EUROPEAN
COMMISSION

Brussels, 25.2.2025
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COMMISSION IMPLEMENTING DECISION

of 25.2.2025

partially granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Bjerringbro Fornikling A/S 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/EC[1], and in particular Article 64(8) thereof,

Whereas:

(1) Chromium trioxide 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 18 November 2022, Bjerringbro Fornikling A/S ('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 electroplating (by a job plater) of metal substrates using chromium trioxide to achieve functional surfaces.

(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 18 December 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 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/ddb47f95-2171-b5a5-3fb5-555fd410d35b

(5) In its opinion, RAC concluded that the risk management measures and operational conditions described in the application are not appropriate and effective in limiting the risk to human health posed by the use of chromium trioxide described in the application. Consequently, RAC recommended imposing additional conditions for authorisation, including the implementation of physical segregation between the manual tasks and the electroplating lines and the installation of lids. Moreover, RAC recommended monitoring programmes on both occupational exposure to hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide, and environmental releases of it with a view to address shortcomings in the exposure assessment and to corroborate the appropriateness and effectiveness of the risk management measures and operational conditions. Having evaluated RAC's assessment, the Commission agrees with its conclusion.

(6) 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 use outweigh the risk to human health arising from that use.

(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 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 in the Union. The Commission, having evaluated SEAC's assessment and the relevant information available, notes that alternatives providing the overall functionality needed for the use for which authorisation is sought are commercially available in the Union. The Commission, however, recognises that those alternatives imply a loss of performance in terms of requirements of functional nature, including corrosion and chemical resistance, hardness, as well as colour consistency and stability. Thus, the Commission considers 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 to make it technically feasible. The Commission therefore agrees with SEAC's conclusion and considers that, although suitable alternatives are available in the Union, they are not yet technically feasible for the applicant.

(10) The applicant considered that there were 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 applicant should be considered as a substitution plan within the meaning of Article 62(4), point (f), of Regulation (EC) No 1907/2006.

(11) In its opinion, SEAC concluded that the substitution plan submitted by the applicant is credible and consistent with the analysis of alternatives and the socio-economic analysis. 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 applicant, that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternative substances or technologies.

(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 as limited by 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.

(13) Nevertheless, taking into account the information submitted in the application as assessed by SEAC, the Commission considers that the description of the use for which the authorisation is sought is very broad. In particular, the Commission notes that the applicant's analysis of alternatives provides more detailed information on products covered by the use for which authorisation is sought. Therefore, for legal clarity and to ensure that the use description properly reflects SEAC's assessment, the Commission considers it appropriate to limit the authorised use accordingly.

(14) 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 emissions to be included in the review report.

(15) 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 nine years. SEAC noted that the 12-year review period requested by the applicant was not warranted, taking into account that industry's intensifying efforts are expected to speed up substitution, and that the substitution plan does not provide sufficient justification for the duration of some phases, whereas for some other phases a further concomitance would have been possible. SEAC acknowledged that the applicant is looking for an alternative that would not imply the use of boric acid, required in the trivalent chromium (Cr(III)) technology, and considered that, given the early stage of technological development, substitution towards such an alternative seems to require more time than the implementation of other alternatives, such as the Cr(III) technology with boric acid. Therefore, SEAC concluded that a 9-year review period was warranted. The Commission takes into account that conclusion and recommendation, considering the relevant elements from RAC's and SEAC's assessments and, in particular, SEAC's conclusion on the risk to human health and on the socio-economic benefits of the

continued use of the substance, as well as the time needed for research, development and implementation of a boric acid-free alternative.

(16) However, the Commission notes SEAC's doubts about the 12-year review period requested by the applicant as well as the vagueness of the substitution plan concerning collaborations with suppliers, despite the applicant's dependence on the suppliers' research progress in the development of an alternative. The Commission further notes that there is a lack of justification also in support of a 9-year review period, as recommended by SEAC. In that regard, the Commission recalls that the aim of the authorisation system is to ensure that substances of very high concern are progressively replaced by suitable alternative substances or technologies where they are available and technically and economically viable. Applicants should therefore make all efforts to achieve a complete phase-out of the substances included in Annex XIV of Regulation (EC) No 1907/2006 by the end of a review period. Therefore, the Commission, taking into account the potential risks posed by the use of chromium trioxide, considers that a shorter review period is appropriate to ensure that substitution of chromium trioxide is achieved as early as possible.

(17) 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.

(18) 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

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[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).

national binding occupational limit values which may be stricter than the applicable limit values under Union law.

(19) 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.

(20) 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/25/6/0	Bjerringbro Fornikling A/S	Electroplating of metal substrates to achieve functional surfaces for the products listed in the Annex

The authorisation is not granted for the use of chromium trioxide in electroplating of metal substrates to achieve functional surfaces for products other than those listed in the Annex.

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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).

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 Article 2.

Article 2

1. The authorisation is subject to the conditions set out in paragraphs 2 and 3.

2. By 25 February 2026, the authorisation holder shall implement a physical segregation between tasks with foreseeable exposure to hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide, and other tasks.

3. The authorisation holder shall ensure that, where respiratory protective equipment ('RPE') is needed to minimise exposure to Cr(VI), the workers:

   (a) are provided with adequate RPE, which is subject to a fit test prior to its first use;

   (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).

Article 3

1. The review period shall expire on 31 December 2028.

2. The authorisation shall cease to be valid on 31 December 2028 if the authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 30 June 2027.

Article 4

1. The monitoring arrangements set out in paragraphs 2 to 7 shall 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) 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), in particular the tasks with short duration and potentially high exposure and 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;

[12] https://ec.europa.eu/docsroom/documents/58854

(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 continue its monitoring programme measuring the environmental releases of Cr(VI) to the air and wastewater. The programme shall include measurements which shall:

(a) include sampling at the emission point of the internal exhaust ventilation of the reduction tank;

(b) 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);

(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 by way of the measurements referred to in paragraphs 2, 3 and 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 their assessment of the combined exposure for the different groups of workers and their 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 workplace exposure to 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 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 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 holder shall document the steps taken to substitute chromium trioxide, including information on the efforts to convince the authorisation holder's customers to accept alternative Cr(VI)-free solutions and justification in case its customers do not accept alternative Cr(VI)-free solutions. Any information on contingency measures taken shall also be documented. The authorisation holder shall make such documentation 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:

(a) the information referred to in Article 4(6) and (7);

(b) a detailed justification as to why a complete phase-out of chromium trioxide is not expected to be achieved by the end of the review period;

(c) figures detailing the reduction of the quantity of chromium trioxide used in the authorised use, as part of the substitution plan to be submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006.

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:

Bjerringbro Fornikling A/S, Hedemølle Erhvervsvej 10, 8850, Bjerringbro, Denmark.

Done at Brussels, 25.2.2025

For the Commission
Stéphane SÉJOURNÉ
Executive Vice-President

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION