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COMMISSION IMPLEMENTING DECISION

of 26.7.2024

**granting an authorisation under Regulation (EC) No 1907/2006 of the European
Parliament and of the Council to Monroe Czechia s.r.o. 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 subjected to the authorisation requirement in Article 56(1), point (a), of that Regulation.
- (1) On 18 November 2021, Monroe Czechia s.r.o. ('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 shock absorber rods.
- (2) 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 20 December 2022, the Commission received the opinions.
- (3) In its opinions, 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://echa.europa.eu/documents/10162/0e834ce2-f8da-24cd-492f-557894bd6630>.

- (4) 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.
- (5) Nevertheless, in order to further minimise the exposure of workers to hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide, RAC recommended additional conditions, including a study on the feasibility of using the liquid form of chromium trioxide instead of the solid one and the implementation of automated bath adjustment and bath sampling systems. In addition, in order to remedy some minor shortcomings due to the absence of measured data for specific worker contributing scenarios, RAC also recommended monitoring arrangements.
- (6) Having evaluated RAC's assessment, the Commission agrees with its conclusions and recommendations. Nevertheless, the Commission notes that the estimated excess cancer risk values for workers are higher than as regards other comparable applications for authorisation for the use of Cr(VI) substances. Although the Commission acknowledges that those values are conservative estimates of the most likely excess risk values taken for the purpose of carrying out a risk-benefit analysis, it considers it appropriate to set out the measures concerning occupational exposure, recommended by RAC as monitoring arrangements, as a condition for authorisation.
- (7) In its opinion, SEAC concluded that the societal costs of not granting an authorisation are higher than the monetised risk to human health arising from the use of chromium trioxide. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that the applicant has demonstrated that the socio-economic benefits of the continued use of chromium trioxide outweigh the risk to human health arising from that use.
- (8) For an alternative to be suitable it needs to be safer, available, and technically and economically feasible. Where suitable alternatives are available in the Union, but not technically or economically feasible for the applicant or its downstream users, the 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.
- (9) 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 available 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 the shock absorber piston rods produced by the applicant, needing functional requirements, such as corrosion protection, wear and abrasion resistance, to ensure the appropriate performance of shock absorber rods, linked to, among others, safety and service-life requirements. 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.
- (10) 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. For the sake of clarity, the description of the use authorised by this Decision should be ‘functional chrome plating of shock absorber rods for the automotive sector’.

- (11) 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.
- (12) 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 seven years, until November 2028. SEAC noted that the 12 years review period requested by the applicant was not warranted, taking into account that the substitution plan does not provide adequate justifications, among other elements, as regards certain specific phases of the plan which were considered too long compared to similar applications in the automotive sector, but that it warrants seven years only.
- (13) The Commission, while considering that the substitution may take longer than seven years in view of the current technological status concerning the identified alternatives, 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 as well as SEAC’s conclusion on the applicant’s commitment to the substitution of chromium trioxide and both the socio-economic benefits and monetised risk of the continued use of the substance.
- (14) 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.
- (15) 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 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

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>).

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.

- (16) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC⁸ or Directive 2010/75/EU⁹ of the European Parliament and of the Council, nor any obligation to comply with emission limit values set to achieve compliance with the environmental quality standards established by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council¹⁰ or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council¹¹. Compliance with the provisions of this Decision does not necessarily imply compliance with any emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.
- (17) 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):

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/24/29/0	Monroe Czechia s.r.o.	Functional chrome plating of shock absorber rods for the automotive sector

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

Article 2

1. The authorisation is subject to the conditions set out in paragraphs 2 to 6.
2. By 26 July 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 CrO₃ flakes with liquid CrO₃ solutions;
 - (b) the installation of automated or closed systems to perform bath adjustment and bath sampling tasks, where exposure to hexavalent chromium (Cr(VI)) is expected and where workers currently rely on the use of personal protective equipment.

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

Until the implementation of the actions referred to in the second subparagraph is finalised, the authorisation holder shall put in place additional risk management measures to prevent exposure of the workers to chromium trioxide dust.
3. 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/or static inhalation exposure sampling, including for the activities referred to in Working Contributing Scenario 7, 8 and 10;
 - (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 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 conduct an annual biomonitoring programme for a representative number of workers potentially exposed to Cr(VI).

¹² <https://ec.europa.eu/docsroom/documents/49394>.

5. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraphs 3 to 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 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 this 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.
6. The authorisation holder shall document and maintain the information from the monitoring programmes referred to in paragraphs 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 paragraphs 2 and 5 and shall make that information, including pseudonymised or aggregated biomonitoring results, available, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 3

The review period shall expire on 18 November 2028.

The authorisation shall cease to be valid on 18 November 2028 if the authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 18 May 2027.

Article 4

1. The monitoring arrangements set out in paragraphs 2 to 4 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 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 uses 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 this review, the authorisation holder shall introduce measures to further reduce to a level as low as technically and practically possible Cr(VI) emissions to the environment.

4. The authorisation holder shall document and maintain the information from the monitoring programme referred to in paragraph 2, including the contextual information associated with each set of measurements, as well as the 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.

Article 5

If a review report is submitted, it shall include the information pursuant to Article 2(6), as well as in Article 4(4).

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 Monroe Czechia s.r.o., Rychnovská 383, 46342 Hodkovice nad, Mohelkou, Czechia

Done at Brussels, 26.7.2024

For the Commission
Thierry BRETON
Member of the Commission

