EUROPEAN
COMMISSION

Brussels, 15.12.2020
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COMMISSION IMPLEMENTING DECISION

of 15.12.2020

partially granting an authorisation for a use of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Cromomed S.A. and others)

(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)(a) of that Regulation.

(2) On 19 November 2015, Cromomed S.A., Cronor S.A., Cromo Europa S.A., Chromatlantique Industriel S.A. and Vila Electroquímica S.A. ('the applicants') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for use of chromium trioxide in functional chrome plating.

(3) On 15 December 2016, the Commission received the opinion on the application adopted by the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency[2] and sent to it pursuant to the third subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.

(4) On 24 October 2019, the European Parliament adopted a resolution[3] concerning the draft of this authorisation for a use of chromium trioxide. The Commission took note of that resolution.

(5) 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

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

[2] https://echa.europa.eu/documents/10162/50002b75-2f4c-5010-81de-bcc01a8174fc

[3] http://www.europarl.europa.eu/doceo/document/TA-9-2019-0046_EN.pdf

authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.

(6) In its opinion, RAC further concluded that the risk management measures and operational conditions described in the application are effective in limiting the risk to workers, provided that those measures and conditions are adhered to and recommended additional conditions and monitoring arrangements for the authorisation. The Commission, having evaluated RAC's assessment, agrees with its conclusion and recommendation.

(7) In its opinion, SEAC concluded that the overall socio-economic benefits arising from the use of chromium trioxide applied for outweigh the risk to human health and the environment arising from that use. The Commission, having evaluated SEAC's assessment, agrees with that conclusion.

(8) 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 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 interests at stake, or a low net balance of 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.

(9) In its opinion, SEAC concluded that there are no suitable alternative substances or technologies available by the sunset date. However, given the broad scope of the use covered by the application, SEAC could not exclude possible uncertainty with regard to the technical feasibility of alternatives for some specific utilisations falling under the scope of the intended use. The Commission, in order to address any uncertainty inherent to the broadly defined use, considers necessary to limit the description of the use by referring it to uses where any of the following key functionalities or properties is necessary for the intended use, as assessed by SEAC: wear resistance, hardness, layer thickness, corrosion resistance, coefficient of friction, and effect on surface morphology. The Commission considers that the applicant discharged its burden of proof in demonstrating the absence of suitable alternatives only with regard to such limited scope of the use.

(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 use of chromium trioxide as limited by this Decision, provided that the risk management measures and operational conditions described in the application and in particular in the chemical safety report referred to in Article 62(4)(d) of Regulation (EC) No 1907/2006, as well as the conditions and monitoring arrangements set out in this Decision, are fully applied. The

authorisation should not be granted for the part of use where the specified key functionalities are not necessary.

(11) 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 assessment 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.

(12) In its opinion, SEAC recommended that the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 be set at seven years. The Commission agrees with that recommendation, taking into account the fact that the risk management measures and operational conditions described in the application are considered to be effective to manage the risk to workers posed by the use of chromium trioxide described in the application, the additional conditions and monitoring arrangements recommended by RAC, the applicants' research and development activities which indicate that no suitable alternative will be available within a shorter time period, the lack of any convincing evidence to suggest that a longer time period would be necessary to substitute, and the significant adverse socio-economic impact on the applicants and their supply chains if the authorisation was not granted.

(13) Therefore, it is appropriate, as regards the use of chromium trioxide described in the application, as limited by this Decision, to set the review period at seven years from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006.

(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 holders 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 holders 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 holders 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[4], 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[5], 92/85/EEC[6], 94/33/EC[7], 98/24/EC[8] and

[4] 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).

[5] 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, 29.06.1989, p. 1).

Directive 2004/37/EC, nor does it affect any national binding occupational limit values which may be stricter than the applicable Union limit values.

(16) This Decision does not affect any obligation to comply with other regulatory provisions including emission limit values set in accordance with Directive 2008/50/EC of the European Parliament and of the Council[9] or Directive 2010/75/EU of the European Parliament and of the Council[10], 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[11] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[12]. 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.

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

Authorisation number	Authorisation holder	Authorised use
REACH/20/19/0	Cromomed S.A.	Use in functional chrome plating where any of the following key functionalities or properties is necessary for
REACH/20/19/1	Cronor S.A.	
REACH/20/19/2	Cromo Europa S.A.	
REACH/20/19/3	Chromatlantique Industriel S.A.	

6 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).

7 Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work (OJ L 216, 20.08.1994, p. 12).

8 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, 05.05.1998, p. 11).

9 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).

10 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).

11 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).

12 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).

REACH/20/19/4	Vila Electroquímica S.A.	the intended use: wear resistance, hardness, layer thickness, corrosion resistance, coefficient of friction, and effect on surface morphology

An authorisation for the use of chromium trioxide is not granted for functional chrome plating where none of the key functionalities listed in the first subparagraph is necessary for the authorised use.

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[13] as well as to the conditions set out in Article 2 of this Decision.

Article 2

The authorisation shall be subject to the following conditions:

(a) the authorisation holders shall verify and demonstrate the appropriateness of the risk management measures and operational conditions at all sites without undue delay, and at the latest by 15 June 2022, and shall implement any changes and adopt best practices, necessary to reduce workers' exposure to chromium trioxide and its emissions to the environment to as low a level as technically and practically feasible;

(b) the authorisation holders shall ensure that the use of surfactants as mist suppressants on chrome plating baths to reduce air-borne mist generation, covering the baths during plating operations, and the feasibility of implementing segregation of the electroplating areas, are investigated and, where appropriate, implemented at all sites to limit workers' exposure and emissions to the environment.

Article 3

1. The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 September 2024.

2. The authorisation shall cease to be valid on 21 September 2024 with regard to the holders of the authorisation who have not submitted a review report by 21 March 2023.

Article 4

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

2. The authorisation holders shall implement the following monitoring programmes for chromium (VI):

a) regular occupational exposure measurements. Those measurements shall:

(i) take place annually;

(ii) be performed at and be comparable for all sites covered by this Decision and in a comparable way at each site;

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

[13] https://ec.europa.eu/docsroom/documents/20640

(iv) ensure a sufficiently low detection limit;

(v) comprise both static and personal inhalation exposure sampling;

(vi) be appropriate to the duration of the tasks and be representative of the range of tasks with possible exposure to chromium (VI) and of the total number of workers that are potentially exposed;

(vii) recorded as to include contextual information about the tasks with possible exposure to chromium (VI).

b) measurements of emissions to air. Those measurements shall:

(i) be conducted at least annually;

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

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

3. The authorisation holders shall use the information gathered in all available measurements, including those referred to in paragraph 2 and related contextual information to regularly review the appropriateness and effectiveness of the risk management measures and operational conditions and, if needed, to introduce measures to further reduce workplace exposure to chromium (VI) and emissions to the environment to as low a level as technically and practically feasible.

4. The authorisation holders shall document and keep the information obtained from the monitoring programmes referred to in paragraph 2, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 3, and submit that information, upon request, to the competent authority of the Member State where the authorised use takes place.

5. If an authorisation holder submits a review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006, it shall include the information documented in accordance with paragraph 4 of this Article in that report.

Article 5

Upon request, the authorisation holders 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 6

This Decision is addressed to:

1. Cromomed S.A., Polígono Ingruinsa C/Forjas 66 A, 46520 Puerto Sagunto, Valencia, Spain;

2. Cronor S.A., Peña Redonda, Parcela R-15 – Polígono de Silvota, 33192 Llanera, Asturias, Spain;

3. Cromo Europa S.A., Andrés Larrazabal s/n, 48970 Basauri, Bizkaia, Spain;

4. Chromatlantique Industriel S.A., ZA des Rosais, 35550 Sixt sur Aff, France;

5. Vila Electroquímica S.A., Viérnoles 32, 39315 Torrelavega, Cantabria, Spain.

Done at Brussels, 15.12.2020

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION