EUROPEAN
COMMISSION

Brussels, 16.9.2024
C(2024) 6363 final

COMMISSION IMPLEMENTING DECISION

of 16.9.2024

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Talleres Aykrom, S.A., for a use of chromium trioxide

(Only the English text is authentic)

COMMISSION IMPLEMENTING DECISION

of 16.9.2024

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Talleres Aykrom, S.A., for a use of chromium trioxide

(Only the English text is authentic)

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 4 May 2022, Talleres Aykrom, S.A. ('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 functional chrome plating of metallic pieces required in different industrial sectors such as corrugated rolls to meet hardness, wear resistance, corrosion resistance, good surface condition, low friction coefficient and coating adhesion requirements.

(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 25 August 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, 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://www.echa.europa.eu/documents/10162/209ff2b6-f762-1ed9-c8d5-1fbfdddf4008

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, RAC expressed major concerns due to a lack of engineering controls and regarding the way the manual activities are performed in several worker contributing scenarios, resulting in high concentrations of hexavalent chromium (Cr(VI)), the hazardous component of chromium trioxide, in the work environment, and, consequently, in a high dependence on the use of respiratory protective equipment to reduce exposure levels. Therefore, RAC recommended imposing additional conditions for authorisation, including, in particular, the installation of local exhaust ventilation and air abatement systems, a system that continuously controls the correct functioning of the LEV, as well as bath coverage. The Commission notes that the implementation of such ventilation and air abatement systems, as well as the bath coverage, has been finalised after the adoption of the RAC opinion, as communicated by the applicant.

(6) Moreover, RAC recommended monitoring arrangements with the aim to address minor shortcomings in exposure estimates and to provide information on the trends in exposure and emissions during the review period, for both occupational exposure to, and environmental release of, Cr(VI) as well as to obtain reliable further information on the effectiveness of operational conditions and risk management measures implemented as a result of additional conditions.

(7) Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations. Nevertheless, the Commission notes that the estimated excess cancer risk value for workers is higher than as regards other comparable applications for authorisation for the use of Cr(VI) substances. Therefore, the Commission considers it appropriate to set out the measures concerning occupational exposure, recommended by RAC as monitoring arrangements, as a condition for authorisation.

(8) In its opinion, SEAC concluded that the societal costs of not granting an authorisation are higher than the monetised risk to human health arising from the use 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 use outweigh the risk to human health arising from that use.

(9) For an alternative to be suitable it needs to be safer, available, and technically and economically feasible. Where suitable alternatives are available in the Union, but not technically or economically feasible for the applicant or its downstream users, the applicant is required by Article 62(4), point (f), of Regulation (EC) No 1907/2006 to submit a substitution plan. 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.

(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 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, although acknowledging that the identified alternative to chromium trioxide is already being used within the Union for other applications, notes that it is not applicable for the use for which the authorisation is sought, due to the

specific geometries and shapes of the plated items, not allowing to meet the key requirements needed by the applicant, in particular adhesion. The Commission also acknowledges that the alternative requires further development and testing to be considered technically feasible for the specific use applied for. Therefore, the Commission, while agreeing with SEAC's conclusion that there are no suitable alternatives for the applicant, considers that there are no suitable alternatives available in the Union.

(11) 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. Nevertheless, the description of the use authorised by this Decision should be refined as to read 'functional chrome plating of corrugated rolls, industrial plates and manufacturing tool parts required in different industrial sectors to meet hardness, wear resistance, corrosion resistance, good surface condition, low friction coefficient and coating adhesion requirements' for clarity and to align it with the analysis of alternatives.

(12) 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.

(13) 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. The Commission takes note of that recommendation and the relevant elements from RAC's and SEAC's assessments, 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.

(14) However, the Commission notes that, as explained in the analysis of alternatives, the identified alternative is estimated to be fully developed, industrially implemented and qualified by the end of 2028, thus substitution is expected to be achieved by that date. It is therefore appropriate to set a review period until 31 December 2028.

(15) 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.

(16) This Decision does not affect the obligation of the authorisation holder to ensure that the use of a substance does not adversely affect human health or the environment, having regard to the principle set out in Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, this Decision does not affect the obligation of the

authorisation holder under Article 60(10) of that Regulation to ensure that the exposure is reduced to as low a level as is technically and practically possible or the obligation of the employer under Article 4(1) and Article 5 of Directive 2004/37/EC of the European Parliament and of the Council[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], 98/24/EC[7] and Directive 2004/37/EC, or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

(17) 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.

---

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).

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).

(18) 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/24/42/0	Talleres Aykrom, S.A.	Functional chrome plating of corrugated rolls, industrial plates and manufacturing tool parts required in different industrial sectors to meet hardness, wear resistance, corrosion resistance, good surface condition, low friction coefficient and coating adhesion requirements

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 9.

2. Without delay, and at the latest by 16 October 2024, the authorisation holder shall install the following:

   (a) a local exhaust ventilation ('LEV') system based on lip extraction and an effective air abatement system connected thereto that prevents uncontrolled releases of hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide, to the air and minimises releases into the environment;

   (b) a system for covering the baths when the plating process takes place;

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

   Upon installation, and afterwards, the authorisation holder shall ensure that those systems are effective in minimising the workers' exposure and the exposure of the general local population to Cr(VI) by implementing a regular cleaning and maintenance programme of those systems, including their filters.

3. Without prejudice to paragraphs 6 and 7, 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 (a) to (c). If necessary, additional risk management

[12] https://ec.europa.eu/docsroom/documents/55700

measures or operational conditions shall be implemented to further reduce exposure to Cr(VI) to a level as low as technically and practically feasible.

Until the exposure data pursuant to the measurements referred to in the first subparagraph and paragraphs 6 and 7 allow for a conclusion that exposure to Cr(VI) is at a level as low as technically and practically feasible, the authorisation holder shall ensure that directly exposed workers use respiratory protective equipment ('RPE'), taking into account the duration of the tasks and the comfort of the workers during their use.

4. The authorisation holder shall ensure that workers:

(a) are provided with adequate RPE, subjected to a fit test prior to its first use;

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

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

5. By 16 September 2025 and afterwards each time when new relevant information becomes available, the authorisation holder shall carry out a study to assess the feasibility of:

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

(b) the automation of the concentration adjustment of the baths using either solid or liquid chromium trioxide within a closed system;

(c) the implementation of an automated or closed system to perform the bath sampling.

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

6. The authorisation holder shall carry out a monitoring programme measuring occupational exposure to Cr(VI). The programme shall include measurements which shall:

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

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

(c) ensure a sufficiently low limit of quantification;

(d) comprise personal and 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 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 holder shall conduct an annual biomonitoring programme for all workers potentially exposed to Cr(VI). The programme shall include measurements which shall:

(a) include, as a minimum, a pre shift urine sample at the beginning of each working week and a post shift urine sample at the end of each working week;

(b) be based on relevant standard methodologies;

(c) be aligned with the monitoring programme referred to in paragraph 6.

8. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraphs 3, 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 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 the 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) in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

9. The authorisation holder shall document and maintain the information from the monitoring programmes referred to in paragraphs 3, 6 and 7, including the contextual information associated with each set of measurements, as well as the outcome of the study and conclusions of the reviews and 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 use takes place.

Article 3

1. The review period shall expire on 31 December 2028.

2. The authorisation shall cease to be valid on 31 December 2028 if the authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 30 June 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 and wastewater. The programme shall include measurements which shall:

(a) take place at least annually, or more frequently if the production process is modified, 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 the 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 programmes referred to in paragraph 2, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the reviews and any measure taken in accordance with paragraph 3, and shall make that information available, 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 in accordance with the substitution plan, including information on the efforts to convince the authorisation holder's customers to accept alternative Cr(VI)-free solutions and justification in case its customers do not accept alternative Cr(VI)-free solutions. Any deviations from the initial substitution plan and information on 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 information referred to in Article 2(9) and in Article 4(4) and (5).

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:

Talleres Aykrom, S.A., Calle miravalles, nº 37, 01013, Vitoria-Gasteiz, Spain.

Done at Brussels, 16.9.2024

For the Commission
Margrethe VESTAGER
Executive Vice-President

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION