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COMMISSION IMPLEMENTING DECISION

of 28.8.2020

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Società Chimica Bussi S.p.A. for a use of sodium dichromate

(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/EC¹, and in particular Article 64(8) thereof,

Whereas:

- (1) Sodium dichromate 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 20 February 2019, Società Chimica Bussi S.p.A. ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for a use of sodium dichromate. The use for which authorisation was sought is as an additive for suppressing parasitic reactions and oxygen evolution, pH buffering and cathode corrosion protection in the electrolytic manufacturing of sodium chlorite.
- (3) On 25 February 2020, 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 Agency² and sent to it pursuant to the second 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 carcinogenicity properties of the substance in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore sodium dichromate 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.

¹ OJ L 396, 30.12.2006, p. 1.

² <https://echa.europa.eu/documents/10162/dfc9b455-6929-07fe-40d7-10ccb0332c89>

- (5) RAC concluded that the risk management measures and operational conditions described in the application, and further detailed by the applicant at RAC's request, are expected to be appropriate and effective to limit the risk to workers and to the members of the general population via the environment. Having evaluated RAC's assessment, the Commission agrees with that conclusion.
- (6) In order to improve the assessment of emissions and exposure of workers, RAC recommended imposing monitoring arrangements. Having evaluated the RAC assessment, the Commission agrees with that recommendation.
- (7) In its opinion, SEAC raised no reservations on the quantitative or the qualitative elements of the applicant's assessment of the socio-economic benefits and the risk to the environment associated with the use of sodium dichromate described in the application. Having evaluated the SEAC assessment, the Commission concludes that the applicant has demonstrated that the socio-economic benefits of use of sodium dichromate applied for outweigh the risk to the environment arising from that use.
- (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 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 to be technically viable where such losses to performance or technical compromises are not minor. Nevertheless, the Commission considers that 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 difference between the socio-economic benefits and the risk to human health or the environment. The Commission 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. Having evaluated the SEAC assessment, the Commission agrees with that conclusion and considers that the applicant has demonstrated that no potential alternatives provide the level of technical performance functionally necessary for the use applied for and has discharged its burden of proof in demonstrating the absence of suitable alternatives.
- (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 sodium dichromate described in the application, provided that the risk management measures and operational conditions described in the chemical safety report are fully applied.
- (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 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.

- (12) SEAC recommended in its opinion 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 expected to be effective in limiting the risk to workers and to members of the general population via the environment, the likelihood that substitution will not be possible within shorter timelines, as well as the conclusion that the socio-economic benefits of the use applied for significantly outweigh the risk.
- (13) The applicant submitted its application for authorisation after the latest application date specified in accordance with Article 58(1)(c)(ii) of Regulation (EC) No 1907/2006 and the applicable sunset date specified in Annex XIV to that Regulation has already been reached. The start date for the review period should therefore be set as the date of adoption of this Decision. It is appropriate for the review period to be set at 12 years from the date of adoption of this Decision.
- (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 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.
- (15) 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 Council³ 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/EEC⁴, 92/85/EEC⁵, 94/33/EC⁶, 98/24/EC⁷, and Directive

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 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).

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).

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).

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).

2004/37/EC as well as 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 emission limit values set in accordance with Directive 2008/50/EC of the European Parliament and of the Council⁸ or Directive 2010/75/EU of the European Parliament and of the Council⁹, 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 Council¹⁰ or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council¹¹. 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 sodium dichromate (EC No 234-190-3; CAS No 7789-12-0, 10588-01-9):

Authorisation number	Authorised use
REACH/20/16/0	Additive for suppressing parasitic reactions and oxygen evolution, pH buffering and cathode corrosion protection in the electrolytic manufacturing of sodium chlorite

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report¹².

Article 2

1. The review period shall expire on 28 August 2032.
2. The authorisation shall cease to be valid on 28 August 2032 if the review report for that use has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 28 February 2031.

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).

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).

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).

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).

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).

¹² <https://ec.europa.eu/docsroom/documents/40381>

Article 3

1. The monitoring arrangements set out in paragraphs 2 to 8 shall apply.
2. The authorisation holder shall implement the following monitoring programmes for chromium (VI):
 - (a) occupational exposure measurements, which shall:
 - (i) be conducted at least annually;
 - (ii) be based on relevant standard methodologies or protocols;
 - (iii) comprise both static and personal inhalation exposure sampling;
 - (iv) be representative of the range of tasks undertaken where exposure to chromium (VI) is possible, including tasks involving maintenance workers, and be representative of the operational conditions and risk management measures typical for each of these tasks and of the number of workers potentially exposed;
 - (v) be recorded as to include contextual information about the tasks with possible exposure to chromium (VI).
 - (b) measurements of emissions to wastewater and air from local exhaust ventilation, which 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 site where the authorised use takes place.
3. The authorisation holder shall use the information gathered via the measurements referred to in paragraph 2 and related contextual information to confirm the effectiveness of the risk management measures and operational conditions as well as to review annually the effectiveness of the risk management measures and operational conditions in place 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 holder shall ensure that the application of risk management measures at their site is in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.
5. The authorisation holder shall document and maintain 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 it, upon request, to the competent authority of the Member State where the authorised use takes place.
6. Following implementation of the risk management measures and operational conditions, the authorisation holder may reduce the frequency of measurements, once they clearly demonstrate to the competent authority of the Member State where the use takes place that exposure of humans and releases into the environment have been

reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions function appropriately.

7. Where the frequency of measurements has been reduced in accordance with paragraph 6, any subsequent changes to the operational conditions or risk management measures that may affect the exposure at the site where the use takes place shall be documented. The authorisation holder shall assess the impact of such changes by monitoring to demonstrate that exposure of workers and emissions to the environment continue to be reduced to as low a level as technically and practically possible.
8. In the event that a review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 is submitted, it shall include the information documented in accordance with paragraph 5.

Article 4

Upon request, the authorisation holder shall submit a succinct 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 Società Chimica Bussi S.p.A., Piazzale Elettrochimica 1, 65022, Bussi sul Tirino, Italy.

Done at Brussels, 28.8.2020

For the Commission

Thierry BRETON

Member of the Commission

