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**COMMISSION IMPLEMENTING DECISION**

**of 19.3.2020**

**partially granting an authorisation for a use of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (HAPOC GmbH & Co KG S.A.)**

(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<sup>1</sup>, 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 laid down in Article 56(1)(a) of that Regulation.
- (2) On 14 March 2016, HAPOC GmbH & Co KG, S.A. ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for the use of chromium trioxide in solid form and in aqueous solution of any composition to modify the properties of surfaces made of brass, bronze, copper and other copper alloys for medical engineering, aviation and automation products.
- (3) On 24 September 2018, the Commission received the opinions on the application adopted by the Committee for Risk Assessment (RAC) and by the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency<sup>2</sup> ('the Agency') and sent to it pursuant to the third subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.
- (4) RAC concluded in its opinion that it is not possible to determine a derived no-effect level (DNEL) 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)(a) of that Regulation. As a result, paragraph 2 of Article 60 of Regulation (EC) No 1907/2006 does not apply to that substance and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.

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<sup>1</sup> OJ L 396, 30.12.2006, p. 1.

<sup>2</sup> <https://echa.europa.eu/documents/10162/f5bc5117-2581-acb3-5100-74dedd9e36e7>.

- (5) In its opinion, RAC concluded that the risk management measures and operational conditions described in the application are effective in limiting the risk to workers and to the general population that could potentially be exposed via the environment. However, the evaluation of their appropriateness and effectiveness would be reinforced by basing it on a more extensive workplace and air emission measurements data set. Therefore, RAC recommended monitoring arrangements. The Commission, having evaluated RAC's assessment, agrees with its conclusion and recommendation.
- (6) An authorisation may be granted under Article 60(4) of Regulation (EC) No 1907/2006 if there are no suitable alternative substances or technologies. In order to be considered technically feasible, an alternative to the substance should be capable of providing the level of technical performance functionally necessary for the use applied for. Some potential alternatives may provide this functionality but at some loss to performance or in a manner that involves technical compromises. The Commission considers that, given the economic and other incentives towards substitution that already arise from inclusion in the authorisation system, and in the light of the objective of progressive substitution, as a starting point, the Commission should not consider a potential alternative technically viable where such losses to performance or technical compromises are not minor. Nevertheless, the Commission considers it must be possible to depart from this approach where justified by particular circumstances, including the specific function of the substance for the use applied for, the public interest at stake, or a low net difference between the socio-economic benefits and the risk to human health or the environment. The Commission also considers that no particular factors justify less strict technical feasibility requirements in this case. Where the Commission is able to conclude on lack of technically feasible alternatives to the substance, it is unnecessary to consider economic feasibility of substitution.
- (7) Pursuant to a clarification by the applicant that the application for authorisation, and the analysis of alternatives in particular, only cover the final preparation of surfaces made of brass and bronze and the transparent plating of an interior housing part of an anaesthesia evaporator for further incorporation into anaesthetic machines for hospitals and clinics, SEAC recommended to limit the scope of the use accordingly. The Commission concurs with SEAC's recommendation and considers that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternatives only with regard to such limited scope of the use and that it has demonstrated that no potential alternatives provide the level of technical performance functionally necessary for the use applied for.
- (8) In its opinion, SEAC concluded that the socio-economic benefits arising from the use of chromium trioxide described in the application outweigh the risk to human health arising from that use and that there are no suitable alternative substances or technologies. The Commission, having evaluated SEAC's assessment, agrees with that conclusion.
- (9) 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, as limited in this Decision, provided that the risk management measures and operational conditions described in the chemical safety report, referred to in Article 62(4)(d) of Regulation (EC) No 1907/2006, are fully applied. The authorisation should not be granted for the part of the use other than for the final preparation of surfaces made of brass and bronze and the transparent plating of an interior housing part of an anaesthesia evaporator for further incorporation into anaesthetic machines for hospitals and clinics.

- (10) The Commission has based its assessment on all relevant scientific evidence currently available, as assessed by RAC, and based its conclusions on the existence of a sufficient weight of evidence allowing it to conclude. Nevertheless, additional scientific evidence would allow the Commission to perform its assessments on a more robust or broad evidentiary base in the future. Hence, it is appropriate to require the generation of additional exposure and emission information.
- (11) In its opinion, SEAC recommended that the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 should 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, the conclusion that the risk management measures and operational conditions are effective in limiting the risk to workers and the general population, the time necessary for development, industrialisation, qualification and regulatory approval of an alternative, the likelihood that substitution will not be possible within shorter timelines, as well as the conclusion that the socio-economic benefits of continued use significantly outweigh the risk.
- (12) Therefore, it is appropriate, as regards the use of chromium trioxide described in the application, as limited in this Decision, to set the review period at 12 years from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006.
- (13) The language used to describe of the risk management measures and operational conditions included in the application for authorisation may be different from the official languages of the Member State where the use takes place. Therefore, in order to facilitate the enforcement of 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 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 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 Articles 4(1) and 5 of Directive 2004/37/EC of the European Parliament and of the Council<sup>3</sup> 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 worker's 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<sup>4</sup>, 92/85/EEC<sup>5</sup>, 94/33/EC<sup>6</sup> and 98/24/EC<sup>7</sup>, and Directive

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<sup>3</sup> 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).

<sup>4</sup> 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).

<sup>5</sup> 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).

<sup>6</sup> 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).

2004/37/EC, as well as any national binding occupational limit values which may be stricter than the applicable Union limit values.

- (15) This Decision does not affect any obligation to comply with emission limit values set in accordance with Directive 2008/50/EC of the European Parliament and of the Council<sup>8</sup> or Directive 2010/75/EU of the European Parliament and of the Council<sup>9</sup> 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<sup>10</sup> or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council<sup>11</sup>. Compliance with the provisions of this Decision does not necessarily imply compliance with emission limit values or environmental quality 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 for the following use of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0):

Authorisation number	Authorised use
REACH/20/8/0	Use in solid form and in aqueous solution of any composition to modify the properties of surfaces made of brass or bronze for medical engineering products, exclusively for the final preparation of such surfaces and the transparent plating of an interior housing part of an anaesthesia evaporator for further incorporation into anaesthetic machines for hospitals and clinics

The authorisation is granted subject to the full application of the risk management measures and operational conditions described in the chemical safety report<sup>12</sup>.

An authorisation is not granted for the use of chromium trioxide to modify the properties of surfaces made of brass, bronze, copper and other copper alloys for aviation and automation

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<sup>7</sup> 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).

<sup>8</sup> 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).

<sup>9</sup> 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).

<sup>10</sup> 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).

<sup>11</sup> 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).

<sup>12</sup> <https://ec.europa.eu/docsroom/documents/34182>

products, and for medical engineering products for a use other than that referred to in the first paragraph.

#### *Article 2*

1. The review period shall expire on 21 September 2029.
2. The authorisation shall cease to be valid on 21 September 2029 if the review report has not been submitted by 21 March 2028.

#### *Article 3*

1. The monitoring arrangements set out in paragraphs 2 to 4 shall apply.
2. The authorisation holder shall implement the following monitoring programmes for chromium (VI):
  - (a) At least annual air monitoring programmes on occupational exposure to chromium (VI) in accordance with Article 5(5)(e) of Directive 2004/37/EC. Those programmes shall:
    - be based on relevant standard reference methodologies and protocols and ensure a sufficiently low detection limit;
    - comprise both static and personal inhalation exposure sampling;
    - be appropriate to the duration of the tasks and be representative of the range of tasks undertaken, with possible exposure to chromium (VI) and of the total number of workers potentially exposed;
    - include contextual information about the tasks with possible exposure to chromium (VI).
  - (b) At least annual air monitoring programmes measuring the emissions of chromium (VI). Those programmes shall be based on relevant standard methodologies or protocols and be representative of the operational conditions and risk management measures as well as environmental conditions.
3. The authorisation holder shall use the information gathered via the measurements referred to in paragraph 2 and related contextual information to regularly review the appropriateness and effectiveness of the risk management measures and operational conditions in place and to introduce measures to further reduce exposure and emissions. The authorisation holder shall respect the principles of the hierarchy of control when selecting risk management measures.
4. The authorisation holder shall document the results of the measurements referred to in paragraph 2, as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 3, submit them upon request to the competent authority of the Member State where the authorised use take place and, where applicable, shall include them in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006.

*Article 4*

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 5*

This Decision is addressed to HAPOC GmbH & Co KG, S.A, In der Neuen Welt 8, 87700, Memmingen, Germany.

Done at Brussels, 19.3.2020

*For the Commission*

*Thierry BRETON*

*Member of the Commission*

