EUROPEAN
COMMISSION

Brussels, 16.9.2024
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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 Gessi S.p.A. and San Marco Rubinetteria S.r.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/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 10 June 2021, Gessi S.p.A. and San Marco Rubinetteria S.r.l. ('the applicants') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for a use chromium trioxide. The use for which authorisation was sought is electroplating of metal substrates with the purpose of creating a long-lasting high durability surface with bright look for kitchen and bathroom sanitaryware (functional plating 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), third subparagraph, of Regulation (EC) No 1907/2006. On 30 September 2022, 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/10162/944dd8a4-9ef6-b7d9-e162-010a5a97da70

and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.

(5) The chemical safety report provided in the application includes only one exposure scenario. However, since the risk management measures and operational conditions differ at the two sites where the use takes place, for legal clarity, it is appropriate to reflect that differentiation by providing two exposure scenarios to be covered by this Decision. Therefore, the site of Gessi S.p.A. should be referred to as exposure scenario 1 ('ES1') and the site of San Marco Rubinetteria S.r.l. as exposure scenario 2 ('ES2').

(6) In its opinion, RAC concluded that the risk management measures and operational conditions in ES1 are appropriate and effective in limiting the risk to human health posed by the use of chromium trioxide described in the application. Nevertheless, 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 some minor shortcomings in exposure estimates and to provide information on the trends in exposure and emissions during the authorisation period, RAC recommended imposing additional monitoring arrangements for both occupational exposure to and environmental release of Cr(VI).

(7) As regards ES2, RAC concluded that the risk management measures and operational conditions in place 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 noted that the risk management measures do not follow the hierarchy of control principles considering that workers operate a manual plating line with fully open chromium plating baths and manually dip the parts as well as the absence of physical segregation between different work areas and the lack or inappropriate use of respiratory protective equipment. Consequently, RAC recommended imposing additional conditions for authorisation. Moreover, in order to address some minor shortcomings in exposure estimates, to provide information on the trends in exposure and emissions during the authorisation period, and to ensure the availability of sufficient data on workers' exposure after the expected increase of the use of chromium trioxide in ES2, RAC recommended imposing additional monitoring arrangements for both occupational exposure to and environmental release of Cr(VI).

(8) Having evaluated RAC's assessment, the Commission agrees with its conclusions and recommendations.

(9) 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 use outweigh the risk to human health arising from that use.

(10) 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.

(11) 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.

(12) 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. The Commission, having evaluated SEAC's assessment and the relevant information available, notes that alternatives providing the overall functionality needed for the use for which authorisation is sought are commercially available in the Union. The Commission, however, recognises that those alternatives imply a loss of performance in terms of requirements of technical nature, such as corrosion resistance, as well as of decorative nature, such as colour consistency and brightness, 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 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.

(13) The applicants consider that there are no suitable alternatives in the Union and therefore submitted a development plan, instead of a substitution plan. In its opinion, SEAC concluded that the plan submitted provides all the necessary elements and information required for a substitution plan, including factors affecting substitution, actions, milestones, timetable, and monitoring, and that, therefore, it should be considered as a substitution plan. The Commission agrees with that conclusion and considers that the 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.

(14) In its opinion, SEAC concluded that the substitution plan 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 assessed, that the applicants have discharged their burden of proof in demonstrating the absence of suitable alternative substances or technologies.

(15) 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.

(16) 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.

(17) 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 12-year review period requested by the applicants was not warranted, taking into account that the substitution plan does not provide concrete milestones and that the duration of some phases of the substitution plan is not properly substantiated, and, therefore, recommended a review period of 7 years. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, RAC's conclusion that the risk management measures and operational conditions are appropriate and effective to limit the risk in ES1 as well as the additional authorisation conditions imposed based on RAC's conclusions that the current risk management measures and operational conditions are not appropriate and effective in limiting the risk in ES2, SEAC's conclusion on the monetised risk to human health and on the socio-economic benefits of the continued use of chromium trioxide, as well as SEAC's conclusion on the substitution plan.

(18) The Commission recalls that the aim of the authorisation system is to ensure that substances of very high concern are progressively replaced by suitable alternative substances or technologies where these are available and technically and economically viable. Applicants should therefore make all efforts to achieve a complete phase-out of those substances by the end of a review period.

(19) 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.

(20) 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'

[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).

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.

(21) 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.

(22) 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):

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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).

Authorisation number	Authorisation holder	Authorised use
REACH/24/44/0	Gessi S.p.A.	Electroplating of metal substrates with the purpose of creating a long-lasting high durability surface with bright look for kitchen and bathroom sanitaryware (functional plating with decorative character)
REACH/24/44/1	San Marco Rubinetteria S.r.l.	

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 and 3.

Article 2

1. The authorisation bearing number REACH/24/44/0 is subject to the conditions set out in paragraphs 2 and 3.

2. 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 implementing the following measures:

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

   (b) the installation of an automated system to perform the bath adjustment;

   (c) the installation of a closed or automated system to perform bath 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 to limit the risk for workers.

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

3. The authorisation holder shall document and keep the information on the outcome and conclusions of the feasibility study and any measure taken in accordance with paragraph 2 and shall make that information available, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 3

1. The authorisation bearing number REACH/24/44/1 is subject to the conditions set out in paragraphs 2 to 7.

2. 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 implementing the following measures:

   (a) the installation of a closed or automated system to perform the bath adjustment and the installation of a closed or automated system to perform

[12] https://ec.europa.eu/docsroom/documents/51559

bath sampling tasks, where exposure to Cr(VI) is expected and where currently personal protective equipment is used to limit the risk for workers;

(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;

(c) automation of the manual plating line;

(d) the segregation of the loading and unloading areas from the plating area, either by the introduction of a physical barrier or by moving the loading and unloading tasks away from the plating area;

(e) the installation of bath covers for all open baths or the segregation of electroplating emission sources to ensure that exposure to Cr(VI) at the plating lines is at a level as low as technically and practically feasible.

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

3. At the latest by 16 March 2026, the authorisation holder shall implement additional risk management measures and operational conditions to ensure that exposure to Cr(VI) is at a level as low technically and practically possible, taking into account the outcome of the feasibility study referred to in paragraph 2. Such measures shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

4. 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 3. 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 is technically and practically feasible.

5. Until adequate technologies or improved operational conditions and risk management measures referred to in paragraph 3 are implemented, and exposure data pursuant to the measurements referred to in paragraph 4 or Article 5(2) and (3) 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 workers performing the tasks related to immersion or dipping of parts into treatment baths, bath sampling and bath concentration adjustment use appropriate respiratory protective equipment (‘RPE’), taking into account the duration of the tasks and the comfort of the workers during its use;

6. The authorisation holders shall ensure that workers:

(a) are provided with adequate RPE, which is 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 test referred to in point (a) and trained to undertake the fit checks referred to in point (b).

7. The authorisation holder shall document and keep the information on the outcome and conclusions of the feasibility study, the information gathered by way of the control measurements referred to in paragraph 4 and information on any measure taken in accordance with paragraphs 2 to 6 and shall make that information

available, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 4

The review period shall expire on 10 June 2028.

The authorisation shall cease to be valid on 10 June 2028 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 10 December 2026.

Article 5

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

2. The authorisation holders shall carry out a monitoring programme measuring occupational exposure to Cr(VI), the toxic component of chromium trioxide. The programme shall include measurements which shall:

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

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

   (c) ensure a sufficiently low limit of quantification;

   (d) comprise personal or static inhalation exposure sampling for worker contributing scenarios with possible exposure, including worker contributing scenario 7 (‘Maintenance of the electroplating line’);

   (e) be representative of all the tasks with possible exposure to Cr(VI), including the tasks with short duration and potential high exposure, the operational conditions and risk management measures for each of such 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 continue to 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 measurements referred to in paragraphs 2, 3 and 4 to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions in place. 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 outcomes of these 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 outcome and conclusions of the reviews and any measure taken in accordance with paragraph 5 and shall make that information available, including pseudonymised or aggregated biomonitoring results, upon request, to the competent authority of the Member State where the authorised use takes place.

7. The authorisation holders shall document the steps taken to substitute chromium trioxide in the form of biannual reports, 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 contingency measures taken shall also be documented. 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 6

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

(a) 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.

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

(c) as regards the authorisation bearing number REACH/24/44/0, the information referred to in Article 2(3), Article 5(6) and Article 5(7).

(d) as regards the authorisation bearing number REACH/24/44/1 the information referred to in Article 3(7), Article 5(6) and Article 5(7).

Article 7

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 8

This Decision is addressed to:

1. Gessi S.p.A., Parco Gessi, Serravalle Sesia, 13037, Vercelli, Italy;

2. San Marco Rubinetteria S.r.l, Via Carducci, 10, 13867 Pray, Italy.

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