Department for Environment Food & Rural Affairs

Authorisation Decision

by Jo Churchill MP

Parliamentary Under Secretary of State

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

Decision date: 24 January 2022

Application Ref: ID 0146-01

UK REACH authorisation number:

Authorisation number	Authorisation holder	Authorised use
UKREACH/22/02/0	Tata Steel UK Ltd	The use of Chromium (VI) for the manufacture of Electrolytic Chromium/Chromium oxide Coated Steel (ECCS)

Preliminary Matters

- Chromium trioxide is listed in Annex 14 to EUR 2006/1907 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH)[1]. As such, it is subject to the authorisation requirement referred to in Article 56(1) of that Regulation.
- Chromium trioxide was included in Annex XIV to Regulation (EC) No 1907/2006[2] because of its carcinogenicity (category 1A, 'may cause cancer') and mutagenicity (category 1B, 'may cause genetic defects').
- Hexavalent chromium ('Cr(VI)') is the form of chromium in chromium trioxide.

[1] References to 'EUR 2006/1907' are to the retained version of Regulation (EC) No 1907/2006. The retained version of that Regulation is available online at https://www.legislation.gov.uk/eur/2006/1907/contents

[2] References to "Regulation (EC) No 1907/2006" are to that Regulation as it has effect in EU law.

- The application is made by:

  Tata Steel UK Ltd. of Tata Steel, Trostre Works, Llanelli, Camarthenshire, S. Wales, SA14 9SD ('the Applicant').

- On 10 April 2019, the Applicant made an application for authorisation ('the Original Application') to the European Chemicals Agency (ECHA) for the use of chromium trioxide as Chromium (VI) for the manufacture of Electrolytic Chromium/Chromium oxide Coated Steel (ECCS).

- On 12 June 2020, ECHA sent the consolidated opinion of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) ('the RAC Opinion' and 'the SEAC Opinion' respectively; the consolidated opinion is referred to as 'the ECHA Opinion') to the European Commission.

- On 29 June 2021, the Applicant notified the Secretary of State of the Original Application in accordance with Article 127G of EUR 2006/1907.

- The Original Application related to the use of chromium trioxide in one site in Great Britain.

- In reaching this decision I have considered the likely risks to human health and the likely socio-economic benefits in respect of Great Britain.

Decision

1. This Decision is addressed to the Applicant.

2. An authorisation is granted in accordance with Article 60(4) of EUR 2006/1907 for the following use of chromium trioxide as set out in the table above titled 'UK REACH authorisation number':

   > The use of Chromium (VI) for the manufacture of Electrolytic Chromium/Chromium oxide Coated Steel (ECCS).

3. The review period referred to in Article 60(9)(e) of EUR 2006/1907 ends on 31 December 2027. The authorisation shall cease to be valid on 1 January 2028 unless the authorisation holder submits a review report in accordance with article 61(1) by 30 June 2026.

4. The authorisation is subject to the following condition (as well as the requirement in Article 60(10) of EUR 2006/1907 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 and operational conditions described in the chemical safety report referred to in Article 62(4)(d) of EUR 2006/1907[3].

5. The following monitoring arrangements must be applied by the authorisation holder:

a. The authorisation holder must implement and conduct an occupational exposure monitoring programme for Cr(VI). Measurements must be taken at least once a year, with no more than 12 months between measurements. The first measurements must be taken within three months of this decision. The authorisation holder must use a suitable procedure[4] when carrying out this monitoring programme. It must be comprised of both static and personal inhalation exposure sampling. The measurements taken as part of the programme must reflect:

i. the range of tasks undertaken where exposure to Cr(VI) is possible, including tasks involving maintenance workers;

ii. the operational conditions and risk management measures typical for each of these tasks;

iii. the number of workers potentially exposed.

b. The authorisation holder must conduct a monitoring programme for Cr(VI) emissions to wastewater, and to air from local exhaust ventilation. Measurements must be taken at least once a year, with no more than 12 months between measurements. The first measurements must be taken within three months of the date of this decision. The authorisation holder must use a suitable procedure[5] when carrying out this monitoring programme. The monitoring programme must take account of the operational conditions and risk management measures in place at the site.

c. The information gathered through the measurements referred to in subparagraphs (a) and (b) and the contextual information associated with the measurements must allow the authorisation holder to evaluate the effectiveness of the operational conditions and risk management measures in place. It must also allow the authorisation holder to identify any necessary further steps to ensure compliance with Article 60(10) of EUR 2006/1907 (such as introducing a closed loading system

[3] This is a reference to the chemical safety report dated 10 April 2019, submitted by the Applicant as part of the Original Application. The risk management measures and operational conditions are described in sections 9 (exposure assessment (and related risk characterisation)) and 10 (risk characterisation related to combined exposure).
[4] "Suitable procedure" has the same meaning as in Regulation 10(1) of the Control of Substances Hazardous to Health Regulations 2002 (S.I. 2002/2677).
[5] "Suitable procedure" has the same meaning as in Regulation 10(1) of the Control of Substances Hazardous to Health Regulations 2002 (S.I. 2002/2677).

for the substance, and the use of powered respirators instead of non-powered full face masks). Any additional risk management measures or operational conditions must be implemented in accordance with the hierarchy of control principles[6].

d. The authorisation holder must record the following in respect of all measurements: details of the procedure(s) used, the reasons for choosing those procedure(s), the results and the associated contextual information. The authorisation holder must also record any further steps identified in accordance with subparagraph (c) to ensure compliance with Article 60(10) of EUR 2006/1907. This information must be made available to the UK REACH Agency (the Health and Safety Executive) on request.

6. In the event that a review report is submitted in accordance with article 61(1), it should include the following information:

a. The information referred to in paragraph 5(d).

Background

7. This decision is made under Article 64(8) of EUR 2006/1907.

8. In making this decision, I have taken into account: -

a. The Original Application.

b. The elements referred to in Article 60(4)(a) to (d) of EUR 2006/1907, and the aspects referred to in Article 60(5).

c. The ECHA Opinion.

d. That the use applied for takes place in Wales so all the data and analysis supplied in the Original Application and the ECHA Opinion is in relation to that site. Therefore, that information is all relevant to Great Britain (England, Wales and Scotland).

Reasons

9. In its opinion, RAC confirmed that it is not possible to determine a derived no-effect level (DNEL) for the carcinogenic or mutagenic properties of chromium trioxide and therefore chromium trioxide is a substance for which it is not possible to determine a threshold.

10. In accordance with Article 60(3)(a) of EUR 2006/1907, this means that Article 60(2) of that Regulation does not apply. Article 60(2) does not apply to substances for which it is not possible to determine a threshold in accordance

[6] The current hierarchy is set out in the leadership and worker involvement toolkit, in a document titled "Management of risk when planning work: The right priorities", developed by the construction industry's Leadership and Worker Engagement Forum (hosted by HSE November 2011): (https://www.hse.gov.uk/construction/lwit/assets/downloads/hierarchy-risk-controls.pdf).

with Section 6.4 of Annex 1. Therefore, an authorisation may only be granted on the basis of Article 60(4) of that Regulation.

11. An authorisation may only be granted under Article 60(4) of EUR 2006/1907 if it is shown that the socio-economic benefits outweigh the risks to human health or the environment and there are no suitable alternative substances or technologies. A suitable alternative should be safer, available, and technically and economically feasible.

Risks to human health

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

Risk management measures and operational conditions

13. The RAC Opinion concluded that the Applicant has demonstrated that the risk management measures and operational conditions as described in the Original Application are appropriate and effective in limiting the risks to workers and humans via the environment. In reaching this conclusion, RAC noted that the risk management measures implemented by the Applicant follow the hierarchy of control principles and so were evaluated to be appropriate. Therefore, RAC did not propose any additional conditions to those described in the Application.

14. Having evaluated RAC's assessment, I agree with its conclusion that the risk management measures and operational conditions as described in the Original Application are appropriate and effective in limiting the risks to workers and humans via the environment. In reaching this conclusion, I note that all of the workplace exposures and environmental releases referred to in the Original Application and RAC Opinion take place in Great Britain.

Monitoring arrangements

15. The RAC Opinion identified minor shortcomings in the exposure estimates for workers and humans via the environment due to the low number of measurements provided by the Applicant. One shortcoming identified by RAC was that the Applicant only provided modelled data for maintenance activities. RAC noted that major maintenance is carried out over a five day period every year, and minor maintenance activity is carried out every nine weeks over an eight hour shift. RAC also found shortcomings in the Applicant's estimate of emissions to the air as they were based on only three measurements. RAC further noted that although the release to wastewater is considered to be negligible, the Applicant did not provide a worst-case estimate.

16. The RAC Opinion noted that the Applicant said some activities are carried out on the production line and other activities are carried out in a control room located 20 metres away from the production line where Cr(VI) is used. The Applicant did not provide modelled or actual data for emissions from activities carried out in the control room. The Applicant argued that there are expected to be zero emissions from activities carried out in the control room because it

is located 20 metres away from the production line where Cr(VI) is used. The Applicant further argued that it would not be possible for liquid droplets of Cr(VI) to reach the control room due to low vapour pressure. However, the RAC Opinion stated that this was not well substantiated by the measurements provided by the Applicant.

17. To address these minor shortcomings, RAC recommended additional monitoring arrangements. Having evaluated RAC's assessment, and the risk management measures and operational conditions described in the Original Application, I agree that additional monitoring arrangements are required. I believe that these monitoring arrangements will address the minor shortcomings in the exposure estimates for workers and humans via the environment. In reaching this conclusion, I note that all of the risk management measures and operational conditions referred to in the Original Application and RAC Opinion would take place in Great Britain.

Socio-economic analysis

18. The SEAC Opinion concluded that SEAC had no substantial reservations on the quantitative and qualitative elements of the Applicants' assessment of the benefits and the monetised risks to human health associated with the continued use of Cr(VI). I agree with this conclusion and consider it to be applicable to the benefits and risks in respect of Great Britain.

19. The SEAC Opinion concluded that the quantified estimated benefits due to avoided profit losses and job losses are over one hundred million euros[7]. In reaching this conclusion, SEAC considered that the estimated profit losses are conservative because they considered the Applicant's most likely non-use scenario to be optimistic. SEAC agreed with the Applicant that the most likely non-use scenario would be that the Applicant would cease production and customers would change to suppliers outside of Great Britain. The non-use scenario predicted that the Applicant would continue to work on substitution and regain all their customers if substitution is successful. SEAC considered it unlikely, though, that the Applicant would be able to regain all their customers once an alternative is developed. SEAC also concluded that the Applicant had correctly valued the social impacts of unemployment in a non-use scenario. Having evaluated the Original Application and the SEAC Opinion, I agree with these conclusions and I note that all quantified benefits are applicable to Great Britain.

20. The SEAC Opinion concluded there were further potential socio-economic impacts if the authorisation was not granted that were assessed qualitatively. This included disruption to the Applicant's supply chain and additional costs to the Applicant's customers in moving to a more expensive or less preferred

[7] The Original Application was submitted to ECHA while the UK was still an EU member state and therefore provided all monetary calculations in euros. On the date of decision, the Bank of England exchange rate was EUR/GBP = 0.8372.

product. I agree with SEAC's conclusions and consider them to be applicable to Great Britain.

21. The SEAC Opinion identified minor shortcomings in the Applicant's monetisation of health impacts due to the Applicant's lack of consideration of cancer treatment costs. SEAC also identified shortcomings resulting from the Applicant's use of outdated survival statistics that did not take account of workers diagnosed with cancer after leaving employment, which meant no latency effects were accounted for in respect of these workers. However, SEAC considered that these shortcomings were minor and would likely have a marginal impact or no impact at all on the health impact assessment. Therefore, SEAC concluded that the health impact assessment was accurate and in line with ECHA guidance. Having considered SEAC's assessment of the shortcomings identified, I agree with SEAC's conclusion that the health impact assessment was accurate and I consider this applicable to Great Britain.

22. The SEAC Opinion acknowledged that for workers and for the general population exposed to Cr(VI), the Applicant quantified risks using ECHA's note on the dose-response relationship for the carcinogenicity of Cr(VI) (2013, RAC-27) [8] . The Applicant also used ECHA's guidance on Socio Economic Analysis for the valuation of fatal and non-fatal cases of lung cancer, as well as the ECHA note on the reference willingness to pay values for monetising the health impacts of chemicals[9]. Based on these calculations, the SEAC Opinion stated that the maximum monetised excess risk of continued use was forty thousand euros[10] over the review period. Having considered the applicant's calculations and SEAC's analysis, I agree with this assessment.

23. The SEAC Opinion concluded that the Applicant's assumption that lung cancer is the only relevant end point for human health impacts via the environment was reasonable for on-site and nearby workers. This is because it is assumed that food and drinking water for these workers is not locally sourced and therefore oral intake is not relevant. Having considered this conclusion and the information on oral intake given in the application I agree with this conclusion. I note that any potential exposure for on-site and nearby workers would take place in Great Britain.

24. Having considered the information in the Original Application, and SEAC's conclusions, I conclude that the quantitative benefits in respect of Great

[8] Application for Authorisation: Establishing a Reference Dose Response Relationship for Carcinogenicity of Hexavalent Chromium, (RAC 27/2013/06 Rev. 1, agreed at RAC 27, dated 4 December 2013).
[9] Guidance on the preparation of socio-economic analysis as part of an application for authorisation (version 1, dated January 2011); Willingness-to-pay values for various health endpoints (SEAC/32/2016/05.2 Rev.1, dated 12 April 2017).
[10] The Original Application was submitted to ECHA while the UK was still an EU member state and therefore provided all monetary calculations in euros. On the date of decision, the Bank of England exchange rate was EUR/GBP = 0.8372.

Britain are likely to be at least one hundred million euros. I also conclude that the monetised health impact in Great Britain is likely to be approximately forty thousand euros. In addition, I conclude that the qualitatively assessed benefits described in the Original Application are relevant to Great Britain.

Conclusion on whether the benefits outweigh the risks

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

    a. The likely significant quantified benefits such as avoided profit losses and job losses;

    b. The likely significant qualitative benefits such as avoided disruption to supply chains;

    c. The likely low quantified risk of continued use.

Alternatives

26. The SEAC Opinion concluded that there were no alternative substances or technologies with the same function and a similar level of performance that are safer, and technically and economically feasible for the Applicant, by the time of adoption of the ECHA Opinion. In reaching this conclusion, SEAC noted the Applicant's past research and development efforts, which included international collaboration and membership of an international consortium. SEAC further noted that the Applicant's assessment of alternatives was transparent and showed the Applicant's commitment to substitution at an industrial scale.

27. SEAC considered that the Applicant's assessment was sufficient to understand why the Applicant only considered substitution with one alternative; trivalent chromium coating technology (TCCT). SEAC agreed with the Applicant that because the development of the TCCT process is at an advanced stage, assessing other potential alternatives would be more costly and take longer than continuing research and development efforts into TCCT. SEAC found the Applicant's explanation of the issues they faced in implementing substitution credible. Therefore, SEAC concluded that TCCT was not a technically feasible alternative for the Applicant at the time the ECHA Opinion was finalised and that the Applicant's timelines for substitution were credible.

28. SEAC agreed with the Applicant that moving to the TCCT process is not economically feasible for them, because the investment costs are so high. SEAC noted that the production costs for TCCT and ECCS are equivalent and the sale value to the Applicant's customers are equivalent and therefore the applicant will be at a financial loss in moving to TCCT. Nevertheless, I note that the Applicant is continuing to work on substitution to TCCT.

29. Having evaluated SEAC's assessment on the economic and technical feasibility of alternatives, I agree with SEAC's conclusions and consider that

the Applicant has discharged its burden of proof in demonstrating the absence of suitable alternatives. In reaching this conclusion, I have considered SEAC's assessment of the technical and economic feasibility of alternative substances already on the market and consider it to be applicable to Great Britain.

Review period

30. The SEAC Opinion recommended that the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 should end on 31 December 2027. In making this recommendation, SEAC considered the time needed for the Applicant to develop and implement a suitable alternative. This includes time for the Applicant to carry out long-term testing and for the Applicant's customers to run qualification tests on TCCT materials to ensure TCCT has equivalent technical characteristics to ECCS. SEAC acknowledged that the Applicant's substitution plan is dependent on technical weaknesses in the implementation of the TCCT process being resolved. Therefore, SEAC's recommendation also included time for the Applicant to prepare and submit a review report if required.

31. I agree with that recommendation. In reaching this conclusion, I have considered SEAC's conclusion that the substitution timelines proposed by the Applicant are reasonable considering the resources and time period needed for substitution. I consider that SEAC's assessment is applicable to Great Britain.

Conclusion

32. 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.

33. Scottish and Welsh Ministers have given their consent to this decision in accordance with Articles 4A and 64(8) of EUR 2006/1907.

Minister Jo Churchill

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