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COMMISSION IMPLEMENTING DECISION

of 8.11.2024

partially granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Electro-Durocrom S.L. 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/EC¹, 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 15 February 2022, Electro-Durocrom S.L. ('the applicant') 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 the industrial use for the hard chromium plating of moulds, dies and custom made finished parts on any metal base, in order to provide hardness, wear resistance, corrosion resistance, demoulding properties, low friction ratio, for the manufacture of high-quality metal parts in several sectors as automotive, pharmaceutical, food and packaging industries.
- (3) The European Chemicals Agency sent the opinions² 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 30 May 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

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/f5f30e1e-d0f6-6a0f-b591-31c213f9d78d>.

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 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 not appropriate and effective in limiting the risk to human health posed by the use of chromium trioxide described in the application. In particular, as regards occupational exposure, RAC expressed concerns regarding the risk resulting from the open, manual nature of the dipping and immersion of the parts, removal operations and sampling tasks, the unclear separation of the activities as well as concerns related to the implementation of the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC of the European Parliament and of the Council³. Therefore, RAC recommended imposing additional conditions for authorisation, including technical improvements to the operational conditions and risk management measures. Moreover, in order to address moderate shortcomings in exposure and emissions estimates and to corroborate the appropriateness and effectiveness of the risk management measures and operational conditions in place, RAC recommended imposing additional monitoring arrangements for both the occupational exposure to hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide, and the environmental release of it.
- (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 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 measures concerning occupational exposure, recommended by RAC as monitoring arrangements, as conditions for authorisation. Moreover, the Commission notes that the applicant detected a certain concentration of Cr(VI) in the wastewater discharged into the collective sewage network and, taking into account the investigation on the source of the contamination carried out by the applicant, considers it appropriate to impose additional conditions for authorisation to prevent any future Cr(VI) contamination of the wastewater.
- (7) 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 described in the application. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that the applicant has demonstrated that the benefits of the continued use outweigh the risk to human health arising from that use.
- (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

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>).

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 SEAC concluded that there were no technically feasible alternative substances or technologies available for the applicant but that there were technically or 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, acknowledges that the identified alternative is partially in use by the applicant for a limited number of parts and, therefore, can be considered to provide the overall functionality for at least some parts covered by the use applied for. However, the Commission also notes that the identified alternative implies some loss of performance in terms of technical requirements, such as adhesion, hardness and corrosion resistance, and considers that the applicant has demonstrated that it is not yet able to accommodate such loss of performance and would need more time to further develop and implement the identified alternative. 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 applicant.
- (11) In its opinion, SEAC concluded that the substitution plan submitted by the applicant is credible and consistent with the analysis of alternatives. 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 applicant, that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternative substances or technologies.
- (12) 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, 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.
- (13) 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. In particular, the Commission notes that the analysis of alternatives provides more detailed information on the products covered by the use for which an 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 the authorised use accordingly.
- (14) 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 exposure and emissions in the review report.

- (15) 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 7 years. SEAC noted that the 9-year review period requested by the applicant was not warranted, taking into account that the timeline of the substitution plan is not fully justified, but that only 7 years were warranted. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, the additional authorisation conditions imposed to limit the risk based on RAC's conclusions that the current risk management measures and operational conditions are not appropriate and effective in limiting the risk, SEAC's conclusion on the monetised risk to human health and on the socio-economic benefits of the continued use of the substance, as well as SEAC's conclusion on the substitution plan.
- (16) 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 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.
- (17) 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 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/EEC⁴, 92/85/EEC⁵ 94/33/EC⁶, 98/24/EC⁷ and

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>).

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

- (18) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC⁸ or Directive 2010/75/EU⁹ 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 Council¹⁰ or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council¹¹. 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.
- (19) 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 person for the following use of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0):

Authorisation number	Authorisation holder	Authorised use
REACH/24/72/0	Electro-Durocrom S.L.	Hard chromium plating of metal parts for the products listed in the Annex

The authorisation is not granted for the use of chromium trioxide in hard chrome plating of metal parts for products other than those listed in the Annex.

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report¹², and to the conditions set out in Article 2.

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>).

¹² <https://ec.europa.eu/docsroom/documents/54720>

Article 2

1. The authorisation is subject to the conditions set out in paragraphs 2 to 11.
2. Without delay, and at the latest by 8 November 2025, the authorisation holder shall implement additional risk management measures and operational conditions to ensure that exposure to hexavalent chromium (Cr(VI)) is at a level as low technically and practically possible. Such measures shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC and shall include at least the following measures:
 - (a) the segregation of the chrome plating area from other work areas to ensure that workers do not need to be close to the baths during loading and unloading operations;
 - (b) the installation of a system for the remote operation of the hoists to reduce the presence of workers in proximity of the Cr(VI)-containing baths.
3. The authorisation holder shall conduct control measurements to validate the appropriateness and effectiveness of the additional risk management measures and operational conditions implemented in accordance with paragraph 2. If necessary, additional risk management measures or operational conditions shall be implemented to further reduce exposure to Cr(VI) to a level as low as technically and practically possible.
4. Until additional risk management measures and operational conditions as referred to in paragraph 2 are implemented, and the exposure data obtained pursuant to the measurements referred to in paragraph 3 allow for a conclusion that exposure to Cr(VI) is at a level as low as technically and practically possible, the authorisation holder shall ensure that workers involved in the worker contributing scenario 2 'Functional plating', referred to in the chemical safety report, use respiratory protective equipment, taking into account the duration of the tasks and the comfort of the workers during their use.
5. The authorisation holder shall ensure that workers:
 - (a) are provided with adequate respiratory protective 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).
6. By 8 November 2025 and afterwards each time that new relevant information becomes available, the authorisation holder shall carry out a study to assess the feasibility of the installation of a closed or automatic system to perform bath sampling tasks, where exposure to Cr(VI) is expected and where currently personal protective equipment is used to limit the risk for workers.

The authorisation holder shall act in accordance with the outcome of that study.
7. The authorisation holder shall, at least quarterly, perform control measurements at the control point of the cooling system to identify any potential Cr(VI) contamination of the wastewater discharged into the collective sewage network. If necessary, based on the outcome of those measurements, the authorisation holder shall implement

additional measures to prevent Cr(VI) emissions to the wastewater and conduct control measurements to validate the appropriateness of the measures implemented.

8. 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 the latest by 8 May 2025 and afterwards 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 and 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.
9. The authorisation holder shall continue to conduct a biomonitoring programme for all workers potentially exposed to Cr(VI) which shall:
 - (a) take place at least annually;
 - (b) include, as a minimum, a pre-shift urine sample at the beginning of a working week and a post-shift urine sample at the end of the same working week;
 - (c) be based on relevant standard methodologies;
 - (d) be conducted in conjunction with the annual occupational monitoring programme referred to in paragraph 8.
10. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraphs 8 and 9 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 that 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). Such measures shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.
11. The authorisation holder shall document and maintain the information from the measurements referred to in paragraph 7 and the information from the monitoring programmes referred to in paragraphs 8 and 9, 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 2, 3, 4, 5, 6, 7 and 10 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.

Article 3

The review period shall expire on 15 February 2029.

The authorisation shall cease to be valid on 15 February 2029 if the authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 15 August 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 the environmental releases of Cr(VI) to the air. 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 use takes place;
 - (e) be recorded so as to include contextual information associated with each set of measurements.
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 exposure of the general population via the environment. If needed, based on the outcome of that review, the authorisation holder 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 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 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 use takes place.
5. The authorisation holder shall document the steps taken to substitute chromium trioxide, 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 use takes place.

Article 5

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

- (a) the information referred to in Article 2(11) and Article 4(4) and (5);
- (b) an improved exposure assessment for the worker contributing scenario 2 ‘Functional plating’ referred to in the chemical safety report, by splitting it into additional contributing sub-scenarios to cover specific tasks separately, including loading and unloading, manual plating and semi-automated plating.

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

Article 7

This Decision is addressed to:

Electro-Durocrom S.L., Pol. Ind. Can Castells, Avda. Can Castells 9E, 08420 Canovelles (Barcelona), Spain.

Done at Brussels, 8.11.2024

For the Commission
Margrethe VESTAGER
Executive Vice-President

