chromium trioxide:
 - a. Use 1: For the etch pre-treatment step for functional chromium plating with decorative character for automotive, sanitary, heating and other applications
 - b. Use 2: For functional chrome plating with decorative character for automotive, sanitary, heating and other applications
- On 4 August 2023 and 10 August 2023, the Agency sent its opinions for Use 1 and Use 2 (the 'Opinion for Use 1' and the 'Opinion for Use 2' respectively, together the 'Opinions') to the Secretary of State for Environment, Food and Rural Affairs, and Scottish and Welsh Ministers.

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

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 uses:
 - a. UKREACH/24/08/0 Industrial use of chromium trioxide for the etch pretreatment step for functional chrome plating with decorative character for automotive, sanitary, heating and other applications (Use 1)
 - b. UKREACH/24/08/1 Industrial use of chromium trioxide for the etch pretreatment step for functional chrome plating with decorative character for automotive, sanitary, heating and other applications (Use 1)
 - UKREACH/24/08/2 Industrial use of chromium trioxide for functional chrome plating with decorative character for automotive, sanitary, heating and other applications (Use 2)
 - d. UKREACH/24/08/3 Industrial use of chromium trioxide for functional chrome plating with decorative character for automotive, sanitary, heating and other applications (Use 2)
 - UKREACH/24/08/4 Industrial use of chromium trioxide for functional chrome plating with decorative character for automotive, sanitary, heating and other applications (Use 2); and
 - f. UKREACH/24/08/5 Industrial use of chromium trioxide for functional chrome plating with decorative character for automotive, sanitary, heating and other applications (Use 2)
- 3. The review period referred to in Article 60(9)(e) of UK REACH is set at 12 years from the sunset date for authorisation numbers UKREACH/24/08/0 and UKREACH/24/08/1 (Use 1). These will cease to be valid on 30 June 2034 unless a review report is submitted in accordance with Article 61(1) by 30 December 2032.
- 4. The review period referred to in Article 60(9)(e) of UK REACH is set at 10 years from the sunset date for authorisation numbers UKREACH/24/08/2, UKREACH/24/08/3, UKREACH/24/08/4 and UKREACH/24/08/5 (Use 2). These will cease to be valid on 30 June 2032 unless a review report is submitted in accordance with Article 61(1) of UK REACH by 30 December 2030.
- 5. Authorisation for Use 1 and Use 2 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 holders 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 REACH³
- 6. The Authorisation for Use 1 is not subject to any monitoring arrangements.
- 7. The Authorisation for Use 2 is subject to the following monitoring arrangements.
 - a. The authorisation holders shall each undertake measurements of personal exposures to Cr(VI) at least once in any 6-month period at their site. In every case, these exposure measurements should:
 - (a) be based on the methodology specified in BS ISO 16740:2005⁴
 - (b) be supported by appropriate contextual information regarding the descriptions of the work activities being undertaken during each monitoring period
 - (c) include personal inhalation exposure sampling measured on the lapel, and on the outside of any respiratory protection equipment that may be worn
 - (d) be representative of the range of tasks with possible exposure to Cr(VI) and of the total number of workers that are potentially exposed
 - (e) include the gathering and recording of suitable contextual information that can be used to interpret and inform results
 - b. Once the authorisation holders have 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, further air monitoring for that particular job role can be reduced to a minimum of annual monitoring.
 - c. For each of the authorisation holders, where the 90th percentile of the plating operator's personal exposure to Cr(VI) measured using the methodology that is given in BS ISO 16740:2005 exceeds 5 µg/m³ as an 8-hour TWA, then either a suitable, purpose-designed local exhaust ventilation (LEV) should be installed by the authorisation holder on both chrome plating tanks, or the RMMs shall be modified for the authorisation holder concerned such that the

³ This is a reference to the chemical safety report dated 30 June 2022 submitted by CrO34UK Group 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 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 micrograms to 10 micrograms of hexavalent chromium per sample, without dilution.

- 90th percentile exposure is below the benchmark of 5 $\mu g/m^3$ as an 8-hour TWA.
- d. If 7.c. applies the authorisation holder shall undertake a personal monitoring survey on the chrome plater at least 6 times per year using the methodology specified in BS ISO 16740:2005 until they have obtained a minimum of 10 personal exposure data points per job role where 5 μg/m³ was exceeded. After 10 personal exposure data points have been achieved, personal monitoring surveys can be reduced to a minimum of annual measurements.
- 8. The Agency has set out recommendations for the authorisation holders in section 10 of the Agency Opinions, 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 future 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 Opinions.

Reasons

- 11. In accordance with the criteria set out in Annex XIII of UK REACH, chromium trioxide is carcinogenic and mutagenic. In the Agency Opinions, 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.
- 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 this Application. Therefore, an authorisation may only be granted on the basis of Article 60(4) of UK REACH.
- 13. 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

- 14. At the sites where both uses take place, workers are directly exposed to Cr(VI) via inhalation when performing tasks described in the worker contributing scenarios outlined in Table 4 in both Agency Opinions, and this presents a cancer risk.⁵ For both uses, the Agency concluded that the Applicants have in place most of the necessary RMMs and OCs to reduce Cr(VI) exposure to workers to an appropriate and effective level and thereby minimise the risks to human health. The Agency Opinion for Use 2 noted there were uncertainties with the RMMs and OCs for two Applicants; Samuel Heath currently has no LEV system installed, and exposure data for Aalberts is higher than the Agency would have expected based on its current RMMs and OCs. It is worth noting that in the case of Aalberts, their personal exposure levels are below the 5 μg/m³ as an 8-hour TWA.
- 15. The Agency Opinion for Use 2 identified some shortcomings in the personal monitoring of inhalation exposure. All of the Applicants have undertaken some personal monitoring of inhalation exposures. The quantity of exposure data that is currently available for each job role in each of the sites, and the sampling and analysis methodology that appears to have been used in each case has resulted in a significant level of uncertainty about the extent of variability in the exposure distributions for each job within the sites.
- 16. Due to the reasons above, the Agency proposed monitoring arrangements (paragraph (7.a.) and (7.b.)) as a condition of authorisation to ensure that the regular monitoring will continue for the full duration of the authorisation, and will provide assurance that the RMMs will continue to remain effective at minimising the exposures to Cr(VI).
- 17. The Agency Opinion for Use 2 recommended that the following are included as recommendations for the review report to address uncertainties listed in paragraph 14:
 - a. Aalberts to review their RMMs if the results from personal monitoring surveys continue to exceed 1 μg/m³ as an 8-hour time TWA
 - b. Samuel Heath should fit a purpose-designed LEV if personal exposure to Cr(VI) exceeds 5 µg/m³ as an 8-hour TWA

For the recommendation set out at 17.a. I agree with the Agency that Aalberts has in place all the appropriate RMMs and OCs, which is evidenced by their personal exposure being below the Agency benchmark of 5 μ g/m³ as an 8-hour

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⁵ The cancer risk is estimated according to the Committee for Risk Assessment (RAC) reference dose-response relationships for Cr(VI) carcinogenicity (<u>RAC/27/2013/06 Rev.1</u>). 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.

- TWA. Therefore, I agree that the above should remain as a recommendation. However, I believe the Agency's recommendation set out at 17.b. should instead be included as a monitoring arrangement, (where personal exposure to Cr(VI) exceeds 5 μ g/m³ as an 8-hour TWA), with the authorisation holders given the option to amend their RMMs instead of installing LEV to reduce exposure to Cr(VI). This will provide assurances that all the RMMs and OCs for Use 2 are appropriate and effective at minimising the exposure of Cr(VI) to workers.
- 18. Having evaluated the Agency's assessment, and the RMMs and OCs described in the Agency Opinion for Use 2, I believe that the above monitoring arrangements will address minor shortcomings in the personal monitoring of inhalation exposure, and will corroborate the effectiveness of the authorisation holders' RMMs and OCs, and confirm that they are appropriate and effective in limiting the risk. I agree with the Agency that such ongoing monitoring represents good industrial practice, and the data collected will facilitate the evaluation of risks in the next review report.
- 19. The Agency assessed the monetised human health impacts to directly exposed workers to be £1,000 over the 12-year review period for Use 1 and £75,000 to £130,000 over the 10-year review period for Use 2.
- 20. Having evaluated the Agency's assessment, I agree that the Applicants have in place most of the necessary RMMs and OCs to reduce direct Cr(VI) exposure to workers to an appropriate and effective level and thereby minimise the risks for both uses. I agree with the Agency's proposed monitoring arrangements (paragraph (7.a.) and (7.b.)) and believe that with the additional monitoring arrangements proposed (paragraph (7.c) and (7.d.)), this would provide certainty that the Applicants have all appropriate RMMs and OCs in place to limit risk to workers.
- 21. In its Opinions, the Agency concluded that the RMMs and OCs are likely to be appropriate and effective in limiting exposure to environmental compartments (air, water, soil and waste sludge), provided they are adhered to. In reaching this conclusion, the Agency noted that the emissions to the atmosphere of Cr(VI) have been limited appropriately and effectively for both uses and the release of Cr(VI) to the atmosphere is expected to be low.
- 22. For both uses, the Agency used the measured and predicted exposure data from QPP to assess the effectiveness and appropriateness of the current RMMs and OCs in limiting exposure to water, soil and waste sludge. The Agency used data from QPP because this represented the company with the highest estimated emissions of Cr(VI) mass to air and wastewater, and therefore could be used as a reasonable proxy to address the uncertainty relating to the absence of monitoring data provided by Samuel Heath. For both uses, the Agency

- concluded that the current RMMs and OCs are expected to prevent direct releases of Cr(VI) into soils at the sites.
- 23. The Agency Opinions further concluded that the OCs and RMMs relating to the handling and disposal of other wastes, including sludges and liquid wastes, are likely to be appropriate and effective in limiting exposure via environmental media for both uses.
- 24. The Agency assessed the monetised human health impacts of the surrounding population and indirectly exposed workers to be £21,000 to £38,000 over the 12-year review period for Use 1 and £18,000 to £32,000 over the 10-year review period for Use 2.
- 25. Having evaluated the Agency's assessment for both uses, I agree with their conclusion that RMMs and OCs are expected to be appropriate and effective in limiting exposure to environmental compartments if they are adhered to 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

- 26. In its Opinions, the Agency concluded that the Applicants' socio-economic analysis is considered proportionate, and the evidence within the Application is sufficient to reach a definitive conclusion for both uses. The Agency has not identified any remaining uncertainties of such magnitude that they may affect its conclusions.
- 27. The Agency 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 cost of the most likely non-use scenario (NUS) if the Applicants were not granted authorisation. The most likely NUS for Use 1 is that QPP and Borough would implement a full immediate site closure. The most likely NUS for Use 2 is outsourcing and partial closure for Aalberts and Samuel Heath and a complete shutdown/site closure for QPP and Borough.
- 28. The Agency Opinion for Use 1 concluded that the Applicants have demonstrated that the socio-economic benefits of granting authorisation are estimated to be £10 million to £30 million. This figure accounts for avoided profit losses, avoided decommissioning costs, gained resale value and avoided social cost of unemployment.
- 29. The Agency Opinion for Use 2 concluded that the Applicants have demonstrated that the socio-economic benefits of granting authorisation for Use 2 are estimated to be £25 million to £50 million. This figure accounts for avoided profit losses, avoided decommissioning costs, and avoided social cost of unemployment.

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

Conclusion on whether the benefits outweigh the risk

- 31. The Agency Opinion for Use 1 concluded that the Applicants have demonstrated that the socio-economic benefits of granting an authorisation (£10 million to £30 million) are higher than the risk to human health (£22,000 to £39,000).
- 32. The Agency Opinion for Use 2 concluded that the Applicants have demonstrated that the socio-economic benefits of granting an authorisation (£25 million to £50 million) are higher than the risk to human health (£93,000 to £162,000).
- 33. I consider that the Applicants have shown that the socio-economic benefits of granting authorisation significantly outweigh the risk to human health because of:
 - a. The likely benefits in respect of avoided profit losses, decommissioning costs, avoided social costs of unemployment and outsourcing cost (Use 2 only)
 - b. The likely risks from the applied for uses of chromium trioxide (Use 1 and Use 2)

Alternatives

- 34. In its Opinions, 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 Applicants by the sunset date.
- 35. The Agency Opinions stated that the timescales proposed by the Applicants are theoretical and can be viewed as ambitious as substitution is anticipated to take a minimum of 12 years for Use 1 and 10 years for Use 2. 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 Applicants and quality controlled at various checkpoints. The Agency recognises the requirement for compatibility between Use 1 and Use 2 which adds further difficulties in developing a compatible alternative for both uses. The Applicants have 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.
- 36. 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 Applicants have 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 for the Applicants by the sunset date.

Review period

- 37. In the Agency Opinions, the Agency recommended the review period referred to in Article 60(9)(e) of UK REACH should be set at 12 years from the sunset date for Use 1 and 10 years from the sunset date for Use 2. In reaching its conclusion, the Agency noted:
 - a. The substitution plan is credible for the review period requested in both uses, however given the lack of success in securing a suitable alternative in the chrome plating industry, the substitution is likely to take longer than the review period.
 - b. The requirement for compatibility between Use 1 and Use 2. Given the fact there are no technically and economically feasible alternatives available for electroplating, this adds further uncertainty and difficulty to develop a compatible alternative for the pre-treatment process.
- 38. I agree with the Agency's recommendations for a 12-year review period from the sunset date for Use 1 and a 10-year review period from the sunset date for Use 2.

Conclusion

- 39. 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.
- 40. The Scottish Ministers and the Welsh Ministers have given their consent to this decision in accordance with the requirements of UK REACH.

A.5.74 N.J.55

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