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COMMISSION IMPLEMENTING DECISION

of 24.1.2025

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to MAIER S. COOP., MAIER CZ and MAIER CROMOPLASTICA 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 February 2022, MAIER S. COOP., MAIER CZ and MAIER CROMOPLASTICA S.p.A. ('the applicants') 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 functional chrome plating with decorative character for automotive applications ('use 1') and etching of plastics with chromium trioxide as pre-treatment step for electroplating of plastics for automotive applications ('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), second subparagraph, of Regulation (EC) No 1907/2006. On 21 February 2023, 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,

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

[2] https://www.echa.europa.eu/documents/10162/48b31655-3f29-9eeb-7086-67be38c83088

[3] https://www.echa.europa.eu/documents/10162/38f0a323-479d-76bc-64b5-5d149b53df55

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 use of chromium trioxide described in the application. However, in order to address moderate concerns about the manual handling of solid chromium trioxide, the manual sampling as well as the absence of a continuous control system for the correct functioning of the local exhaust ventilation systems and to ensure that workers perform a sealing test of their respiratory protective equipment, RAC recommended imposing additional conditions for authorisation. Moreover, in order to address moderate shortcomings in the exposure estimates and to corroborate the appropriateness and effectiveness of the operational conditions and risk management measures implemented in accordance with the recommended conditions, RAC recommended imposing additional monitoring arrangements for both the occupational exposure to and the environmental release of hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide.

(6) 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 workers for both uses 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 appropriate to set out the measures concerning occupational exposure, recommended by RAC as monitoring arrangements, as conditions for authorisation.

(7) 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 described in the application. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that the applicants have demonstrated that the benefits of the continued uses outweigh the risk to human health arising from those uses.

(8) 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.

(9) 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.

(10) In its opinion on use 1, SEAC concluded that there were no technically feasible alternative substances or technologies available for the applicants 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 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, but that those alternatives do not provide the required level of performance in terms of corrosion resistance and colour consistency. The Commission considers that the applicants have demonstrated that they are not yet able to accommodate such loss of performance and would need more time to develop and implement one of the most promising alternatives to make it technically feasible. The Commission therefore agrees with SEAC's conclusion and considers that, although suitable alternatives are available in the Union, they are not yet technically feasible for the applicants.

(11) In its opinion on use 2, SEAC concluded that there were no technically and economically feasible alternative substances or technologies available for the applicants and in the Union at the time of the 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 at least for one of the three plastic substrates covered by the use applied for, as also highlighted in one SEAC minority position on the application for authorisation. The Commission, however, recognises that for the other two plastic substrates the identified alternatives imply a loss of performance in terms of appearance, adhesion and temperature resistance. Therefore, the Commission, while agreeing with SEAC's conclusion that there are no suitable alternatives available for the applicants, considers that suitable alternatives are available in the Union.

(12) In its opinions on uses 1 and 2, SEAC concluded that the substitution plans submitted by the applicants are 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 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 applicants, that the applicants have discharged their burden of proof in demonstrating the absence of suitable alternative substances or technologies.

(13) 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 they 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 applicants expect to significantly reduce the overall quantities of chromium trioxide used throughout the review period, in accordance with the figures provided by the applicants to the Commission. Therefore, the Commission considers it appropriate to set out as a condition for authorisation that the quantity of chromium trioxide consumed for the uses for which authorisation is sought should be reduced at least in line with the figures provided by the applicants 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.

(14) 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 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.

(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 holders to generate and include additional information about exposure and 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 7 years. 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 12 years. The Commission agrees with those recommendations, considering the relevant elements from RAC's and SEAC's assessments and, in particular, RAC's conclusions that the current risk management measures and operational conditions are appropriate and effective in limiting the risk, SEAC's conclusion on the risk to human health and on the socio-economic benefits of the continued use of the substance as well as the time required to develop and transition to the identified alternatives. More specifically, the Commission considers that the applicants' 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 periods.

(17) 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 holders 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.

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

[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).

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.

(19) 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.

(20) 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 to the following persons for the following uses of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0)*:*

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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).

Authorisation number	Authorisation holder	Authorised use
REACH/25/2/0	MAIER S. COOP	Functional chrome plating with decorative character for automotive applications
REACH/25/2/1	MAIER CZ s.r.o.	
REACH/25/2/2	MAIER CROMOPLASTICA S.p.A.	
REACH/25/2/3	MAIER S. COOP	Etching of plastics with chromium trioxide as pre-treatment step for electroplating of plastics for automotive applications
REACH/25/2/4	MAIER CZ s.r.o.;	
REACH/25/2/5	MAIER CROMOPLASTICA S.p.A.	

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 9.

2. As regards the authorisations bearing numbers REACH/25/2/0, REACH/25/2/1 and REACH/25/2/2, the authorisation holders shall reduce, by 16 February 2029 at the latest, the total annual quantity of chromium trioxide used for the authorised use by at least 90 %, as compared to the total annual quantity of that substance used in 2022.

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

3. As regards the authorisations bearing numbers REACH/25/2/3, REACH/25/2/4 and REACH/25/2/5, the authorisation holders shall reduce the total annual quantity of chromium trioxide used for the authorised use at least by the following percentages, as compared to the total annual quantity of that substance used in 2022, at the latest by the following dates:

   (a) 57 % by 31 December 2029;

   (b) 67 % by 31 December 2030;

   (c) 75 % by 31 December 2031;

   (d) 84 % by 31 December 2032;

[13] https://ec.europa.eu/docsroom/documents/53816

(e) 92 % by 31 December 2033.

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

4. The authorisation holders shall ensure that workers:

(a) are provided with adequate respiratory equipment, which is subjected to a fit test prior to its first use;

(b) always perform a fit check of the seal of their respiratory protective equipment before starting a relevant task;

(c) are adequately supported to undergo the fit test referred to in point (a) and trained to undertake the fit checks referred to in point (b).

5. By 24 January 2026 and afterwards each time that new relevant information becomes available, the authorisation holders shall carry out a study to assess the feasibility of implementing the following measures:

(a) the substitution of solid chromium trioxide flakes by liquid chromium trioxide solution;

(b) the implementation of a closed or automated system to perform bath sampling tasks, where exposure to hexavalent chromium (Cr(VI)) is expected and where currently personal protective equipment is used to limit the risk for workers;

(c) the installation of a system that continuously controls the local exhaust ventilation and automatically triggers an alarm in case the local exhaust ventilation is not functioning properly and the implementation of appropriate and effective measures to reduce the exposure of workers in case the local exhaust ventilation is not functioning properly.

The authorisation holders shall act in accordance with that study.

6. The authorisation holders 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, 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 exposure sampling.

7. The authorisation holders shall conduct a biomonitoring programme for all workers potentially exposed to Cr(VI).

8. The authorisation holders shall use the information gathered by way of the measurements referred to in paragraphs 6 and 7 to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions in place. While doing so, the authorisation holders shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. If needed, based on the outcome of that review, the authorisation holders shall introduce measures to further reduce to a level as low as technically and practically possible occupational exposure to Cr(VI). Such measures shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

9. The authorisation holders shall document and maintain the information from the monitoring programmes referred to in paragraphs 6 and 7, including the contextual information associated with each set of measurements, as well as the information on the outcome and conclusions of the study and reviews and on any measure taken in accordance with paragraphs 5 and 8, 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.

Article 3

1. As regards the authorisations bearing numbers REACH/25/2/0, REACH/25/2/1 and REACH/25/2/2, the review period shall expire on 16 February 2029.

   The authorisation shall cease to be valid on 16 February 2029 with regard to an authorised use in relation to any authorisation holder who has not submitted the review report for that use in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 16 August 2027.

2. As regards the authorisations bearing numbers REACH/25/2/3, REACH/25/2/4 and REACH/25/2/5, the review period shall expire on 16 February 2034.

   The authorisation shall cease to be valid on 16 February 2034 with regard to an authorised use in relation to any authorisation holder who has not submitted the review report for that use in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 16 August 2032.

Article 4

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

2. The authorisation holders 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 sites where the authorised uses take place;

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

3. The authorisation holders 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 holders shall also review and, if needed, update their assessment of the exposure of the general population via the environment. If needed, based on the outcome of that review, the authorisation holders shall introduce measures to further reduce to a level as low as technically and practically possible Cr(VI) emissions to the environment.

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

5. The authorisation holders shall document the steps taken to substitute chromium trioxide in accordance with the substitution plans, including information on the efforts to convince the authorisation holders' customers to accept alternative Cr(VI)-free solutions and justification in case their customers do not accept alternative Cr(VI)-free solutions. Any deviations from the initial substitution plans and information on contingency measures taken shall also be documented. The authorisation holders shall make such documentation available, upon request, to the competent authority of the Member States 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(2), (3) and (9);

(b) the information referred to in Article 4(4) and (5);

(c) 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;

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

(e) an updated risk assessment including external workers potentially exposed to Cr(VI) at the sites where the authorised use takes place.

Article 6

Upon request, the authorisation holders 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:

(1) MAIER S. COOP, Poli. Ind. Arabieta, 48320 Ajangiz, Spain;

(2) MAIER CZ s.r.o., Průmyslová 4259, 79601 Prostějov, Czechia;

(3) MAIER CROMOPLASTICA S.p.A, Via Oslo 3, 24040 Verdellino, Italy.

Done at Brussels, 24.1.2025

For the Commission
Stéphane SÉJOURNÉ
Executive Vice-President

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION