EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING DECISION

of 25.2.2025

partially granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Cromoplastica C.M.C. S.r.l. 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 18 November 2021, Cromoplastica C.M.C. S.r.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 etching of plastic substrates as a key pre-treatment step for creating an electrically conductive surface to enable electroplating ('use 1') and electroplating of plastic substrates to achieve a protective and durable surface with a silvery finish ('use 2').

(3) The European Chemicals Agency sent the opinions on the application for authorisation 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), third subparagraph, of Regulation (EC) No 1907/2006. On 6 March 2023, 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 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,

[1] OJ L 396, 30.12.2006, p. 1, ELI: https://eur-lex.europa.eu/eli/reg/2006/1907/oj

[2] https://echa.europa.eu/documents/10162/80943111-e8b5-f27f-1235-aad9a35dab54

[3] https://echa.europa.eu/documents/10162/5ff76161-d91a-e1df-da7d-07eeaa10fb2f

Article 60(2) of Regulation (EC) No 1907/2006 does not apply to chromium trioxide and an authorisation may therefore 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 operational conditions described in the application are appropriate and effective in limiting the risk to human health posed by the uses of chromium trioxide described in the application. However, in order to further minimise the exposure of workers to hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide, RAC recommended imposing the carrying out of detailed feasibility studies as condition for authorisation. Moreover, in order to address some shortcomings in exposure estimates and to provide information on the trends in exposure and emissions during the authorisation period, RAC recommended imposing additional monitoring arrangements for both occupational exposure to and environmental release of Cr(VI). Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations.

(6) In its opinions on uses 1 and 2, 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.

(7) 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.

(8) 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.

(9) In its opinion on use 1, SEAC concluded that there were no technically feasible alternative substances or technologies available for the applicant and 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 technically and economically feasible alternatives which are commercially available in the Union, providing the overall functionality of the substance for the use applied for, as also highlighted in one of the two minority positions on the SEAC opinion. However, one alternative does not meet all customer requirements and relevant process functionalities, mostly due to lower performance in terms of surface roughness of the plastic substrate, while the industrial trials have only just started for another alternative, and 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 a

suitable alternative. The Commission therefore agrees with SEAC's conclusion and considers that, although suitable alternatives are available in the Union for use 1, they are not yet technically feasible for the applicant.

(10) In its opinion on use 2, SEAC concluded that there were no technically feasible alternative substances or technologies available for the applicant but that there were technically and economically feasible alternatives 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 an alternative providing the overall functionality needed for the use for which an authorisation is sought is commercially available in the Union and is already being used by other companies in the sector. The Commission, however, recognises that those alternatives imply a loss of performance in terms of requirements of technical nature, such as corrosion and chemical resistance, as well as of decorative nature. The Commission therefore agrees with SEAC's conclusion and considers that, although suitable alternatives are available in the Union for use 2, they are not yet technically feasible for the applicant.

(11) In its opinions on uses 1 and 2, SEAC concluded that the substitution plans submitted by the applicant are credible, noting that they were consistent with the information in the analysis of alternatives and the socio-economic analysis, and that the timelines for substitution presented therein were justified. 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 an authorisation is sought and the substitution plans submitted by the applicant, that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternative substances or technologies.

(12) 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. The Commission also acknowledges that the applicant expects to reduce the overall quantities of that substance used in use 1 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 consumed in use 1 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.

(13) 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 this Decision, provided that the risk management measures described in the chemical safety reports are applied and that the operational conditions described therein, as well as the conditions set out in this Decision, are fulfilled.

(14) Nevertheless, taking into account the information submitted in the application as assessed by SEAC, the Commission considers that the descriptions of the uses for which the authorisation is sought is very broad. In particular, as the Commission notes that the analysis of alternatives provides a number of more detailed applications derived from the applicant's product portfolio that are covered by the use for which

the authorisation is sought, for the sake of legal clarity and to ensure that the use descriptions properly reflect SEAC's assessment, it is appropriate to limit the authorised uses accordingly.

(15) The Commission has based its assessment on all relevant scientific evidence 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 occupational exposure and environmental emissions in the review report.

(16) 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. The Commission agrees with that recommendation, considering the relevant elements from RAC's and SEAC's assessments, in particular RAC's conclusion that the operational conditions and risk management measures are generally appropriate and effective in limiting the risk and SEAC's conclusions on the monetised risk to human health and on the societal benefits of the continued use of the substance. More specifically, the Commission considers that the applicant's strategy to reduce the quantity of chromium trioxide used during the review period is a key factor for its agreement with SEAC's recommendations on the review period.

(17) 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 7 years. 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 and SEAC's conclusion on the monetised risk to human health and on the monetised socio-economic benefits of the use of the substance, as well as SEAC's conclusion on the substitution plan.

(18) 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.

(19) This Decision does not affect the obligation of the authorisation holders 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 holders 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,

[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

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] and 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.

(20) 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.

(21) 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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(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/25/13/0	Cromoplastica C.M.C. S.r.l.	Etching of plastic substrates as a key pre-treatment step for creating an electrically conductive surface to enable electroplating for the applications listed in the Annex
REACH/25/13/1		Electroplating of plastic substrates for the applications listed in the Annex

The authorisation is not granted for the use of chromium trioxide in etching or electroplating of plastic substrates for applications other than the ones listed in the Annex.

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 and 3.

2. As regards the authorisation bearing number REACH/25/13/0, 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 2022, at least by the following amounts and at the latest by the following dates:

   (a) 56% by 31 December 2029;

   (b) 63% by 31 December 2030;

   (c) 71% by 31 December 2031;

   (d) 85% by 31 December 2032;

   (e) 89% by 18 November 2033.

   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 25 February 2026 and afterwards each time when new relevant information becomes available, the authorisation holder shall carry out a study to assess the feasibility of implementing the following measures:

[13] https://ec.europa.eu/docsroom/documents/53818

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

(b) the installation of a closed automated system to perform concentration adjustment of the chromium baths, and of a closed or automatic system to perform bath sampling tasks.

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

The results of that study and information on any action taken shall be made available, upon request, to the competent authority of the Member State where the authorised uses take place.

Article 3

4. As regards the authorisation bearing number REACH/25/13/0 the review period shall expire on 18 November 2033.

The authorisation shall cease to be valid on 18 November 2033 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 18 May 2032.

5. As regards the authorisation bearing number REACH/25/13/1 the review period shall expire on 18 November 2028.

The authorisation shall cease to be valid on 18 November 2028 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 31 May 2027.

Article 4

1. The monitoring arrangements set out in paragraphs 2 to 7 shall apply.

2. The authorisation holder shall carry out a monitoring programme measuring occupational exposure to hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide. 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, 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 exposure sampling.

3. The authorisation holder shall conduct a biomonitoring programme for a representative number of workers potentially exposed to Cr(VI).

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 or 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 set of measurements.

5. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraphs 2, 3 and 4 to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions in place. The authorisation holder shall also review and, if needed, update its assessment of the combined exposure for the different groups of workers and 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 occupational exposure to Cr(VI) and Cr(VI) emissions to the environment. Measures introduced to reduce occupational exposure shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

6. The authorisation holder shall document and maintain the information from the monitoring programmes referred to in paragraphs 2, 3 and 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 paragraph 5 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.

7. The authorisation holder shall document the steps taken to substitute chromium trioxide in accordance with the substitution plans, 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 alternative Cr(VI)-free solutions. information on any contingency measures taken shall also be documented. The authorisation holder shall make such 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) information referred to in Article 2(3) as well as Article 4(6) and (7);

   (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 periods;

(c) figures detailing the reduction of the quantity of chromium trioxide used in the authorised uses, as part of the substitution plans to be submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006.

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:

Cromoplastica C.M.C. S.r.l., Via Gazzo, 11, 24060 Castelli Calepio (BG), Italy.

Done at Brussels, 25.2.2025

For the Commission
Stéphane SÉJOURNÉ
Executive Vice-President

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION