EUROPEAN
COMMISSION

Brussels, 8.5.2024
C(2024) 2864 final

COMMISSION IMPLEMENTING DECISION

of 8.5.2024

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to SRG Global IBI, S.L. for certain uses of chromium trioxide

(Only the Spanish text is authentic)

COMMISSION IMPLEMENTING DECISION

of 8.5.2024

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to SRG Global IBI, S.L. for certain uses of chromium trioxide

(Only the Spanish text is authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[1], and in particular Article 64(8) thereof,

Whereas:

(1) Chromium trioxide is listed in Annex XIV to Regulation (EC) No 1907/2006 and uses of that substance are subject to the authorisation requirement in Article 56(1), point (a), of that Regulation.

(2) On 13 August 2020, SRG Global IBI, S.L. (‘the applicant’) submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for certain uses of chromium trioxide. The uses for which authorisation was sought are the chromium trioxide-based etching as pre-treatment step for electroplating of plastics for transportation applications (‘use 1’) and the functional chrome plating with decorative character for transportation applications (‘use 2’).

(3) The European Chemicals Agency sent the opinions on the application for use 1[2] and use 2[3] adopted by its Committee for Risk Assessment (‘RAC’) and its Committee for Socio-economic Analysis (‘SEAC’) to the Commission pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006. On 10 September 2021, the Commission received the opinions.

(4) In its opinions, RAC concluded that it is not possible to determine a derived no-effect level for the carcinogenic properties of chromium trioxide in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore chromium trioxide is a substance for which it is not possible to determine a threshold for the purposes of

[1] OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj.

[2] https://echa.europa.eu/documents/10162/2ad5320a-3882-433b-b12f-fb59c4cf1834.

[3] https://echa.europa.eu/documents/10162/ce88f4e3-3306-b1e6-a37c-3cbff792aa1d.

Article 60(3), point (a), of that Regulation. As a result, Article 60(2) of Regulation (EC) No 1907/2006 does not apply to that substance. Therefore, an authorisation may only be granted with respect to that substance under paragraph 4 of that Article.

(5) In its opinions on uses 1 and 2, RAC concluded that the risk management measures and the operational conditions described in the application, and further detailed by the applicant at RAC's request, are appropriate and effective to limit the risk to workers and to members of the general population, who could potentially be exposed via the environment, posed by the use of chromium trioxide described in the application. However, in order to address some shortcomings in the exposure estimation and to provide information on the trends in exposure and emissions over the authorisation period, RAC recommended to carry out monitoring programmes for occupational inhalation exposure to, and environmental release of, hexavalent chromium (Cr(VI)). Having evaluated RAC's assessment, the Commission agrees with that conclusion and recommendations. However, the Commission notes that the estimated excess cancer risk values for workers are higher than for most other comparable applications for authorisation for the use of hexavalent chromium (Cr(VI)) substances. Although the Commission acknowledges that those values are conservative estimates of the most likely excess risk values, taken for the purpose of carrying out a risk-benefit analysis, it considers appropriate to set out the measures concerning occupational exposure recommended by RAC as conditions for authorisation.

(6) In its opinions on uses 1 and 2, SEAC concluded that it has no substantial reservations on the quantitative and qualitative elements of the applicant's assessment of the benefits and the monetised risks to human health associated with the continued uses of the substance. Taking into account SEAC's assessment of the socio-economic analysis, RAC's conclusion that the risk management measures and operational conditions are appropriate and effective to limit the risk, the estimated monetised risk of cancer associated with the continued uses in the order of tens of thousands of euro per year for both uses, the estimated monetised socio-economic benefits of the continued uses due to avoided loss of profits and jobs, as well as to avoided costs for dismantling the existing plants and relocating outside the European Economic Area, at minimum in the order of millions of euro per year for both uses, the qualitatively assessed additional socio-economic benefits of the continued uses due to avoided know-how loss for the production of electroplated products, as well as any additional negative distributional impact, the Commission concludes that the applicant has demonstrated that the socio-economic benefits of the continued use of chromium trioxide described in the application outweigh the risk to human health and the environment arising from these uses.

(7) A suitable alternative should be safer, available, and technically and economically feasible. Where suitable alternatives are available in the Union, but not technically or economically feasible for the applicant or its downstream users, the applicant is required to submit a substitution plan. An alternative that provides the functionality and level of technical performance necessary for the use applied for should be considered to be technically feasible. Certain potential alternatives may provide the functionality but at some loss of performance or in a manner that involves technical compromises that would impair the functionality. In such cases, unless justified by particular circumstances, the Commission should not consider a potential alternative to be technically feasible for the applicant where the applicant has demonstrated that it, or its downstream users, are not able to accommodate such losses of performance or

technical compromises by applying a reasonable additional effort, taking into account the circumstances of the case.

(8) In its opinions on uses 1 and 2, SEAC concluded that there were no suitable alternative substances or technologies available for the applicant by the time of adoption of the opinions. The Commission, having evaluated SEAC's assessment and all relevant information available, notes that the identified alternatives to chromium trioxide providing the overall functionality for both uses have been implemented in the Union, are commercially available and are likely to become also technically and economically feasible for the applicant in the future. However, the Commission acknowledges that, without further research and development, the shortlisted alternatives provide a loss of performance in terms of functionalities such as coating adhesion, etching topography, corrosion resistance and surface appearance, thus not meeting customers' specifications. Therefore, the Commission agrees with SEAC's conclusion that there are currently no suitable alternatives for the applicant, but concludes that suitable alternatives are available in the Union.

(9) In its opinions on uses 1 and 2, SEAC concluded that the substitution plan submitted by the applicant is credible and consistent with the analysis of alternatives and the socio-economic analysis. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and, taking into account the availability of suitable alternatives in the Union for uses 1 and 2 and the obligation to submit a substitution plan, considers that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternative substances or technologies.

(10) The Commission recalls that the aim of the authorisation system is to ensure that substances of very high concern are progressively replaced by suitable alternative substances or technologies where these are available and technically and economically viable. The Commission also acknowledges that, as the substitution of chromium trioxide progresses, the applicant expects to reduce the overall quantities of that substance used throughout the review period, in accordance with the figures provided by the applicant to the Commission. Therefore, the Commission considers it appropriate to set out as a condition for authorisation that the quantity of chromium trioxide used in the use for which authorisation is sought should be reduced in line with the figures provided by the applicant to the Commission, in order to ensure that the substitution strategy is duly implemented and to facilitate the enforcement of that obligation.

(11) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the uses of chromium trioxide described in the application, provided that the risk management measures and operational conditions described in the chemical safety report, as well as the conditions set out in this Decision, are fully applied.

(12) The Commission has based its assessment on all relevant scientific evidence currently available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, concluded on the basis of a sufficient amount of material and reliable information. Nevertheless, additional scientific evidence would allow the Commission to perform its assessment on a more robust or broad evidentiary basis in the future. Hence, it is appropriate to require additional exposure and emission information be submitted.

(13) In its opinion on use 1, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 should be until the end of

2032. The Commission agrees with that recommendation, considering the relevant elements from RAC's and SEAC's assessments and, in particular, RAC's conclusion that the risk management measures and operational conditions are appropriate and effective to limit the risk, SEAC's conclusions on the monetised risk to human health and on the socio-economic benefits of the continued use of the substance, the long investment cycles, the applicant's ongoing research and development efforts, as well as the high performance requirements and regulatory approvals in the automotive sector. More specifically, the Commission considers that the applicant's strategy to reduce the quantity of chromium trioxide used during the review period, as reflected in the figures provided by the applicant to the Commission, is a key factor to agree with SEAC's recommendation on the review period.

(14) In its opinion on use 2, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 should be until the end of 2027. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, RAC's conclusion that the risk management measures and operational conditions are appropriate and effective to limit the risk, SEAC's conclusions on the monetised risk to human health and on the socio-economic benefits of the continued use of the substance, the lack of suitable alternatives within a shorter timeline, the applicant's ongoing research and development efforts, as well as the high performance requirements and regulatory approvals in the automotive sector.

(15) The language used to describe the risk management measures and operational conditions in the application for authorisation may be different from the official language of the Member State where the uses take place. Therefore, in order to facilitate supervision and enforcement of compliance with the authorisation, it is appropriate to require the authorisation holder to submit, upon request, a brief summary of those risk management measures and operational conditions to the competent authority of that Member State in an official language of that Member State.

(16) This Decision does not affect the obligation of the authorisation holder to ensure that a use of a substance does not adversely affect human health or the environment, having regard to the principle set out in Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, this Decision does not affect the obligation of the authorisation holder under Article 60(10) of that Regulation to ensure that the exposure is reduced to as low a level as is technically and practically possible or the obligation of the employer under Article 4(1), and Article 5, of Directive 2004/37/EC of the European Parliament and of the Council[4] to reduce the use of carcinogens or mutagens or reprotoxic substances at the place of work, in particular by replacing it, in so far as is technically possible, and to prevent workers' exposure to a risk to their health or safety. This Decision does not affect the application of Union law in the area of health and safety at work, in particular Council Directives 89/391/EEC[5], 92/85/EEC[6], 94/33/EC[7],

[4] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50, ELI: http://data.europa.eu/eli/dir/2004/37/oj).

[5] Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1, ELI: http://data.europa.eu/eli/dir/1989/391/oj).

98/24/EC[8] and Directive 2004/37/EC, or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

(17) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC[9] or Directive 2010/75/EU[10] of the European Parliament and of the Council, nor any obligation to comply with emission limit values set to achieve compliance with the environmental quality standards established by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[11] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[12]. Compliance with the provisions of this Decision does not necessarily imply compliance with any emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.

(18) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS DECISION:

Article 1

An authorisation is hereby granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following uses of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0):

Authorisation number	Authorised use
REACH/24/11/0	Chromium trioxide-based etching as pre-treatment step for electroplating of plastics for transportation applications

---

6 Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 348, 28.11.1992, p. 1, ELI: http://data.europa.eu/eli/dir/1992/85/oj).

7 Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work (OJ L 216, 20.8.1994, p. 12, ELI: http://data.europa.eu/eli/dir/1994/33/oj).

8 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11, ELI: http://data.europa.eu/eli/dir/1998/24/oj).

9 Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1, ELI: http://data.europa.eu/eli/dir/2008/50/oj).

10 Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17, ELI: http://data.europa.eu/eli/dir/2010/75/oj).

11 Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1, ELI: http://data.europa.eu/eli/dir/2000/60/oj).

12 Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84, ELI: http://data.europa.eu/eli/dir/2008/105/oj).

REACH/24/11/1	Functional chrome plating with decorative character for transportation applications

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[13], and to the conditions set out in Article 2.

Article 2

1. The authorisation shall be subject to the conditions set out in paragraphs 2 to 6.

2. As regards the authorisation bearing number REACH/24/11/0, the authorisation holder shall reduce the total annual quantity of chromium trioxide used for the authorised uses, by the following percentages of the total annual quantity of that substance used in 2020, as compared to the total annual quantity of that substance used in 2020, at the latest by the following dates:

   (a) a reduction of 95% by 31 December 2029;

   (b) a reduction of 96% by 31 December 2030;

   (c) a reduction of 97% by 31 December 2031

   (d) a reduction of 97% by 31 December 2032.

   The authorisation holder shall, upon request, provide the relevant documentation, including the reduction progress to the competent authority of the Member State where the authorised use takes place.

3. The authorisation holder shall carry out a monitoring programme measuring occupational exposure to Cr(VI). Those measurements shall:

   (a) take place at least annually, or more frequently if a significant increase of chromium trioxide consumption takes place on site. The frequency of the measurements shall be sufficient to capture any potential increase in exposure of workers to Cr(VI);

   (b) be based on relevant standard methodologies or protocols;

   (c) ensure a sufficiently low limit of quantification;

   (d) comprise personal and static inhalation exposure sampling;

   (e) be representative of all the tasks with possible exposure to Cr(VI), including maintenance tasks, the operational conditions and risk management measures for each of these tasks, and the total number of workers that are potentially exposed;

   (f) include the determination of background concentrations at the plating line, the loading and unloading working areas and the on-site wastewater treatment plant working area;

   (g) be recorded with contextual information about the tasks performed during sampling.

4. The authorisation holder shall use the information gathered via the measurements referred to in paragraphs 2 and 3 and related contextual information to confirm and

[13] https://ec.europa.eu/docsroom/documents/48475.

review, at least annually, the effectiveness of operational conditions and risk management measures in place. While doing so, the authorisation holder shall also review and, if needed, update the assessment of the combined exposure for the different groups of workers. If needed, the authorisation holder shall introduce measures to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically possible, in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

5. As regards the authorisation bearing number REACH/24/11/1, the authorisation holder shall finalise by 8 May 2025, and afterwards when new information becomes available, a study to assess the feasibility to upgrade the dosing system to allow the use of liquid chromium trioxide solution instead of solid chromium trioxide flakes for the concentration adjustment in electroplating baths (workers contributing scenario 5 in the chemical safety report) and to upgrade and further automate the sampling of the etching and electroplating baths, in accordance with the hierarchy of control principles, and shall act in accordance with the outcome of that study.

6. The authorisation holder shall document and keep the information obtained in accordance with paragraph 3, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the review and any action taken in accordance with paragraphs 4 and 5. The authorisation holder shall also make that information available, including pseudonymised or aggregated biomonitoring results, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 3

1. As regards the authorisation bearing numbers REACH/24/11/0, the review period shall expire on 31 December 2032.

   The authorisations bearing number REACH/24/11/0 shall cease to be valid on 31 December 2032 if the review report for that use has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 30 June 2031.

2. As regards the authorisation bearing number REACH/24/11/1, the review period shall expire on 31 December 2027.

   The authorisation bearing number REACH/24/11/1 shall cease to be valid on 31 December 2027 if the review report for that use has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 30 June 2026.

Article 4

1. The monitoring arrangements set out in paragraphs 2 to 5 shall apply.

2. The authorisation holder shall carry out a monitoring programme measuring the environmental releases of Cr(VI). Those measurements shall:

   (a) comprise air emission measurements, to be carried out at least annually or more frequently if a significant increase of the chromium trioxide consumption takes place on site and shall be sufficiently frequent to capture any potential increase in emissions of Cr(VI);

   (b) comprise wastewater emission measurements, to be carried out at least quarterly;

(c) be based on relevant standard methodologies or protocols;

(d) be representative of the operational conditions and risk management measures used at the site where the authorised uses take place;

(e) ensure a sufficiently low limit of quantification;

(f) be recorded with contextual information associated with each set of measurements.

3. The authorisation holder shall use the information gathered via the measurements referred to in paragraph 2 and related contextual information to confirm and review, at least annually, the effectiveness of operational conditions and risk management measures in place. While doing so, the authorisation holder shall also review and, if needed, update its assessment of the exposure of the general population via the environment. If needed, the authorisation holder shall introduce measures to further reduce Cr(VI) emissions to the environment to as low a level as technically and practically possible.

4. The authorisation holder shall document and keep the information obtained in accordance with paragraph 2, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the review, and any action taken in accordance with paragraph 3. The authorisation holder shall make that information available, upon request, to the competent authority of the Member State where the authorised uses take place.

5. The authorisation holder shall document the steps taken to substitute chromium trioxide in accordance with the substitution plan, including information on the efforts to convince the authorisation holder's customers to accept alternative Cr(VI)-free solutions and justification in case its customers do not accept such solutions. Information on any deviations from the initial substitution plan and on contingency measures taken shall also be included in the documentation. The authorisation holder shall make that documentation available, upon request, to the competent authority of the Member State where the authorised uses take place.

Article 5

Where the authorisation holder submits a review report, it shall include the following:

(a) the information referred to in Article 2(6), as well as in Article 4(4) and (5);

(b) the figures detailing the reduction of the quantity of chromium trioxide, in line with the commitments set out in the updated substitution plan.

Article 6

Upon request, the authorisation holder shall submit a brief summary of the applicable risk management measures and operational conditions described in the chemical safety report to the competent authority of the Member State where the authorised uses take place in an official language of that Member State.

Article 7

This Decision is addressed to SRG Global IBI, S.L., Avenida de la Industria 14, 03440, Ibi Alicante, Spain.

Done at Brussels, 8.5.2024

For the Commission
Thierry BRETON
Member of the Commission