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COMMISSION IMPLEMENTING DECISION

of 24.6.2025

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Meoni e Bartoletti S.p.A. 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 19 August 2022, Meoni e Bartoletti S.p.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 for the hard chrome plating of hydraulic and pneumatic cylinders for various applications, and inner tubes of motorbike front suspension for the automotive industry.
- (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), third subparagraph, of Regulation (EC) No 1907/2006. On 2 April 2024, the Commission received the opinions.
- (4) In its opinion, RAC concluded that it is not possible to determine a derived no-effect level for the carcinogenic and mutagenic properties of chromium trioxide in accordance with Section 1.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore chromium trioxide is a substance for which it is not possible to determine a threshold for the purposes of Article 60(3), point (a), of that Regulation. As a result, Article 60(2) of Regulation (EC) No 1907/2006 does not apply to chromium trioxide

¹ OJ L 396, 30.12.2006, p. 1, ELI: <http://data.europa.eu/eli/reg/2006/1907/oj>.

² <https://www.echa.europa.eu/documents/10162/c24b44c7-8f9e-6988-ecce4-ade890464abb>

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

- (5) The chemicals safety report provided in the application includes only one exposure scenario. However, since the risk management measures and occupational conditions differ at the two sites where the use of chromium trioxide described in the application 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 currently operating site in Pistoia, Italy should be referred to as exposure scenario 1 ('ES1') and the future site in Pianoro, Italy as exposure scenario 2 ('ES2').
- (6) In its opinion, RAC concluded that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to human health posed by the use of chromium trioxide described in the application. However, RAC expressed moderate concerns regarding the manual sampling and the absence of a continuous control system for the correct functioning of the local exhaust ventilation systems in ES1. Consequently, 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 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 occupational exposure to Cr(VI) and environmental release of it, as specified in the monitoring arrangements.
- (7) Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations. Nevertheless, the Commission notes that ES2 is not yet in operation and that RAC's conclusions, as regards that site, are therefore based only on existing occupational exposure and environmental emissions information from ES1 site and the information provided by the applicant that the risk management measures and operational conditions at ES2 will be similar to those in place at ES1. To ensure that the risk management measures and operational conditions at the future ES2 will be appropriate and effective to limit the risk to human health, the implementation of the necessary risk management measures and operational conditions should be set as a condition for authorisation for that site. Moreover, to confirm the risk assessment for ES2 once that site will become operational, the Commission considers appropriate to set out the measures concerning occupational exposure and environmental emissions, recommended by RAC as monitoring arrangement, as a condition for authorisation for ES2.
- (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.
- (10) 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.

- (11) 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, notes that although certain identified alternatives are used for other automotive applications in the Union, they are not applicable for the use applied for, due to the specific design features of hydraulic and pneumatic cylinders and front suspensions produced by the applicant, needing functional requirements, such as hardness, layer thickness and lubrication retention, which affect wear and abrasion resistance critical for the service life of vehicles. 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.
- (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 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.
- (13) 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.
- (14) 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 agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, RAC's conclusion on the appropriateness of the risk management measures and operational conditions and the estimated excess cancer risk values, SEAC's conclusions on the socio-economic benefits and costs of the continued use of the substance.
- (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 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.

- (16) This Decision does not affect the obligation of the authorisation holders 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 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 Council³ 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 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/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

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

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.

- (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/25/31/0	Meoni e Bartoletti S.p.A.	Hard chrome plating of hydraulic and pneumatic cylinders for various applications, and inner tubes of motorbike front suspension for the automotive industry

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 Articles 2 and 3.

Article 2

1. The authorisation is subject to the conditions set out in paragraphs 2 to 4.
2. By 24 June 2026, 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 automatic system to perform bath sampling tasks, where exposure to Cr(VI) is expected;
 - (b) the installation of a system that continuously controls the local exhaust ventilation and automatically triggers an alarm in case the local exhaust ventilation is not functioning properly and the implementation of appropriate and effective measures to reduce the exposures of workers in case the local exhaust ventilation is not functioning properly.The authorisation holders shall act in accordance with the outcome of that study.
3. 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;

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/58775>

- (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 tests referred to in point (a) and trained to undertake the fit checks referred to in point (b).
4. The authorisation holder shall document and keep the information on the outcome and conclusions of the feasibility study referred to in paragraph 2 and any measure taken, 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. As regards ES2, the authorisation shall be subject to the conditions set out in paragraphs 2 to 7.
2. The authorisation holder shall implement the necessary risk management measures and operational conditions in accordance with the hierarchy of control principles to ensure that the exposure to Cr(VI) is at a level as low as technically and practically possible, taking into account of the outcome of the feasibility study referred to in Article 2(2).
3. The authorisation holder shall carry out a monitoring programme measuring occupational exposure to Cr(VI). The programme shall include measurements which shall:
 - (a) be carried out without delay, and no later than 3 months after the facility becomes operational and thereafter at least annually, or more frequently if a significant increase of chromium trioxide consumption takes place on site, and shall be sufficiently frequent to capture any potential increase in exposure of workers to Cr(VI);
 - (b) be based on relevant standard methodologies or protocols;
 - (c) ensure a sufficiently low limit of quantification;
 - (d) comprise personal or static inhalation exposure sampling;
 - (e) be representative of all the tasks with possible exposure to Cr(VI), including maintenance tasks, of the operational conditions and risk management measures for each of those tasks, and of the total number of workers that are potentially exposed;
 - (f) be recorded so as to include contextual information about the tasks performed during exposure sampling.
4. The authorisation holder shall implement and conduct a biomonitoring programme for a representative number of workers potentially exposed to Cr(VI).
5. 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) be carried out without delay, and no later than 3 months after the facility becomes operational and thereafter 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) include the sampling at the emission point of the internal exhaust ventilation of the reduction tank;
 - (c) be based on relevant standard methodologies or protocols;
 - (d) ensure a sufficiently low limit of quantification;
 - (e) be representative of the operational conditions and risk management measures used at the site where the authorised use takes place;
 - (f) be recorded so as to include contextual information associated with each set of measurements.
6. The authorisation holder shall use the information gathered via the measurements referred to in paragraphs 3 to 5 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 and its 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 technically and practically possible occupational exposure to Cr(VI) and emissions to the environment of it. Measures introduced to reduce occupational exposure shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.
7. The authorisation holder shall document and maintain the information from the monitoring programmes referred to in paragraphs 3 to 5, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the reviews and measure taken in accordance with paragraphs 2 and 6, 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 4

The review period shall expire on 19 August 2029.

The authorisation shall cease to be valid on 19 August 2029 if the authorisation holders have not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 19 February 2028.

Article 5

1. As regards ES1, the monitoring arrangements set out in paragraphs 2 to 6 apply.
2. The authorisation holder shall carry out a monitoring programme measuring occupational exposure to Cr(VI). The programme shall include measurements which shall:
 - (a) takes place at least annually, or more frequently if a significant increase of chromium trioxide consumption takes place on site, and shall be sufficiently frequent to capture any potential increase in exposure of workers to Cr(VI);
 - (b) be based on relevant standard methodologies or protocols;
 - (c) ensure a sufficiently low limit of quantification;
 - (d) comprise personal or static inhalation exposure sampling;

- (e) be representative of all the tasks with possible exposure to Cr(VI), including maintenance tasks, of the operational conditions and risk management measures for each of those tasks, and of the total number of workers that are potentially exposed;
 - (f) be recorded so as to include contextual information about the tasks performed during exposure sampling.
- 3. The authorisation holder shall conduct a biomonitoring programme for a representative number of workers potentially exposed to Cr(VI).
- 4. 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 shall be sufficiently frequent to capture any potential increase in emission of Cr(VI);
 - (b) include the sampling at the emission point of the internal exhaust ventilation of the reduction tank;
 - (c) be based on relevant standard methodologies or protocols;
 - (d) ensure a sufficiently low limit of quantification;
 - (e) be representative of the operational conditions and risk management measures used at the site where the authorised use takes place;
 - (f) be recorded so as to include contextual information associated with each set of measurements.
- 5. The authorisation holder shall use the information gathered via the measurements referred to in paragraphs 2 to 4 to review, at least annually, the 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 and its 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 technically and practically possible occupational exposure to Cr(VI) and emissions to the environment of it. 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 holder shall document and maintain the information from the monitoring programmes referred to in paragraphs 2 to 4, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the reviews and 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.

Article 6

If a review report is submitted, it shall include the information referred to in Article 2(4), 3(7) and 5(6).

Article 7

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 8

This Decision is addressed to:

Meoni e Bartoletti S.p.A., Via Gora e Barbatole 272, 51100 Pistoia (PT), Italy.

Done at Brussels, 24.6.2025

For the Commission
Stéphane SÉJOURNÉ
Executive Vice-President

