EUROPEAN
COMMISSION

Brussels, 9.7.2024
C(2024) 4583 final

COMMISSION IMPLEMENTING DECISION

of 9.7.2024

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to KaVo Dental GmbH for a use of chromium trioxide

(Only the German text is authentic)

COMMISSION IMPLEMENTING DECISION

of 9.7.2024

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to KaVo Dental GmbH for a use of chromium trioxide

(Only the German text is authentic)

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 October 2021, KaVo Dental GmbH ('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 the chromium trioxide-based functional chrome plating of dental instruments applied by professionals for dental treatment.

(3) The European Chemicals Agency sent the opinion[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 14 November 2022, 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 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.

[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/10162/49084e47-d45a-b5f3-a0c3-6942ca29d389 .

(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. In particular, RAC noted that the measures in place are not in line with the principles of hierarchy of control, further minimisation of exposure can be achieved and, consequently, recommended conditions for authorisation. Moreover, RAC recommended monitoring arrangements with the aim of addressing some shortcomings in exposure estimates and providing information on the trends in exposure and emissions during the authorisation period, for both occupational exposure to, and environmental release of, hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide. Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations.

(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 continued 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) Similarly, an alternative the use of which does not lead to a negative economic impact of a magnitude that would jeopardise the economic viability of the operations related to the use for which an authorisation is sought should be considered economically feasible.

(10) In its opinion, SEAC concluded that there were no suitable alternative substances or technologies available for the applicant at the time of adoption of the opinions but that there were technically and economically feasible alternatives available 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 and already implemented in the Union and that the applicant has already implemented Cr(VI)-free technologies for selected parts of the high price series. However, the Commission also acknowledges that, for the use for which authorisation is sought, those alternatives imply either a loss of performance which does not allow meeting the requirements for the products needed by the applicant, namely, robustness to repeated cleaning and sterilisation in their use in dental care, corrosion on stainless steel surface and layer

thickness, or are not applicable to complex geometry parts, and that, therefore, the applicant would need more time to develop and implement an alternative. In addition, the Commission notes that the latter alternative does not meet the process requirements needed by the applicant in terms of production cost for simple geometry parts. The Commission therefore agrees with SEAC's conclusion and considers that, although suitable alternatives are available in the Union, they are not yet technically or economically feasible for the applicant.

(11) In its opinion, SEAC concluded that the substitution plan submitted by the applicant is credible. 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 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 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.

(13) 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.

(14) 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 11 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 operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk, SEAC's conclusions on the monetised risk to human health and on the socio-economic benefits of the continued use of the substance, as well as their conclusion on the substitution plan, the cost to switch to an alternative, the time needed to implement the alternative and the regulatory approvals required for the applicant's products.

(15) 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 States 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.

(16) 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[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] and 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.

(17) 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.

---

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).

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/2008/105/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).

(18) 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/24/17/0	KaVo Dental GmbH	Chromium trioxide based functional chrome plating of dental instruments applied by professionals for dental treatment

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 to 5.

2. By 9 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 chromium trioxide flakes with liquid chromium trioxide solution;

   (b) the installation of an automated system to perform the bath adjustment, and of a closed/automatic system to perform bath sampling tasks.

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

3. Without prejudice to the condition set out in paragraph 2, by 9 January 2026, the authorisation holder shall implement a technical solution to ensure the following:

   (a) workers do not need to be close to the baths during the loading and unloading operations; and

   (b) the baths are covered when the operations of loading and unloading are not ongoing.

4. Until a technical solution as referred to in paragraph 3 is implemented, and the exposure data obtained pursuant to the measurements referred to in Article 4(2) and (3) allow for a conclusion that there is no exposure, the authorisation holder shall ensure that workers involved in worker contributing scenario 2 ‘Operation of the manual chrome plating line’ use respiratory protective equipment.

5. The authorisation holder shall document and maintain the information from the outcome and conclusions of the study referred to in paragraph 2 and any measure

[12] https://echa.europa.eu/documents/10162/09fbdf48-43ef-abeb-b0ca-5f51705d921e

taken in accordance with paragraphs 2, 3 and 4, and shall make it available, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 3

1. The review period shall expire on 19 October 2032.

2. The authorisation shall cease to be valid on 19 October 2032 if the authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 19 April 2031.

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 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 and/or static inhalation exposure sampling;

   (e) 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 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 with possible exposure to Cr(VI).

3. The authorisation holder shall conduct a biomonitoring programme representative of all 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 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 use takes 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 via the measurements referred to in paragraphs 2, 3 and 4 and related contextual information to review, at least annually, the 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, the authorisation holder shall introduce measures to further reduce to as low a level as technically and practically possible both workplace exposure to Cr(VI) and emissions to the environment of 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 gathered via 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 review and any measure taken in accordance with paragraph 5. The authorisation holder 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.

7. 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 alternative Cr(VI)-free solutions. Any deviations from the initial substitution plan and 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 the information referred to in Article 2(5) and Article 4(6) and (7).

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:

KaVo Dental GmbH, Bismarckring 39, 88400 Biberach, Germany.

Done at Brussels, 9.7.2024

For the Commission
Thierry BRETON
Member of the Commission