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: 13 December 2024

Application Ref: AfA046-01
UK REACH authorisation No.:

Authorisation number	Authorisation holder	Authorised use
UKREACH/24/24/0	APPH Limited	The use of chromium trioxide for functional chrome plating of aircraft components for civil and military sectors that meet the airworthiness requirements[1] and as hydraulic components for military vehicles.

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').[2] 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).

[1] Airworthiness requirements are those set out in assimilated Regulation (EU) No 748/2012 relating to rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, available at Commission Regulation (EU) No 748/2012 of 3 August 2012 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production.
[2] 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.

- Hexavalent chromium (Cr(VI)) is the form of chromium in chromium trioxide to which the hazardous properties are attributed.
- The application is made by APPH Limited, with company registration number 01972451, whose registered office is at 8 Pembroke Court, Chancellor Road, Manor Park, Runcorn, WA7 1TG (the 'Applicant') who is a downstream user of chromium trioxide.
- On 14 April 2023, the Applicant submitted an application for authorisation (the 'Application') to the Health and Safety Executive (the 'Agency'), for the use of chromium trioxide as a plating agent in functional chrome plating of aircraft components for civil and military sectors, and as hydraulic components for military vehicles.
- On 12 June 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. In accordance with Article 60(4) of UK REACH, authorisation is granted to the Applicant as set out under authorisation number UKREACH/24/24/0 for the following use:
    a. UKREACH/24/24/0: Use of chromium trioxide as a plating agent in functional chrome plating of aircraft components for civil and military sectors, and as hydraulic components for military vehicles.
3. The review period referred to in Article 60(9)(e) of UK REACH is set at 12 years. The authorisation will cease to be valid on 13 December 2036 unless a review report is submitted in accordance with Article 61(1) of UK REACH by 13 June 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 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,[3] subject to the monitoring arrangement specified at subparagraph 5.d. below.
5. The authorisation is subject to the following monitoring arrangements:

[3] This is a reference to the chemical safety report submitted by the Applicant on 10 January 2023 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).

a. The authorisation holder must undertake measurements of personal exposures to Cr(VI) via air sampling surveys. These shall be supported by appropriate contextual information regarding descriptions of each specific work task being undertaken during each monitoring period. Air sampling surveys that are considered representative of full-shift exposures must be undertaken by a professionally qualified occupational hygienist, at least biannually. 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, and

    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.

b. 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 likely to occur, the minimum frequency for further air monitoring for that particular job role can be reduced to carrying out annual surveys, provided that the 90th percentile of the measured personal exposures to Cr(VI) are confirmed to be below the Agency's internal benchmark of 5 µg/m^3 as an 8-hour time-weighted average (TWA).

c. As part of the air sampling surveys undertaken as a result of paragraph 5.a, where the 90th percentile of the plating operator's personal exposure to Cr(VI) (measured using the air monitoring methodology that is given in BS ISO 16740:2005) exceeds the Agency's internal benchmark of 5 µg/m³ as an 8-hour TWA, the authorisation holder shall review and modify RMMs within no more than 12 months from the exceedance such that the 90th percentile exposures are then reduced below 5 µg/m³ as an 8-hour TWA.

d. If the RMMs have been modified to reduce exposures, the Applicant must undertake a personal monitoring survey of the plating operators at least 4 times per year using the methodology that is given in BS ISO 16740:2005 until it has obtained a minimum of 10 personal exposure data points, from which the new 90th percentile of the plating operators personal exposure to Cr(VI) after the change in the RMMs shall be determined. Once these 10 data points show that the new 90th percentile of the plating operator's personal exposure to Cr(VI) has been reduced to below the internal benchmark of 5 µg/m³ as an 8-hour TWA, the authorisation holder shall continue to carry out the monitoring arrangements for this particular job role as set out in paragraph 5.a.

e. In addition to the full shift air monitoring outlined in paragraphs 5.a. and 5.b. above, the authorisation holder must undertake personal air

monitoring during any short duration activities where significant airborne Cr(VI) exposure is likely to occur for the duration of each such short duration task using the methodology outlined in BS ISO 16740:2005. This air monitoring should be undertaken on an annual basis for each task. Where it is appropriate, at least some of the surveys should include air monitoring of the task of weighing out of the chromium trioxide flakes when only part of a drum's contents is needed.

f. The authorisation holder should document and include in any future review report the full reports of the exposure measurements referred to in points 5.a., 5.d. and 5.e. including the relevant contextual information and, upon request, submit this information to the Agency.

6. The Agency has set out recommendations for the authorisation holder in section 10 of its Opinion, 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 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); and

   c. the Agency's Opinion.

Reasons

9. 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. 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. 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.

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

Workers

13. In its Opinion, the Agency noted limitations in the data supplied by the Applicant regarding the potential risk to workers, specifically regarding the lack of both sufficient and reliable exposure data on the personal exposure of the plating operators to Cr(VI). This led to uncertainties surrounding the effectiveness of the RMMs. The Agency therefore proposed monitoring arrangements in order to address limitations in the assessment of the plating operators' exposure to Cr(VI). I agree with the Agency that these monitoring arrangements will address uncertainties surrounding the effectiveness of the RMMs.

14. In its Opinion, the Agency concluded that these monitoring arrangements will ensure that evidence is available to demonstrate that exposure of Cr(VI) to workers is being effectively controlled. Furthermore, the Agency explained that the monitoring arrangements will provide assurance that the RMMs remain effective at minimising the exposures to Cr(VI) for the full duration of the authorisation.

15. In its Opinion, the Agency concluded that the OCs and RMMs in place are likely to minimise the exposure of employees to Cr(VI) to an appropriate and effective level, and thereby minimise the risk. The Agency considered that the Applicant has demonstrated that the 90th percentile of personal exposures for each worker contributing scenario ('WCS') is likely to be less than 5 µg/m^3 as an 8-hour TWA. The Agency noted that biomonitoring data provided good evidence to support the conclusion that the RMMs described in the Application were likely to be appropriate and effective at controlling exposures from all routes to workers despite the concerns regarding the lack of sufficiently reliable exposure data on the personal exposures of the plating operators to Cr(VI). Therefore, the Agency concluded that despite the uncertainty created by the limited personal exposure data set, the OCs and RMMs described in the Application are likely to be appropriate and effective in limiting the risk to workers provided they are fully adhered to.

16. The Agency assessed the monetised human health impacts to workers to be less than £1 million over the 12-year review period using the willingness to pay methodology.[4] This accounts for the 7 to 70 directly exposed workers at 1 site in Runcorn, Chesire, GB.

[4] Monetised statistical cancer cases were calculated using the formula - Discount factor x (fatality probability x value of a statistical life + value of cancer morbidity). Figures from an ECHA 2012 willingness to pay study are used for the value of a statistical life (€3.5 - €5m) and value of cancer morbidity (€0.41m).

17. 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 in limiting risk to workers provided they are fully adhered to.

Humans via the environment

18. In its Opinion, the Agency noted that the Applicant had provided a limited data set for the site covered by the Application as there was only one data point available for each year between 2019 and 2022. Therefore, to allow for a more robust assessment of risk to humans via the environment, the Agency used the 90th percentile values from the emissions data to represent a reasonable worst-case scenario in its assessment of risk.

19. In its Opinion, the Agency considered that, based on the worst-case scenario, the Applicant's estimate of human exposure via the environment is likely to be reasonable overall. Based on the information provided, the Agency considers the amounts of Cr(VI) released to the environment to be likely to be low in absolute terms, at less than the emission values given in the best available techniques reference document (<0.01 to 0.2 mg/m^3)[5]. Therefore, the Agency concluded that the OCs and RMMs are likely to be appropriate in limiting the risk to humans via the environment, provided they are fully adhered to.

20. The Agency assessed the monetised human health impacts to humans via the environment to be less than £100,000 over the 12-year review period. This accounts for an estimated general population of between 455 and 555 people within a 1 km radium of the 1 site in Runcorn, Cheshire, GB.

21. 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 in limiting risk to humans via the environment, provided they are fully 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 producer surplus losses, avoided decommissioning costs and avoided social costs of unemployment for this use only, if authorisation was not granted. The Agency estimated this to be between £50 million to £150 million over 12 years.

23. This estimate is further considered to be conservative, as additional socio-economic benefits of granting authorisation have been assessed qualitatively by the Agency but have not been monetised. These consist of the avoided negative impacts on the Applicant's customers, specifically a long production gap that

[5] Integrated Pollution Prevention and Control Reference Document on Best Available Techniques for the Surface Treatment of Metals and Plastics August 2006 available at https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/stm_bref_0806.pdf.

would occur if the Applicant were to move its operations from GB, as well as avoided impacts of the social cost of unemployment on a small component manufacturer (10 to 50 employees) local to the site covered by the Application, which relies on the Applicant as its primary customer and would likely close if the authorisation was not granted.

24. Having evaluated the Agency's assessment, I agree with its conclusions on the quantitative and qualitative benefits.

Conclusion on whether the benefits outweigh the risk

25. In its Opinion, the Agency concluded that the Applicant has demonstrated that the socio-economic benefits of granting authorisation (between £50 million to £150 million over 12 years) are higher than the risk to human health (up to £1 million over 12 years).

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

    a. the likely quantitative benefits in respect of the avoided producer surplus losses, avoided decommissioning costs and avoided social costs of unemployment,

    b. the likely qualitative benefits in respect of avoided negative impacts on customers, and

    c. the assessed risks from the use of chromium trioxide.

Alternatives

27. 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 Applicant by the expiry date of the authorised use under EU REACH[6] of 21 September 2024. There were no comments submitted by interested third parties in the consultation indicating that there are alternatives available that are technically and economically feasible.

28. The Applicant uses chromium trioxide for functional chrome plating on a range of different components for the aerospace and defence (A&D) industry, including structural parts of landing gear systems, items such as hydraulic units (e.g. actuators, valves, accumulators), and flight controls. In the Application, the Applicant submitted a substitution plan focusing on four key stages. These were redesign, requalification, customer approval & certification, and the introduction of new configuration standards and supply chain alignment.

[6] As a result of the conditions of Article 127H of UK REACH having been met, the use of chromium trioxide authorised under EU REACH can continue until 21 September 2024.

29. The Applicant established seven requirements that would need to be met for an alternative to chromium for functional chrome plating to be considered feasible: wear resistance, hardness, corrosion resistance, the coefficient of friction, to provide a surface finish, to be adhesive and to add layer thickness to the component.

30. The Applicant stated that it had carried out extensive consultations and data searches in its efforts to identify functional chrome plating replacements within the A&D industry. Based on this research, the Applicant identified nine potential alternatives to Cr(VI), of which High Velocity Oxygen Fuel (HVOF) and High Velocity Air Fuel (HVAF) thermal spraying were shortlisted as they can be easily applied to equipment and new equipment can be tailored around this technology. However, the Applicant stated that for the HVOF technology to become available it must pass certification before being industrialised for use. When assessing HVOF's compatibility against the key process and performance functionality requirements, the Applicant found that it was not compatible with components with complex geometries. Furthermore, testing for HVAF as a functional chrome plating replacement is still ongoing and results have not yet been published. The Agency therefore judged that technical feasibility of alternatives has not been established and the Applicant has convincingly demonstrated that it is actively working on the substitution of chromium trioxide, and that this is well underway.

31. In its Opinion, the Agency was satisfied with the Applicant's approach for seeking alternative methods and felt this was sufficiently detailed in the Application. The Agency therefore concluded that there are no technically and economically feasible alternatives available with the same function and similar level of performance by the expiry date of the authorised use under EU REACH.

32. Having evaluated the Agency's assessment, I agree with the conclusion that there were no available alternatives by the expiry date of the authorised use under EU REACH and consider that the Applicant 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

33. In its Opinion, the Agency recommended the review period referred to in Article 60(9)(e) of UK REACH should be set at 12 years.

34. In the Application, the Applicant proposed a 12-year review period as this is the minimum timeframe it will require to implement substitution due to the complexity of substitution, as demonstrated in the substitution plan. In its Opinion, the Agency concluded that the Applicant's substitution plan is credible for the review period requested and consistent with the analysis of alternatives and the socio-

economic analysis. The Applicant stated that the execution of the full substitution plan could take up to 20 years, emphasising the many dependencies on activities in terms of supply chain availability, customer approvals, and availability of test specimens.

35. In its Opinion, the Agency concluded that a 12-year time-period is realistic when considering that the Applicant has demonstrated that it is actively working on the substitution of chromium trioxide and agreed with the Applicant that the full substitution plan would more likely require approximately 20 years to complete. The Agency also noted the Applicant's awareness of the potential delays that may arise throughout the process of substitution and agreed that it is realistic with its expectations of progress within the 12-year period.

36. 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

37. 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.

38. 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