EUROPEAN
COMMISSION

Brussels, 16.9.2024
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COMMISSION IMPLEMENTING DECISION

of 16.9.2024

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Ratier-Figeac 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 10 November 2021, Ratier-Figeac ('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 industrial use of chromium trioxide for functional chrome plating of aircraft safety critical steel ball screws used in airplane's actuators, to decrease friction ratio, and enhance wear, corrosion, and endurance resistance, enabling targeted service life ('use 1'), and industrial use of chromium trioxide for the chromic acid anodizing of aluminium spars as critical surface preparation phase for bonding with aircraft safety critical propeller blades to secure reliable bonding performance and enhance spars corrosion resistance ('use 2').

(3) The European Chemicals Agency sent the opinions on the application for authorisation for use 1[2] and use 2[3] 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 1 March 2023, the Commission received the opinions.

(4) 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

[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/10162/4956cfe0-104f-8b3d-fa8f-68536eb3f93a

[3] https://echa.europa.eu/documents/10162/42334070-e22f-0299-b638-e9ddc807fc83

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.

(5) In its opinions 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 those uses. Nevertheless, in order to further minimise the exposure of workers to hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide, RAC recommended imposing additional conditions for authorisation for uses 1 and 2. Moreover, RAC recommended imposing additional monitoring arrangements for both occupational exposure to and environmental release of Cr(VI), among others to address some minor shortcomings in exposure estimates and to provide information on the trends in exposure and emissions during the authorisation period. Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations.

(6) In its opinions 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 uses 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 uses 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 its 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 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.

(9) In its opinions on uses 1 and 2, SEAC concluded that there were no technically feasible alternative substances or technologies available for the applicant and 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 the identified potential alternatives imply a loss of performance, among others in terms of hardness, adhesion, grindability, wear and corrosion resistance and limited fatigue resistance for use 1, and in terms of adhesion and corrosion for use 2, which would not allow meeting the stringent safety requirements in accordance with the applicable standards. In this regard, the Commission acknowledges 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 one of the most promising alternatives for use 1 and use 2 to

make it technically feasible. The Commission therefore agrees with SEAC's conclusion that there are no suitable alternatives for the applicant and 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 and include additional information about exposure and emissions in the review report.

(12) In its opinion on use 1, 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, RAC's conclusion that the risk management measures are appropriate and effective in limiting the risk, SEAC's conclusions on the socio-economic benefits and costs of the continued use of the substance, as well as the time needed for research, development and implementation of an alternative.

(13) In its opinion on use 2 SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set at 9 years. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, RAC's conclusion that the risk management measures are appropriate and effective in limiting the risk, SEAC's conclusions on the socio-economic benefits and costs of the continued use of the substance, as well as the time needed for research, development and implementation of an alternative.

(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 Council[3] to reduce the use of carcinogens, mutagens or reprotoxic substances at the place of work, in particular by replacing those substances, in so far as is technically possible, and to prevent workers' 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.

(16) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC[4] or Directive 2010/75/EU[5] 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[6] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[7]. 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 uses of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0):

Authorisation number	Authorisation holder	Authorised use
REACH/24/38/0	Ratier-Figeac	Industrial use for functional chrome plating of aircraft safety critical steel ball screws used in airplane's actuators, to decrease friction ratio, and enhance wear, corrosion, and endurance resistance, enabling targeted service life

[4] 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).

[5] 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).

[6] 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).

[7] 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).

REACH/24/38/1	Industrial use for the chromic acid anodizing of aluminium spars as critical surface preparation phase for bonding with aircraft safety critical propeller blades to secure reliable bonding performance and enhance spars corrosion resistance

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[8], and to the conditions set out in Articles 2 and 3.

Article 2

1. As regards the authorisation bearing number REACH/24/38/0, the authorisation is subject to the conditions set out in paragraphs 2 and 3.

2. By 16 September 2025, and afterwards each time when new relevant information becomes available, the authorisation holder shall carry out a study to assess the feasibility of implementing the following measures:

   (a) the automation of the functional hard chrome plating line and coverage of the chromium baths like in the chromic acid anodizing line;

   (b) the substitution of solid chromium trioxide pellets with liquid chromium trioxide solution;

   (c) the installation of a closed/automatic system to perform bath sampling tasks;

   (d) the installation of an automated system to perform the bath adjustment.

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

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

Article 3

1. As regards the authorisation bearing number REACH/24/38/1, the authorisation is subject to the conditions set out in paragraphs 2 and 3.

2. By 16 September 2025, and afterwards each time when new relevant information becomes available, the authorisation holder shall carry out a study to assess the feasibility of implementing the following measures:

   (a) the substitution of solid chromium trioxide pellets with liquid chromium trioxide solutions;

   (b) the installation of a closed/automatic system to perform bath sampling tasks;

   (c) the installation of an automated system to perform the bath adjustment.

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

[8] https://ec.europa.eu/docsroom/documents/52968

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

Article 4

1. As regards the authorisation bearing number REACH/24/38/0, the review period shall expire on 10 November 2033.

   The authorisation shall cease to be valid on 10 November 2033 with regard to the authorised use bearing number REACH/24/38/0 if the authorisation holder has not submitted the review report for that use in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 10 May 2032.

2. As regards the authorisation bearing number REACH/24/38/1, the review period shall expire on 10 November 2030.

   The authorisation shall cease to be valid on 10 November 2030 with regard to the authorised use bearing number REACH/24/38/1 if the authorisation holder has not submitted the review report for that use in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 10 May 2029.

Article 5

1. The monitoring arrangements set out in paragraphs 2 to 5 shall apply.

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

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

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

   (c) ensure a sufficiently low limit of quantification;

   (d) comprise personal or static inhalation exposure sampling;

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

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

(c) ensure a sufficiently low limit of quantification;

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

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

4. The authorisation holder shall use the information gathered via the measurements referred to in paragraphs 2 and 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 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 these reviews, the authorisation holder shall introduce measures to further reduce to a level as low as technically and practically possible occupational exposure to Cr(VI) and Cr(VI) emissions to the environment. Measures introduced to reduce occupational exposure shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

5. The authorisation holder shall document and keep the information from the monitoring programmes referred to in paragraphs 2 and 3, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the review and any measure taken in accordance with paragraph 4 and shall make that information available, upon request, to the competent authority of the Member State where the authorised uses take place.

Article 6

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

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:

Ratier-Figeac, Route de Cahors, 46100 Figeac, France.

Done at Brussels, 16.9.2024

For the Commission
Margrethe VESTAGER
Executive Vice-President

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION