EUROPEAN
COMMISSION

Brussels, 12.5.2025
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COMMISSION IMPLEMENTING DECISION

of 12.5.2025

partially granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to HDO Druckguß- und Oberflächentechnik GmbH and HDO SK s.r.o. for a use 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 23 January 2023, HDO Druckguß- und Oberflächentechnik GmbH and HDO SK s.r.o. ('the applicants') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for a use of chromium trioxide. The use for which authorisation was sought is electroplating (by a long-term contractual supplier) of metal substrates using chromium trioxide to achieve functional surfaces with decorative character.

(3) The European Chemicals Agency sent the opinions[2] on the application 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 20 May 2024, 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/10162/244be7af-8bb9-ff6a-d7fb-1c0cefd1c278

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. However, RAC expressed some concerns regarding the use of solid chromium trioxide, the manual nature of certain tasks and the exposure during cleaning tasks. Therefore, in order to further minimise the exposure of workers to hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide, RAC recommended imposing additional conditions for authorisation. Moreover, in order to address minor shortcomings in the exposure assessment and to corroborate the appropriateness and effectiveness of the operational conditions and risk management measures in place, RAC recommended imposing monitoring arrangements. Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations.

(6) 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 use of chromium trioxide. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that the applicants have demonstrated that the benefits of the continued use outweigh the risk to human health arising from that use.

(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 the 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 the 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, 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 date of adoption of that 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 authorisation is sought is commercially available and is already implemented in the Union, at least for some of the products falling within the scope of the application. The Commission, however, recognises that that alternative implies a loss of performance in terms of colour reproducibility, hardness as well as resistance to chemicals, corrosion, heat and abrasion, and 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 an alternative. Therefore, the Commission 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.

(10) The applicants considered that there are no suitable alternatives in the Union and therefore submitted a research and development plan, instead of a substitution plan. In its opinion, SEAC concluded that the plan submitted provides all the necessary elements and information required, including factors affecting substitution, actions, milestones, timetable, and monitoring, for it to be considered as a substitution plan. The Commission agrees that the research and development plan submitted by the applicants should be considered as a substitution plan provided for in Article 62(4), point (f), of Regulation (EC) No 1907/2006.

(11) In its opinion, SEAC concluded that the substitution plan submitted by the applicants 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 considers, taking into account the availability of suitable alternatives in the Union for the use for which an authorisation is sought and the substitution plan submitted by the applicants, that the applicants have discharged their 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 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 use for which an 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.

(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 use 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.

(14) Nevertheless, taking into account the information submitted in the application as assessed by SEAC, the Commission considers that the description of the use for which the authorisation is sought is very broad. The Commission notes that the analysis of alternatives provides detailed information on the products covered by the use for which the authorisation is sought. Therefore, for the sake of legal clarity and to ensure that the use description properly reflects SEAC's assessment, it is appropriate to limit and reword the authorised use 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, based its conclusions on 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 additional information about exposure and emission to be included in the review report.

(16) In its opinion, 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 and, in particular, RAC's conclusion that the risk management measures and operational conditions are appropriate and effective to limit the risk, SEAC's conclusion on the risk to human health and on the socio-economic benefits of the use of the substance, as well as SEAC's conclusion on the substitution plan. 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 recommendation on the review period.

(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 use takes 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 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[3] 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[4], 92/85/EEC[5], 94/33/EC[6] and 98/24/EC[7] and Directive 2004/37/EC, or

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3 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).

4 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).

5 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) .

6 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).

7 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).

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[8] or Directive 2010/75/EU[9] 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[10] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[11]. 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 use of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0):

Authorisation number	Authorisation holder	Authorised use
REACH/25/22/0	HDO Druckguß- und Oberflächentechnik GmbH	Electroplating of metal substrates to produce functional surfaces with decorative character for the applications listed in the Annex.
REACH/25/22/1	HDO SK s.r.o.	

The authorisation is not granted for the use of chromium trioxide in electroplating of metal substrates to produce functional surfaces with decorative character for applications other than the ones listed in the Annex.

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8 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) .

9 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) .

10 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) .

11 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) .

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[12], 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 4.

2. The authorisation holders shall reduce the total annual quantity of chromium trioxide used for the authorised use, compared to the total annual quantity of that substance used in 2023, by the following amounts and at the latest by the following dates:

   (a) 57% by 31 December 2029;

   (b) 60% by 31 December 2030;

   (c) 63% by 31 December 2031;

   (d) 65% by 31 December 2032;

   (e) 70% by 31 December 2033;

   (f) 85% by 31 December 2034;

   (g) 100% by 23 January 2035.

3. By 12 May 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 with liquid chromium trioxide solutions or the installation of a closed or automated system to perform the dilution of solid chromium trioxide;

   (b) the installation of a closed or automated system to perform any subsequent (re-)filling of the baths with liquid solutions;

   (c) the installation of an automated system to perform concentration adjustment of the chromium baths;

   (d) the installation of a closed or automated system to perform sampling tasks, where exposure to hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide, is expected and where currently personal protective equipment is used;

   (e) the implementation of additional risk management measures and operational conditions in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC to ensure that the exposure to Cr(VI) of workers involved in rare maintenance tasks (worker contributing scenario 8) is at a level as low as technically and practically possible, including, at least, the improvement of cleaning practices.

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

4. The authorisation holders shall document and maintain the information on any measure taken in accordance with paragraphs 3 and shall make that information available, upon request, to the competent authority of the Member State where the authorised use takes place.

[12] https://ec.europa.eu/docsroom/documents/60074

Article 3

The review period shall expire on 23 January 2035.

The authorisation shall cease to be valid on 23 January 2035 in relation to any authorisation holder who has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 23 July 2033.

Article 4

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

2. The authorisation holders shall carry out a monitoring programme for 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.

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

4. 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 use takes place;

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

5. The authorisation holders shall use the information gathered by way of the monitoring programmes 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. 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 and their assessment of the exposure of the general

population via the environment. If needed, based on the outcome of those reviews, the authorisation holders 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 holders 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 information on the outcome and conclusions of the reviews and on 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 use takes place.

7. The authorisation holders shall document the steps taken to substitute chromium trioxide, 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. Information on any contingency measures taken shall also be documented by the authorisation holders. The authorisation holders shall make such documentation available, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 5

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

(a) the study referred to in Article 2(4) and the information referred to in Article 4, paragraphs (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 period;

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

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 use takes place. The brief summary shall be drafted in an official language of that Member State.

Article 7

This Decision is addressed to:

(1) HDO Druckguß- und Oberflächentechnik GmbH, Halberstädter Straße 7-13- 33106 Paderborn, Germany;

(2) HDO SK s.r.o., Prostredná 14, 90701 Myjava, Slovakia.

Done at Brussels, 12.5.2025

For the Commission
Stéphane SÉJOURNÉ
Executive Vice-President

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION