EUROPEAN
COMMISSION

Brussels, 15.11.2023
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COMMISSION IMPLEMENTING DECISION

of 15.11.2023

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Dornbracht AG & Co. KG 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 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 November 2018, Aloys F. Dornbracht GmbH & Co. KG[2] ('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 with decorative character for sanitary applications.

(3) The European Chemicals Agency ('the Agency') sent the opinions[3] on the application adopted by the Committee for Risk Assessment (RAC) and by the Committee for Socio-economic Analysis (SEAC) of the Agency to the Commission pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006. On 19 September 2019, the Commission received the opinions.

(4) The judgement of the General Court of 7 March 2019 in Case T-837/16[4], *Sweden v. Commission*, provided an interpretation of the condition set out in Article 60(4) and (5) and Article 62(4), point (f), of Regulation (EC) No 1907/2006 as regards the suitability of alternatives and the requirement of a substitution plan. Therefore, on 8 June 2020, the Commission sent a request to the applicant to complete accordingly the

[1] OJ L 396, 30.12.2006, p. 1.

[2] Aloys F. Dornbracht GmbH & Co. KG subsequently changed its name to Dornbracht AG & Co. KG.

[3] https://echa.europa.eu/documents/10162/1793e84c-54f4-43c7-d201-371820ad21ab

[4] Judgment of the General Court of 7 March 2019, Sweden v. Commission, T-837/16, ECLI:EU:T:2019:144, paragraphs 75 and 76.

information provided in the application for the use for which the authorisation is sought by submitting a substitution plan.

(5) On 8 December 2020, the applicant submitted to the Agency a substitution plan. On 28 July 2021, the Commission received from the Agency an addendum to the opinion adopted by SEAC[5].

(6) 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 6.4 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.

(7) In its opinion, RAC concluded that the risk management measures and operational conditions described in the application are appropriate and effective to limit the risk, both to workers and to members of the general population who could potentially be exposed to hexavalent chromium (Cr(VI)) via the environment, posed by the use of chromium trioxide described in the application. However, in order to corroborate the appropriateness and effectiveness of the risk management measures and operational conditions as well as to address shortcomings in the measurement data provided, RAC recommended a monitoring programme for occupational exposure. Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendation. However, the Commission notes that the estimated excess cancer risk value for workers is higher than for most other comparable applications for authorisation for the use of hexavalent chromium (Cr(VI)) substances. Although the Commission acknowledges that the value is a conservative estimate of the most likely excess risk value, 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 a condition for authorisation.

(8) In its opinion, SEAC concluded that the overall socio-economic benefits arising from the use described in the application outweigh the risk to human health arising from that use. The Commission, having evaluated SEAC's assessment, agrees with that conclusion.

(9) A suitable alternative should 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 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. Certain potential alternatives may provide some functionality but at some loss to 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 to performance or technical compromises by applying a reasonable additional effort, taking into account the circumstances of the case.

[5] https://echa.europa.eu/documents/10162/13343bdb-0e1c-2f09-c029-aae9c1d35340

(10) In its opinion, SEAC concluded that there were no suitable alternative substances or technologies available for the applicant by the time of adoption of the opinion. The Commission, having evaluated SEAC's assessment and all relevant information available, notes that the applicant has identified alternatives to substitute chromium trioxide that provide the overall functionality needed for the use for which authorisation is sought and that are commercially available and have been already implemented in the Union in different market segments. The Commission also acknowledges that the identified alternatives are likely to become technically and economically feasible for the applicant in the future. However, the Commission recognises that those alternatives imply a significant loss of performance in terms of technical requirements such as corrosion resistance. 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 to make it technically feasible for it. Therefore, the Commission agrees with SEAC's conclusion that there are no suitable alternatives for the applicant but concludes that there are suitable alternatives available in the Union.

(11) In its addendum to the opinion, SEAC concluded that the substitution plan submitted by the applicant is credible. In particular, SEAC noted that the overall approach to substitution seems coherent and that the substitution plan contains sufficient detail on the approach to substitution, constraints, milestones and monitoring arrangements. The Commission, having evaluated SEAC's assessment, concurs with that conclusion. Therefore, taking into account the availability of suitable alternatives in the Union for the use for which authorisation is sought and the related obligation to submit a substitution plan, the Commission considers 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 described in the application, provided that the risk management measures and operational conditions described in the chemical safety report, as well as the conditions set out in this Decision, are fully applied.

(13) The Commission has based its assessment on all relevant scientific evidence currently available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, based its conclusions on a sufficient amount of material and reliable information allowing it to conclude. Nevertheless, additional scientific evidence would allow the Commission to perform its assessment on a more robust or broad evidentiary base in the future. Hence, it is appropriate to require that additional occupational exposure information be submitted.

(14) In its opinion, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 should be set at 12 years. The Commission takes into account that recommendation, with 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, the applicant's ongoing research and development activities and the time necessary for the development and implementation of a potential alternative as outlined in the substitution plan.

(15) Nevertheless, 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 these are available and technically and economically viable. The Commission also considers that there is increasingly available information on substitution of Cr(VI) substances in functional chrome plating with decorative character, including from similar applications for authorisation and relevant SEAC opinions, indicating that the applicants should be able to substitute chromium trioxide more rapidly. In order to ensure that substitution of chromium trioxide for the use for which authorisation is sought is achieved as early as possible, and considering the potential risks posed by the use of the substance, the Commission considers that a shorter review period should be laid down.

(16) The language used to describe the risk management measures and operational conditions in the application for authorisation may be different from the official language(s) 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.

(17) 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 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[6] to reduce the use of a carcinogen or mutagen at the place of work, in particular by replacing it, 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[7], 92/85/EEC[8], 94/33/EC[9], 98/24/EC[10] and Directive 2004/37/EC, or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

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6 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 or mutagens 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).

7 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).

8 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).

9 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).

10 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).

(18) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC[11] or Directive 2010/75/EU[12] 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[13] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[14]. 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.

(19) 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 for the following use of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0):

Authorisation number	Authorised use
REACH/23/22/0	Functional chrome plating with decorative character for sanitary applications

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[15], and to the conditions set out in Article 2.

Article 2

1. The authorisation shall be subject to the conditions set out in paragraphs 2 to 5.

2. The authorisation holder shall carry out a monitoring programme measuring occupational exposure to hexavalent chromium (Cr(VI)). Those measurements shall:

   (a) take place at least annually and more frequently where a significant increase of chromium trioxide consumption takes place on site. The frequency of the measurements shall be sufficient to capture any potential increase in exposure of workers to Cr(VI);

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

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11 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).

12 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).

13 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).

14 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).

15 https://ec.europa.eu/docsroom/documents/37223

(c) comprise personal and static inhalation exposure sampling;

(d) ensure a sufficiently low limit of quantification;

(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 the total number of workers that are potentially exposed;

(f) be recorded with contextual information about the tasks performed during sampling.

3. The authorisation holder shall use the information gathered in accordance with paragraph 2 to confirm and review, at least annually, the effectiveness of operational conditions and risk management measures in place. If needed, the authorisation holder shall introduce measures to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically possible and in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

4. The authorisation holders shall finalise by 15 November 2024, and afterwards when new information becomes available, a study to assess the feasibility to upgrade and further automate the sampling of the etching and electroplating baths, in accordance with the hierarchy of control principles. The authorisation holders shall act in accordance with the outcome of that study.

5. The authorisation holder shall document and keep the information obtained in accordance with paragraph 2, 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 paragraphs 3 and 4. The authorisation holder 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 3

The review period shall expire on 31 December 2028.

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 paragraph 2 shall apply.

2. The authorisation holder shall document the steps taken to substitute chromium trioxide in accordance with the substitution plan, 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 such solutions. Information on any deviations from the initial substitution plan and on contingency measures taken shall also be included in the documentation. The authorisation holder shall make that documentation available, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 5

Where the authorisation holder submits a review report, it shall include the information referred to in Article 2(5) and Article 4(2).

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 in an official language of that Member State.

Article 7

This Decision is addressed to Dornbracht AG & Co. KG, Köbbinger Mühle 6, 58640 Iserlohn, Germany.

Done at Brussels, 15.11.2023

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION