EUROPEAN
COMMISSION

Brussels, 8.5.2025
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# COMMISSION IMPLEMENTING DECISION

**of 8.5.2025**

**granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Fabbrica d'armi Pietro Beretta SPA for certain uses 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 13 April 2022, Fabbrica d'armi Pietro Beretta SPA ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for certain uses of chromium trioxide. The uses for which authorisation was sought are chromium trioxide based functional plating of gun barrel bores and auxiliary parts for assault rifles, carbines and pistols for non-civilian uses ('use 1') and chromium trioxide based functional chrome plating of gun barrel bores and auxiliary parts for semi-automatic shotguns, over/under, side-by-side shotguns, pistols and carbines for civilian uses ('use 2').

(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 10 August 2023, the Commission received the opinions.

(4) In its opinion, RAC concluded that it is not possible to determine a derived no-effect level for the carcinogenic 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

[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/10162/10fcfc02-8f18-3f49-feb2-db0598d21d86 https://echa.europa.eu/documents/10162/74cd60a8-7af5-6825-4590-5c4ff056bf26

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.

(5) In its opinion on uses 1 and 2, 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, 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, RAC recommended monitoring arrangements with the aim to address certain shortcomings in exposure estimates and to provide information on the trends in exposure and emissions during the authorisation period, for both the occupational exposure to Cr(VI) and the environmental release of it. Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations.

(6) In its opinion on uses 1 and 2, 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 use outweigh the risk to human health arising from those uses.

(7) 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 the downstream users, the applicant is required by Article 62(4), point (f), of Regulation (EC) No 1907/2006 to submit a substitution plan.

(8) An alternative that provides the functionality and level of technical performance necessary for the use for which an 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 the 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.

(9) Its opinion on uses 1 and 2, SEAC concluded that there were no technically feasible alternative substances or technologies available for the applicant but that there were technically and economically feasible alternatives in the Union at the time of adoption of the opinion. The Commission has evaluated SEAC's assessment and the relevant information available. As regards suitability in the Union, the Commission acknowledges that a potential alternative technology seems to be produced outside the Union, but notes that such claim is not supported by substantial evidence indicating that that technology could be technically and economically feasible in the Union, in particular concerning the compliance with the applicable NATO standards[3] that are required for the purpose of the uses applied for. Moreover, as regards suitability for the applicant, the Commission notes that the shortlisted potential alternatives imply a

[3] STANAG 45162 and STANAG 45173

loss of performance of technical requirements in terms of hardness, corrosion resistance, efficient coating coverage, layer thickness and adhesion properties, and that the applicant has demonstrated that it is not yet able to accommodate such loss of performance and would need more time to develop and implement an alternative. 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 uses 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.

(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 additional information about exposure and emission to be included in the review report.

(12) In its opinion on uses 1 and 2, 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. SEAC noted that the 12 years review period requested by the applicant was not warranted, under the assumption that the existence of technical and economically feasible alternatives in the Union allows the applicant to substitute the uses of the substance in a shorter timeframe than the one requested. The Commission acknowledges that recommendation but considers that the review period requested by the applicant is warranted in view of the absence of suitable alternatives in the Union, and that the time required to conduct research and development activities to implement the most promising alternative is in line with other applications of the same sector[4]. Therefore, taking into account the relevant elements from RAC's and SEAC's assessments, including RAC's conclusion that the risk management measures and operational conditions are appropriate and effective to limit the risk and SEAC's conclusion on the risk to human health and on the socio-economic benefits of the use of the substance, the Commission concludes that a 12 years review period is warranted.

(13) 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 uses take 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.

(14) This Decision does not affect the obligation of the authorisation holder to ensure that a use of a substance does not adversely affect human health or the environment, having

[4] Commission Implementing Decision C(2024) 3970 granting an authorisation to Chrom-Mueller Metallveredelung GmbH for certain uses of chromium trioxide , with a review period of 12 years.

regard to the principle set out in Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, this Decision does not affect the obligation of the authorisation holder under Article 60(10) of that Regulation to ensure that the exposure is reduced to as low a level as is technically and practically possible or the obligation of the employer under Article 4(1) and Article 5 of Directive 2004/37/EC of the European Parliament and of the Council[5] 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[6], 92/85/EEC[7], 94/33/EC[8] and 98/24/EC[9] and Directive 2004/37/EC, or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

(15) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC[10] or Directive 2010/75/EU[11] 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[12] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[13]. Compliance with the provisions of this Decision does not necessarily imply compliance with any emission limit values or environmental quality

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5 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).

6 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).

7 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).

8 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).

9 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).

10 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).

11 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).

12 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).

13 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).

standards under any other provisions of Union law, which may include further or more onerous requirements.

(16) 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 uses of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0):

| Authorisation number | Authorisation holder | Authorised use |
|---|---|---|
| REACH/25/23/0 | Fabbrica d'armi Pietro Beretta SPA | Chromium trioxide based functional plating of gun barrel bores and auxiliary parts for assault rifles, carbines and pistols for non-civilian uses |
| REACH/25/23/1 | | Chromium trioxide based functional chrome plating of gun barrel bores and auxiliary parts for semi-automatic shotguns, over/under, side-by-side shotguns, pistols and carbines for civilian uses |

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[14], and to the condition set out in Article 2.

*Article 2*

The authorisation is subject to the following condition: the authorisation holder shall ensure that workers operating under the worker contributing scenario 6 wear appropriate respiratory protective equipment during baths sampling with exposure to hexavalent chromium (Cr(VI)), without prejudice to the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

*Article 3*

1. The review period shall expire on 13 April 2034.

2. The authorisation shall cease to be valid on 13 April 2034 if the authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 13 October 2032.

*Article 4*

1. The monitoring arrangements set out in paragraphs 2 to 6 apply.

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

[14] https://ec.europa.eu/docsroom/documents/62314

(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);

(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 sampling with possible exposure to Cr(VI).

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 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 or if the production process is modified, and shall be sufficiently frequent to capture any potential increase in emission of Cr(VI);

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

(c) ensure a sufficiently low limit of quantification;

(d) be representative of the operational conditions and risk management measures used at the site where the authorised uses take place;

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

5. The authorisation holder shall use the information gathered by way of the monitoring programmes referred to in paragraphs 2, 3 and 4 and related contextual information 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 that review, the authorisation holder shall introduce measures to further reduce to a level as low as technically and practically possible both occupational exposure to Cr(VI) and 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 holder 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 information on the outcome and conclusions of the reviews and on 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 uses take place.

*Article 5*

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

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

*Article 7*

This Decision is addressed to:

Fabbrica d'armi Pietro Beretta SPA, Via Pietro Beretta 18, 25063 Gardone Valtrompia (BS), Italy.

Done at Brussels, 8.5.2025

*For the Commission*
*Stéphane SÉJOURNÉ*
*Executive Vice-President*

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION