EUROPEAN
COMMISSION

Brussels, 21.10.2020
C(2020) 7104 final

COMMISSION IMPLEMENTING DECISION

of 21.10.2020

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to ThyssenKrupp Rasselstein GmbH for certain uses 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)(a) of that Regulation.

(2) On 30 November 2018, ThyssenKrupp Rasselstein GmbH ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for certain uses of chromium trioxide. The uses for which authorisation was sought are passivation of tin-plated steel ('use 1') and electrolytic chromium coating of steel ('use 2'). As a result of those uses coils of coated steel are produced to manufacture metal packaging in various food- and non-food applications. A small percentage of the coated steel is used in non-packaging applications. A significant part of the coated steel production (about 65% of use 1, and about 85% of use 2) is used to produce tin cans for food packaging, an application with high product quality requirements related to food safety.

(3) On 5 September 2019, 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[2] and sent to it pursuant to the third subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.

(4) RAC concluded in its opinions 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

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

[2] https://echa.europa.eu/documents/10162/50efef53-9a88-20d1-e030-d4a23b402697 https://echa.europa.eu/documents/10162/b8868c30-3feb-3a0b-bf3e-1ce775c967dc

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.

(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 appropriate and effective to limit the risk to workers and to members of the general population who could potentially be exposed via the environment. Having evaluated the RAC assessment, the Commission agrees with that conclusion.

(6) In order to confirm and to regularly review the effectiveness of the operational conditions and risk management measures, RAC recommended imposing additional air emission monitoring arrangements. In addition, in case the 'dissolving chromium trioxide' worker contributing scenario 10 for use 1 and respective worker contributing scenario 9 for use 2 are implemented, RAC suggested to immediately conduct monitoring of worker exposure resulting from this specific task in order to confirm the appropriateness and effectiveness of the proposed operational conditions and risk management measures. Having evaluated the RAC assessment, the Commission agrees with that recommendation.

(7) SEAC concluded that the socio-economic benefits arising from the uses of chromium trioxide described in the application outweigh the risk to human health arising from those uses. Having evaluated the SEAC assessment, the Commission 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 to the substance should be capable of providing the level of technical performance functionally necessary for the use for which authorisation is sought. 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 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) SEAC concluded that there are currently no suitable alternative substances or technologies for either of the uses for which authorisation is sought. The applicant, through its own research and development efforts, has identified one promising, but not yet technically feasible potential alternative that could be developed for each use. SEAC considers that substitution to these potential alternatives may be possible, but not certain, within a normal review period for use 1 and, for use 2, within the review period requested by the applicant. The Commission agrees with SEAC's conclusion

and considers that there are no suitable alternatives available for the applicant or on the market and the applicant has demonstrated that no potential alternatives currently provide the level of technical performance functionally necessary for the uses for which authorisation is sought 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 chromium trioxide 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 derived from measurements conducted as part of the monitoring arrangements would allow the Commission to perform its assessment on a more robust or broad evidentiary base in the future.

(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 seven years for use 1 and until 31 December 2028, as requested by the applicant, for use 2. For both uses, the Commission agrees with those recommendations, taking into account the relevant elements from RAC's and SEAC's assessments, and in particular RAC's assessment of the remaining risk and the conclusion that the risk management measures in place are appropriate and effective in limiting the risk, and SEAC's assessment that the socio-economic benefits of the continued use clearly outweigh the associated monetised risk to human health. The Commission also takes into account the ongoing substitution efforts by the applicant, including one new round of research and development, as well as long term packaging and qualification tests for use 1 and, for use 2, two new rounds of research and development, storage tests, customer qualification, as well as the construction of a new production line.

(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. The applicable sunset date specified in Annex XIV to that Regulation has already been reached. It is therefore appropriate for the review period to be set at seven years from the date of adoption of this Decision for use 1 and until 31 December 2028 for use 2.

(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 Council[3] 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[4], 92/85/EEC[5], 94/33/EC[6], 98/24/EC[7] and Directive 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 Council[8] or Directive 2010/75/EU of the European Parliament and of the Council[9], 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 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 uses of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0):

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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).

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).

Authorisation number	Authorised Use
REACH/20/15/0	Passivation of tin-plated steel
REACH/20/15/1	Electrolytic chromium coating of steel

The authorisation is granted subject to the application of risk management measures and operational conditions described in the chemical safety reports[12].

Article 2

1. As regards the authorisation bearing number REACH/20/15/0 the review period shall expire on 21 October 2027.
2. As regards the authorisation bearing number REACH/20/15/1 the review period shall expire on 31 December 2028.
3. The authorisation bearing number REACH/20/15/0 shall cease to be valid on 21 October 2027 if the review report has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 21 April 2026.
4. The authorisation bearing number REACH/20/15/1 shall cease to be valid on 31 December 2028 if the review report has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 30 June 2027.

Article 3

1. The monitoring arrangements set out in paragraphs 2 to 6 shall apply.
2. If the authorisation holder implements the worker contributing scenarios entitled 'Dissolving chromium trioxide', it shall immediately conduct static monitoring measurements related to this task. After implementation of this task, the foreseen workplace exposure measurements described in the chemical safety reports referred to in the second subparagraph of Article 1, as well as the additional static monitoring measurements, shall be included in the occupational exposure monitoring programmes described in these chemical safety reports. These measurements shall:
    (a) be based on relevant standard methodologies and protocols;
    (b) ensure a sufficiently low detection limit;
    (c) be appropriate to the duration of the tasks and be representative of the scenario with possible exposure to chromium (VI) and of the total number of workers that are potentially exposed;
    (d) be recorded so as to include contextual information about the tasks with possible exposure to chromium (VI).
3. The authorisation holder shall conduct air emission measurements. These measurements shall:
    (a) take place at least every three years;
    (b) be based on relevant standard methodologies or protocols;

[12] For use 1: https://echa.europa.eu/documents/10162/287dd08e-cde2-fc08-4caf-4c94bb488c5e,
For use 2: https://echa.europa.eu/documents/10162/1c28669b-0b18-3018-ee4c-d21b07f51927

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

4. The authorisation holder shall use the information gathered via the measurements referred to in paragraphs 2 and 3 and related contextual information to confirm and regularly review the effectiveness of operational conditions and risk management measures in place. If needed, the authorisation holder shall introduce measures to further reduce workplace exposure and air emissions of chromium (VI) to as low a level as technically and practically feasible.

5. The authorisation holder shall document and maintain the information from the monitoring programmes referred to in paragraphs 2 and 3, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the reviews and any action taken in accordance with paragraph 4, and shall make it available, upon request, to the competent authority of the Member State where the authorised use takes place.

6. Where the authorisation holder submits a review report, it shall include the information documented in accordance with paragraph 5.

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 ThyssenKrupp Rasselstein GmbH, Koblenzer Str. 141, 56626 Andernach, Germany.

Done at Brussels, 21.10.2020

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION