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 0211-01

UK REACH authorisation numbers:

Authorisation number	Authorisation holder	Authorised use
UKREACH/22/01/0 [chromium trioxide] UKREACH/22/01/1 [sodium dichromate]	Tata Steel UK Ltd.	Use of Chromium Trioxide and Sodium Dichromate for Passivation of Electrolytic Tinplate (ETP)

Preliminary Matters

- Chromium trioxide and sodium dichromate are listed in Annex 14 to EUR 2006/1907 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH)[1]. As such, they are 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').
- Sodium dichromate was included in Annex XIV to Regulation (EC) No 1907/2006 because of its carcinogenicity (category 1B, 'may cause cancer'),

[1] References to 'EUR 2006/1907' are to the retained version of Regulation (EC) No 1907/2006, as amended. 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.

mutagenicity (category 1B, ‘may cause genetic defects’) and reproductive toxicity (category 1B, ‘may damage fertility/the unborn child’).

- Hexavalent chromium (‘Cr(VI)’) is the form of chromium in chromium trioxide and sodium dichromate.
- The Application is made by:

  Tata Steel UK Ltd. of Tata Steel, Trostre Works, Llanelli, Camarthenshire, S. Wales, SA14 9SD (‘the Applicant’).
- On 3 December 2019, the Applicant made an application for authorisation (‘the Original Application’) to the European Chemicals Agency (ECHA) for the use of chromium trioxide and sodium dichromate for passivation of electrolytic tinplate (ETP).
- On 28 December 2020, ECHA sent the consolidated opinions 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 and sodium dichromate in one site in Great Britain and one site in the Netherlands.
- 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. Authorisation is granted in accordance with Article 60(4) of EUR 2006/1907 for the following use of chromium trioxide and sodium dichromate as set out in the table above titled ‘UK REACH authorisation numbers’:

   Use of chromium trioxide and sodium dichromate for passivation of electrolytic tinplate (ETP)
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. If the authorisation holder implements the dissolution of chromium trioxide and sodium dichromate (workplace control scenario 8 (WCS 8) as described in the chemical safety report[5] in the Original Application), they must immediately conduct static control measurements. Further static control measurements must then be taken as part of the monitoring programme referred to in subparagraph (a) while WCS 8 remains in place.

c. The authorisation holder must conduct a monitoring programme for Cr(VI) emissions to the air. 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[6] 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.

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[3] This is a reference to the chemical safety report dated 28 November 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] WCS 8 is described in sections 9 and 10 of the chemical safety report dated 28 November 2019 submitted by the Applicant as part of the Original Application.

[6] "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).

d. The information gathered through the measurements referred to in subparagraphs (a) to (c) and the contextual information associated with all 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. Any additional risk management measures or operational conditions must be implemented in accordance with the hierarchy of control principles[7].

e. 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 necessary further steps identified in accordance with subparagraph (d) 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(e).

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. Further information provided by the Applicant regarding the benefits arising from the use within Great Britain (England, Wales and Scotland).

   e. That in the Original Application and the ECHA Opinion, the information and data on the risks were site specific. Only the information on the risks in respect of the Wales site is relevant to the decision for Great Britain (England, Wales and Scotland).

Reasons

[7] 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).

9. In its opinion, RAC confirmed that it is possible to determine a derived no-effect level (DNEL) for the reproductive toxicity of sodium dichromate in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006. Therefore, regarding its toxicity to reproduction, sodium dichromate is a threshold substance. RAC concluded that the risk to reproductive effects from the use of sodium dichromate applied for is adequately controlled provided that the risk management measures and operational conditions described in the Original Application and the Chemical Safety Report are fully applied.

10. However, RAC also confirmed that it is not possible to determine a DNEL for the carcinogenic or mutagenic properties of chromium trioxide and sodium dichromate. Therefore, chromium trioxide and sodium dichromate are substances for which it is not possible to determine a threshold.

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

12. 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: workers

13. Chromium trioxide and sodium dichromate present a risk to human health due to their carcinogenic and mutagenic properties. Sodium dichromate may also be toxic for reproduction when its use is not adequately controlled.

Risk management measures and operational conditions

14. The RAC Opinion concluded that the Applicant has demonstrated that for both chromium trioxide and sodium dichromate, the risk management measures and operational conditions as described in the Original Application are appropriate and effective in limiting the risks to workers. Therefore, RAC did not propose any additional conditions to those already described in the Original Application. In reaching this conclusion, RAC noted that for all relevant exposure routes in respect of sodium dichromate, the risk of reproductive effects is considered to be adequately controlled. Therefore, RAC concluded that the assessment of carcinogenic risk is central to the risk-benefit analysis for authorisation purposes.

15. The RAC Opinion stated that the Applicant had estimated carcinogenic risks in accordance with the RAC reference dose response relationship for

carcinogenicity of Cr(VI)[8]. RAC concluded that the Applicant's risk characterisation might be an overestimate. This is because workers not engaged in any specific tasks related to Cr(VI) exposure were included in the highest risk calculations. However, RAC noted that any such overestimation of the risk does not change the risk characterisation.

16. Having evaluated RAC's assessment, and the risk management measures and operational conditions described in the Original Application, I agree that no additional conditions are required. In reaching this conclusion, I have considered the need for risk management measures and operational conditions in respect of the use of chromium trioxide and sodium dichromate in Great Britain.

Monitoring arrangements

17. The RAC Opinion concluded that there were minor shortcomings in the exposure estimates carried out by the Applicant, because the exposure assessment for workers was principally based on modelled data. RAC noted that the Applicant took some effort to underpin the modelled data with monitoring data from their sites as well as pooled data from an international consortium and a German MEGA database[9]. RAC noted further minor shortcomings due to the small dataset of Cr(VI) measurements for the measured data at the site in Great Britain. Therefore, RAC recommended additional monitoring arrangements.

18. Having evaluated RAC's assessment, I agree that monitoring arrangements are required. I believe that the recommended monitoring arrangements will address the minor shortcomings in the workplace exposure estimates for the site in Great Britain and uncertainties created by the Applicant's reliance on modelled data. In reaching this conclusion, I have considered the need for monitoring arrangements in respect of the use of chromium trioxide and sodium dichromate in Great Britain.

<u>Risks to human health: via the environment</u>

Risk management measures and operational conditions

19. The RAC Opinion concluded that the Applicant has demonstrated that the risk management measures and operational conditions described in the Original Application are appropriate and effective in limiting the risks to human health via the environment. RAC therefore did not propose any additional conditions to those described by the Applicant.

[8] RAC 27/2013/06 Rev. 1, agreed at RAC 27

[9] Institut für Arbeitsschultz's (IFA) exposure database "Measurement data relating to workplace exposure to hazardous substances" (**M**essdaten zur **E**xposition gegenüber **G**efahrstoffen am **A**rbeitsplatz" in German; the underlying data were measured by stationary sampling at German workplaces between 2000 and 2009).

20. In reaching this conclusion, RAC noted that oral exposure via drinking water and fish was taken into account. RAC also noted that for air emissions, the exposure assessment carried out by the Applicant can be considered a worst-case estimate. This is because measurements on chromium generally (rather than Cr(VI) specifically) were used for the estimates.

21. Having evaluated RAC's assessment, and the risk management measures and operational conditions described in the Original Application, I agree that no additional conditions are required. In reaching this conclusion, I have considered the need for risk management measures and operational conditions in respect of the use of chromium trioxide and sodium dichromate in Great Britain.

Monitoring arrangements

22. The RAC Opinion concluded that there were shortcomings in the exposure estimates in the Original Application because the exposure assessment for humans via the environment was principally based on modelled data. RAC noted further shortcomings due to the small dataset in respect of Cr(VI) measurements at the site in Great Britain. RAC stated that the exposure assessment should be based on site-specific data for humans via the environment. Therefore, RAC recommended additional monitoring arrangements.

23. Having evaluated RAC's assessment, I agree that monitoring arrangements are required. I believe the recommended monitoring arrangements will address the shortcomings in the lack of site-specific measurements on emissions to air from the site in Great Britain. In reaching this conclusion, I have considered the need for monitoring in respect of the use of chromium trioxide and sodium dichromate in Great Britain.

<u>Socio-economic analysis</u>

24. 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 chromium trioxide and sodium dichromate. I agree with this conclusion and consider it to be applicable to the benefits and risks in respect of Great Britain.

25. The SEAC Opinion concluded that the quantified estimated benefits due to avoided profit losses, job losses and increased CO_2 emissions are less than two hundred and seventy four million euros[10]. In reaching this conclusion, SEAC considered the Applicant's main non-use scenario was credible. This scenario predicted that 45-65% of the Applicant's customers would import ETP from Asia, increasing their costs and CO_2 emissions. It predicted, in a

[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.

best case scenario, that the rest of their customers could switch to different packaging materials produced in the EU potentially including some produced by the Applicant. However, the non-use scenario also predicted that as a result of lower demand and loss of sales, the Applicant could have to shut down both sites because the profits would no longer cover their fixed costs. Having evaluated the Original Application and the SEAC Opinion, I agree with SEAC's conclusions.

26. The SEAC Opinion concluded there were further potential socio-economic impacts if the authorisation was not granted that were assessed qualitatively. This included impacts relating to the Applicant's customers having to use ETP from elsewhere or different packaging. The use of different packaging could have a cumulative effect on retailers, consumers and importers due to the increased cost and decreased shelf life of products. SEAC also noted the potential need for the Applicant to restructure production, including the potential for relocation and closure, and the Applicant's loss of competitiveness in the market. I agree with SEAC's conclusions and consider them to be applicable to Great Britain.

27. The SEAC Opinion acknowledged that for workers and those exposed to Cr(VI) through the environment, the Applicant quantified risks using ECHA's note on the dose-response relationship for the carcinogenicity of Cr(VI) (2013, RAC-27) [11]. However, SEAC recalculated the health impacts assessed by the Applicant based on the risk characterisation proposed by RAC (see paragraph 15) to give lower excess risk values. Based on these calculations, the SEAC Opinion stated that the monetised excess risk of continued use in respect of the site in Wales was less than thirteen thousand euros[12] over the review period. Having considered SEAC's analysis and the information in the Original Application, I agree with SEAC's conclusion and consider that it is applicable to the risks in Great Britain.

28. When considering Great Britain only, the Applicant provided a breakdown of the quantified impacts in respect of Great Britain showing total aggregated socio-economic benefits of less than one hundred and twenty million euros[13] over the review period. Having considered the information provided by the Applicant, and SEAC's conclusions, I conclude that the quantitative benefits in respect of Great Britain are likely to be less than one hundred and twenty million euros. I also conclude that the monetised health impact in Great Britain is likely to be less than thirteen thousand euros. In addition, I conclude that

[11] 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.

[12] 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.

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the qualitatively assessed benefits described in the Original Application are relevant to Great Britain.

Conclusion on whether the benefits outweigh the risks

29. 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, avoided import costs to the Applicant's customers, avoided job losses and avoided CO_2 emissions;

    b. The likely significant qualitative benefits such as avoided closure and relocation costs, avoided loss of the Applicant's market competitiveness and avoided impacts on the Applicant's customers, retailers and consumers;

    c. The likely low quantified risk of continued use.

Alternatives

30. 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 at the time of the adoption of the ECHA Opinion. In reaching this conclusion, SEAC noted that the Applicant's assessment of alternatives was transparent and included not only alternative substances and processes, but also alternative substrates and packaging materials. SEAC further noted that the Applicant's substitution plan clearly outlined the actions needed to complete substitution, the timetable for implementing the changes and the current status of the substitution schedule.

31. SEAC accepted the Applicant's position that an alternative must result in a product with the same technical characteristics associated with Cr(VI). SEAC agreed with the Applicant that the most viable alternative to ETP is chromium free passivation alternative (CFPA). CFPA is the only potential alternative that the Applicant identified that fulfils all the technical characteristics of ETP except customer acceptance. SEAC noted that CFPA requires full shelf-life testing and that initial trials of CFPA failed due to detinning of the can in the Applicant's customer's retorting processes. Furthermore, SEAC noted that production lines will need to be converted gradually in line with the Applicant's customers' gradual adoption of CFPA. Therefore, SEAC found that CFPA would not currently be a technically feasible alternative for the Applicant.

32. SEAC noted that the process of substitution to CFPA will involve research and development costs as well as implementing new production lines, which would have high economic costs to the Applicant that would not be recovered. Therefore, SEAC agreed with the Applicant that due to the costs of implementation, CFPA would not be an economically feasible alternative for the Applicant before 2027.

33. Having evaluated SEAC's assessment on the technical and economic feasibility of alternatives for the Applicant, 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 for the Applicant and consider it to be applicable to Great Britain.

Review period

34. The SEAC Opinion recommended 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 noted that the Applicant has already begun the substitution process to CFPA and has involved their downstream users in their substitution efforts. SEAC also noted that the substitution to CFPA requires further research and development activities and will be dependent on the behaviour of the Applicant's downstream users. SEAC also noted that the Applicant is already covered by an existing authorisation for the same use that will expire in 2024 and therefore the Original Application was to extend that authorisation period. SEAC concluded that the substitution to CFPA would not be complete before that authorisation expires in 2024.

35. 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 the substitution. I consider that SEAC's assessment is applicable to Great Britain.

Conclusion

36. 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 and sodium dichromate referred to in paragraph 2, and that there are no suitable alternative substances or technologies.

37. 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