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COMMISSION IMPLEMENTING DECISION

of 24.1.2025

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Benoni S.r.l. and Cromatura Cristofoletti s.r.l. for a use of chromium trioxide

(Only the Italian text is authentic)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[1], and in particular Article 64(8) thereof,

Whereas:

(1) Chromium trioxide is listed in Annex XIV to Regulation (EC) No 1907/2006 and uses of that substance are subject to the authorisation requirement in Article 56(1), point (a), of that Regulation.

(2) On 16 November 2022, Benoni S.r.l. and Cromatura Cristofoletti s.r.l. ('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 the functional chrome plating of mechanical components (including hydraulic cylinders, columns, moulds and various machinery parts).

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

[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/f5a8cebc-12ea-4c65-0f86-d245fa9533b9

(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 Benoni S.r.l. should be referred to as exposure scenario 1 ('ES1') and the site of Cromatura Cristofoletti s.r.l. as exposure scenario 2 ('ES2').

(6) In its opinion, RAC concluded that the risk management measures and operational conditions in ES1 and ES2 described in the application are not appropriate and effective in limiting the risk to workers posed by the use of chromium trioxide described in the application. In particular, RAC noted that the risk management measures and operational conditions do not follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC of the European Parliament and of the Council[3], and expressed major concerns about the open baths and the effectiveness of the local exhaust ventilation systems since elevated concentrations of hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide, were measured near the chromium plating baths.

(7) RAC also concluded that, in contrast to ES1, the risk management measures and operational conditions in ES2 described in the application are not appropriate and effective in limiting the risk to the general population, exposed via the environment, posed by the use of chromium trioxide described in the application In particular, RAC expressed concerns about the releases to the air compartment in ES2 due to the unknown efficiency of the risk management measures applied. Consequently, in order to further reduce the exposure of workers to Cr(VI) in both ES1 and ES2, and environmental releases in ES2, RAC recommended imposing additional conditions for authorisation, Moreover, RAC recommended imposing additional monitoring arrangements for both occupational exposure to Cr(VI) and environmental release of it, with the aim of addressing minor shortcomings in exposure and emissions estimates and of corroborating the appropriateness and effectiveness of the risk management measures and operational conditions in place.

(8) Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations. Nevertheless, the Commission notes that, as regards ES2, the estimated excess cancer risk values for the general population, exposed via the environment, 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 environmental emissions, recommended by RAC as monitoring arrangements, as a condition for authorisation for ES2.

(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 described in the application. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that the applicants have

[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.

demonstrated that the benefits of the continued 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 at the time of adoption of the opinion, although those alternatives may only cover a narrow segment of the market served by the applicants. The Commission, having evaluated SEAC's assessment and the relevant information available, notes that there are technically and economically feasible alternatives which are commercially available in the Union, providing the overall functionality of the substance for the use for which an authorisation is sought, but that additional research is needed to improve and adapt the most promising ones in order to eliminate technical limitations, as well as to minimise the loss of performance in terms of hardness, adhesion properties and microcracking. Thus, the Commission considers that the applicants have demonstrated that they are not yet able to accommodate such loss of performance and would need more time to develop and implement the most promising alternatives to make them technically feasible. Therefore, the Commission agrees with SEAC's conclusion and considers that, although suitable alternatives are available in the Union, they are not yet technically and economically feasible for the applicants.

(13) The applicants consider 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 research and development 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 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 submitted by the applicants, 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 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. Nevertheless, for the sake of aligning the authorised use with the information included in the analysis of alternatives as assessed by SEAC, the use description should read 'functional chrome plating of cylinder tubes and piston rods for hydraulic cylinders, columns for hydraulic presses, copper moulds, moulds for rubber manufacturing, and various machinery parts'.

(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 12 years. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, the estimated excess cancer risk values, the additional authorisation conditions imposed to limit the risk based on RAC's conclusion that the existing risk management measures and operational conditions are not appropriate and effective in limiting the risk for workers and for the general population, SEAC's conclusions on the socio-economic benefits and costs of the continued use of the substance, as well as SEAC's conclusion on the substitution plan.

(18) 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 States 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.

(19) 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/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.

(20) 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.

(21) 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	Authorised use

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).

	holder	
REACH/25/5/0	Benoni S.r.l.	Functional chrome plating of cylinder tubes and piston rods for hydraulic cylinders, columns for hydraulic presses, copper moulds, moulds for rubber manufacturing, and various machinery parts
REACH/25/5/1	Cromatura Cristofoletti 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 Articles 2 and 3.

Article 2

1. The authorisation is subject to the conditions set out in paragraphs 2 to 5.

2. Without delay, and at the latest by 24 January 2026, the authorisation holders shall implement the necessary technical improvements to the risk management measures and operational conditions to minimise the concentration of hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide, near the plating baths and to ensure that the exposure of workers to Cr(VI) is at a level as low as is technically and practically possible. Such measures shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

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

   (a) the substitution of solid chromium trioxide flakes with liquid chromium trioxide solution or the installation of a closed or automated system to perform the dissolution of solid chromium trioxide flakes and any subsequent (re-) filling of the baths with liquid solutions;

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

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

5. The authorisation holders shall document and keep the information on the outcome and conclusions of the study referred to in paragraph 4 and on any measure taken in accordance with paragraphs 2, 3 and 4, and shall make that information available,

[12] https://ec.europa.eu/docsroom/documents/58757

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

Article 3

1. The authorisation bearing number REACH/25/5/1 shall be subject to the conditions set out in paragraph 2 to 5.

2. At the latest by 24 April 2025, the authorisation holder shall analyse the results of the monitoring programme measuring the environmental releases of Cr(VI) to the air carried out in 2023 and recalculate the release factor for the air at its site.

   If the release factor is not of the same order of magnitude or lower than the one derived for the authorisation bearing number REACH/25/5/0, the authorisation holder shall conduct a root cause analysis and implement, without delay, appropriate additional risk management measures to reduce the environmental releases of Cr(VI) to the air to a level as low as technically and practically possible.

   The authorisation holder shall conduct control measurements to confirm the impact of any measure taken. The "control measurement – analysis – action" cycle shall be continued until a release factor for the air of the same level of magnitude or lower than in the authorisation bearing number REACH/25/5/0 site is achieved.

3. 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 in chromium trioxide consumption takes place on site, and be sufficiently frequent to capture any potential increase in emission of Cr(VI);

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

   (b) ensure a sufficiently low limit of quantification;

   (c) be representative of the operational conditions and risk management measures used at the site where the authorised use takes place;

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

4. The authorisation holder shall use the information gathered via the measurements referred to in paragraph 3 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 their assessment of the exposure of the general population via the environment. If needed, based on the outcome of this review, the authorisation holder shall introduce measures to further reduce to as low a level as is technically and practically possible Cr(VI) emissions to the environment.

5. The authorisation holder shall document and maintain the information from the monitoring programme referred to in paragraph 3, 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 paragraphs 2 and 4, 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 16 November 2034.

The authorisation shall cease to be valid on 16 November 2034 in relation to any authorisation holders who has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 16 May 2033.

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 programme shall include measurements which shall:

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

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

   (b) ensure a sufficiently low limit of quantification;

   (c) comprise personal or static inhalation exposure sampling;

   (d) 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;

   (e) 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. As regards the authorisation bearing number REACH/25/5/0, 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 a significant increase in chromium trioxide consumption takes place on site, and be sufficiently frequent to capture any potential increase in emission of Cr(VI);

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

   (b) ensure a sufficiently low limit of quantification;

   (c) be representative of the operational conditions and risk management measures used at the site where the authorised use takes place;

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

5. The authorisation holders shall use the information gathered via the measurements referred to in paragraphs 2, 3 and, if applicable, 4 of this Article 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, if applicable, their assessment of the exposure of the general population via the environment. If needed, based on the outcome of such 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, if applicable, 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, if applicable, 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 accordance with the substitution plan, including information on the efforts to convince the authorisation holders' customers to accept alternative Cr(VI)-free solutions and justification in case their customers do not accept alternative Cr(VI)-free solutions. Any deviations from the initial substitution plan and information on contingency measures taken shall also be documented. The authorisation holders shall make such documentation available, upon request, to the competent authority of the Member States where the authorised use takes place.

Article 6

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

(a) the information referred to in Article 2(5), as well as Article 5(6) and (7);

(b) as regards the authorisation bearing number REACH/25/5/1, in addition, the information referred to in Article 3(5).

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

Article 8

This Decision is addressed to:

(1) Benoni S.r.l., Via Romolo Gessi 24, 25135 Brescia, Italy;

(2) Cromatura Cristofoletti s.r.l., Via per Ospitaletto 171, 25046 Cazzago San Martino, Italy.

Done at Brussels, 24.1.2025

For the Commission
Stéphane SÉJOURNÉ
Executive Vice-President