EUROPEAN
COMMISSION

Brussels, 26.7.2024
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COMMISSION IMPLEMENTING DECISION

of 26.7.2024

partially granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Cromaplast S.p.A. for certain uses of chromium trioxide

(Only the English text is authentic)

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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 16 August 2021, Cromaplast S.p.A. ('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 pre-treatment (etch) in the chrome plating process of automotive plastic components ('use 1') and the chrome plating of automotive plastic components ('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 18 August 2022, the Commission received the opinions.

(4) In its opinion, RAC concluded that it is not possible to determine a derived no-effect level for the carcinogenic and mutagenic properties of chromium trioxide in accordance with Section 1.4 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 Article 60(3), point (a), of that Regulation. As a result, Article 60(2) of Regulation (EC) No 1907/2006 does not apply to chromium trioxide

[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/10162/920dee2c-b0fa-dd35-7b98-63cec0d041d9.

[3] https://echa.europa.eu/documents/10162/b3c85605-abc0-0061-1289-0d82054dafcb.

and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.

(5) In its opinion, RAC concluded that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to human health posed by the use of chromium trioxide described in the application.

(6) Nevertheless, in order to further minimise the exposure of workers to hexavalent chromium (Cr(VI)), the hazardous component of chromium trioxide, RAC recommended imposing additional conditions for authorisation for uses 1 and 2. Moreover, RAC recommended imposing monitoring arrangements for uses 1 and 2 with the aim to address certain shortcomings in exposure estimates and to provide information on the trends in exposure and emissions during the authorisation period, for both the occupational exposure to Cr(VI) and the environmental release of it.

(7) Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations. Nevertheless, the Commission notes that the estimated excess cancer risk values for the general population, exposed via the environment, are higher than as regards other comparable applications for authorisation for the use of 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 it appropriate to set out the corresponding measures concerning environmental emissions, recommended by RAC, as a condition for authorisation.

(8) In its opinion, SEAC concluded that the societal costs of not granting an authorisation are higher than the monetised risk to human health arising from the uses of chromium trioxide. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that the applicant has demonstrated that the benefits of the continued uses outweigh the risk to human health arising from those uses.

(9) For an alternative to be suitable it needs to 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 by Article 62(4), point (f), of Regulation (EC) No 1907/2006 to submit a substitution plan.

(10) An alternative that provides the functionality and level of technical performance necessary for the use for which authorisation is sought 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.

(11) In its opinion on use 1, SEAC concluded that there were no technically feasible alternative substances or technologies available for the applicant or in the Union at the time of adoption of the opinion. The Commission, having evaluated SEAC's assessment and the relevant information available, notes that there are indications that other users have already implemented alternatives to chromium trioxide for etching on plastics for the automotive sector. The Commission, however, acknowledges that

without further development and testing, especially under industrial production conditions and for large parts, or because of process reliability issues, the alternatives imply a significant loss of performance in terms of technical requirements and further notes that the applicant has demonstrated that it is not yet able to accommodate such loss of performance and would need more time to implement an alternative and obtain customer validation. The Commission therefore agrees with SEAC's conclusion that there are no suitable alternatives for the applicant but concludes that suitable alternatives are available in the Union.

(12) In its opinion on use 2, SEAC concluded that there were no technically feasible alternative substances or technologies available for the applicant at the time of adoption of the opinion but that there were technically and economically feasible alternatives in the Union. The Commission, having evaluated SEAC's assessment and the relevant information available, notes that alternatives providing the overall functionality needed for use 2 are commercially available in the Union. The Commission, however, recognises that those alternatives imply a significant loss of performance in terms of technical requirements such as corrosion resistance, process reliability as well as colour consistency and that the applicant has demonstrated that it is not yet able to accommodate such loss of performance and would need more time to develop and implement the most promising alternative and obtain customer validation. The Commission therefore agrees with SEAC's conclusion that there are no suitable alternatives for the applicant, and that there are suitable alternatives in the Union.

(13) 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, however, for use 2, the substitution plan does not justify the nine-year review period requested. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers, taking into account the availability of suitable alternatives in the Union for the uses for which authorisation is sought and the substitution plan submitted by the applicant, that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternative substances or technologies.

(14) The applicant has clarified that the scope of uses 1 and 2 covers the etching and electroplating of plastic parts in exterior automotive applications only. Therefore, the Commission considers it appropriate to limit the authorised uses accordingly.

(15) 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. Applicants should therefore make all efforts to achieve a complete phase-out of those substances by the end of a review period. In that respect, the Commission acknowledges that the applicant expects to significantly reduce the overall quantities of chromium trioxide 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 at least 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, without prejudice to a potentially more ambitious reduction allowing a complete phase-out by the end of the review period.

(16) 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 1 and 2 of chromium

trioxide, as limited by this Decision, provided that the risk management measures described in the chemical safety report are applied, and that the operational conditions described therein, as well as the conditions set out in this Decision, are fulfilled.

(17) 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, has 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 the authorisation holder to generate and include additional information about exposure and emissions in the review report.

(18) 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 be set at 12 years, until 16 August 2033. 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 are appropriate and effective in limiting the risk, SEAC's conclusion on the socio-economic benefits and costs of the continued use of the substance, as well as the existence and length of binding contracts and the necessity of customer approvals. 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.

(19) 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 be set at seven years, until 16 August 2028. SEAC considered that for use 2, the substitution plan includes excessive safety margins and does not provide sufficient justification for the nine-year review period requested but warrants seven years only. 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 are appropriate and effective in limiting the risk, SEAC's conclusion on the socio-economic benefits and costs of the continued use of the substance, as well as the time needed to substitute and scale up production.

(20) 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.

(21) This Decision does not affect the obligation of the authorisation holder to ensure that the 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, mutagens or reprotoxic substances at the place of work, in particular by replacing those substances, 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], 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.

(22) 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.

(23) 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,

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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).

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).

HAS ADOPTED THIS DECISION:

Article 1

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

Authorisation number	Authorisation holder	Authorised use
REACH/24/25/0	Cromaplast S.p.A.	Pre-treatment (etch) in the chrome plating process of exterior automotive plastic components
REACH/24/25/1		Chrome plating of exterior automotive plastic components

An authorisation is not granted for the use of chromium trioxide in pre-treatment (etch) and in the chrome plating of interior automotive plastic components.

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 is subject to the conditions set out in paragraphs 2 to 6.

2. As regards the authorisation bearing number REACH/24/25/0, the authorisation holder shall reduce the total annual quantity of chromium trioxide used for the authorised uses, compared to the total annual quantity of that substance used in 2021, at least by the following amounts and at the latest by the following dates:

   (a) 50% by 31 December 2029;

   (b) 51,12% by 31 December 2030;

   (c) 52,25% by 31 December 2031;

   (d) 53,71% 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. By 26 July 2025, and afterwards each time when new relevant information becomes available, the authorisation holder shall carry out a study to assess the feasibility to implement the following measures:

   (a) substitution of solid chromium trioxide flakes with liquid chromium trioxide;

   (b) installation of a closed or automated system to perform the bath adjustment with liquid chromium trioxide in both plating lines;

   (c) installation of a closed or automated system to perform bath sampling tasks in line A1A2;

[13] https://ec.europa.eu/docsroom/documents/51135.

(d) installation of an automatic system of skimming the etching bath and stirring the baths;

(e) coverage of the baths of line A1A2.

The authorisation holder shall act in accordance with the outcome of that study.

4. The authorisation holder shall carry out a monitoring programme measuring the environmental releases of Cr(VI) to the air and wastewater. The programme shall include measurements which shall:

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

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

(c) ensure a sufficiently low limit of quantification;

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

(e) be recorded so as to include contextual information associated with each of the measurements.

5. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraph 4 to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions 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, based on the outcome of this review, the authorisation holder shall introduce measures to further reduce to a level as low as technically and practically possible Cr(VI) emissions into the environment.

6. The authorisation holder shall document and maintain the information from the monitoring programme referred to in paragraph 4, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the reviews and any measure taken in accordance with paragraphs 2, 3 and 5, and shall make that information available, upon request, to the competent authority of the Member State where the authorised uses take place.

Article 3

1. As regards the authorisation bearing number REACH/24/25/0, the review period shall expire on 16 August 2033.

The authorisation shall cease to be valid on 16 August 2033 with regard to the authorised use bearing number REACH/24/25/0 if the authorisation holder has not submitted the review report for that use in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 16 February 2032.

2. As regards the authorisation bearing number REACH/24/25/1, the review period shall expire on 16 August 2028.

The authorisation shall cease to be valid on 16 August 2028 with regard to the authorised use bearing numbers REACH/24/25/1 if the authorisation holder has not submitted the review report for that use in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 16 February 2027.

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 occupational exposure to Cr(VI). The programme shall include measurements which shall:

   (a) take place at least annually, or more frequently if a significant increase of chromium trioxide consumption takes place on site, and shall be sufficiently frequent 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 or static inhalation exposure sampling;

   (e) be representative of all the tasks with possible exposure to Cr(VI), including maintenance tasks (worker contributing scenario 8) and waste and wastewater management (worker contributing scenario 9), of the operational conditions and risk management measures for each of those tasks, and of the total number of workers that are potentially exposed;

   (f) be recorded so as to include contextual information about the tasks performed during occupational exposure sampling.

3. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraph 2 to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions in place. While doing so, the authorisation holder shall also review and, if needed, update its assessment of the combined exposure for the different groups of workers. If needed, based on the outcome of this review, the authorisation holder shall introduce measures to further reduce to a level as low as technically and practically possible workplace exposure to Cr(VI) in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

4. The authorisation holder shall document and maintain the information from the monitoring programme referred to in paragraph 2, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the reviews and any measure taken in accordance with paragraph 3 and shall make that information available, including pseudonymised or aggregated biomonitoring results, 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 Cr(VI) 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

If a review report is submitted, it shall include the following:

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

(b) a detailed justification as to why a complete phase-out of chromium trioxide is not expected to be achieved by the end of the review period;

(c) 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. The brief summary shall be drafted in an official language of that Member State.

Article 7

This Decision is addressed to Cromaplast S.p.A., Via Gasdotto 37, 36078 Valdagno, Italy.

Done at Brussels, 26.7.2024

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION