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**COMMISSION IMPLEMENTING DECISION**

**of 22.11.2021**

**granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Thyssenkrupp Electrical Steel GmbH and Thyssenkrupp Electrical Steel UGO S.A.S. for a use of chromium trioxide**

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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(ONLY THE ENGLISH 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<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 in Article 56(1)(a) of that Regulation.
- (2) On 20 February 2019, Thyssenkrupp Electrical Steel GmbH and Thyssenkrupp Electrical Steel UGO S.A.S. ('the applicants') 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 surface treatment for the manufacture of grain-oriented electrical steel used in magnetic circuits of electric devices, in particular magnetic cores of high-performance transformers.
- (3) On 24 March 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 Agency<sup>2</sup> 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 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/10162/21c74ed4-f445-1c69-af55-8194d3bf07cc>

- (5) RAC concluded in its opinion that the risk management measures and operational conditions described in the application, and further detailed by the applicants 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, posed by the use of chromium trioxide described in the application. RAC also noted that a cleaning technique used in some tasks described in the application was not state of the art. Meanwhile, the applicants have adopted the automated cleaning process announced in the application and updated the chemical safety report accordingly. However, in order to corroborate the appropriateness and effectiveness of the risk management measures and operational conditions as well as to strengthen the measurement data provided, RAC recommended occupational exposure measurements. Having evaluated the RAC assessment, the Commission agrees with that conclusion and recommendation.
- (6) In its opinion, SEAC concluded that it has no reservations on the quantitative and qualitative elements of the applicants' assessment of the benefits and the monetised risks to human health associated with the continued use of the substance. Taking into account SEAC's assessment of the socio-economic analysis, RAC's conclusion that the risk management measures and operational conditions are appropriate and effective to limit the risk, the estimated monetised excess risk associated with the continued use in the order of hundreds of thousands of euros, the estimated monetised socio-economic benefits of continued use due to avoided loss of profits and jobs in the order of hundreds of millions of euros, and the additional qualitatively assessed socio-economic benefits due to avoided loss of profits and jobs in the supply chain, the Commission concludes that the applicants have demonstrated that the socio-economic benefits of continued use of chromium trioxide outweigh the risk to human health and the environment arising from that use.
- (7) A suitable alternative should 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, an authorisation may be granted if the applicant for authorisation submits a substitution plan. 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. Certain potential alternatives may provide some functionality but at some loss to 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 to performance or technical compromises by applying an additional effort which is reasonable taking into account the circumstances of the case.
- (8) In its opinion, SEAC concluded that there are no suitable alternative substances or technologies. After evaluating SEAC's assessment, the Commission acknowledges that the identified alternatives provide some functionality needed for the use applied for but at a certain loss of performance. Taking into account the necessary characteristics of the production process, allowing to achieve the insulation coating required for the energy efficiency and control of noise level of the transformers, such loss of performance would imply a significant lack of mandatory key functionalities in terms of the desired surface properties of the product. The Commission therefore considers that the identified alternatives should not be considered suitable in this case,

since the degree of the loss of performance does not allow achieving the standards that the final products need to meet and does not provide the functionality needed for the use applied for. Consequently, the Commission agrees with SEAC's conclusion and considers that the applicants have discharged their burden of proof in demonstrating the absence of suitable alternatives both in the Union and for the applicant.

- (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, provided that the risk management measures and operational conditions described in the chemical safety report as referred to in Article 62(4)(d) of that Regulation are fully applied. However, for the sake of legal clarity, the description of the use authorised by this Decision should be 'surface treatment for the manufacture of grain-oriented electrical steel used in magnetic cores of high-performance transformers and related electromagnetic devices'.
- (10) The Commission has based its assessment on all relevant scientific evidence currently available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, based its conclusions on a sufficient amount of material and reliable information allowing it to conclude.
- (11) 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 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 risk management measures and operational conditions are appropriate and effective to limit the risk, the applicants' long investment cycle, their ongoing research and development activities, the time necessary for the development, implementation and qualification of a potential alternative, and the indications that substitution would not be achievable within shorter timelines. Considering that, according to the applicants, the substitution process is scheduled to be completed in 2029, the Commission finds it is appropriate to set the end of the review period on 31 December 2029.
- (12) 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.
- (13) 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

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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).

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<sup>4</sup>, 92/85/EEC<sup>5</sup>, 94/33/EC<sup>6</sup>, 98/24/EC<sup>7</sup> and Directive 2004/37/EC, as well as any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

- (14) This Decision does not affect any obligation to comply with other regulatory requirements, including 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 any emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.
- (15) 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 persons for the following use of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0):

Authorisation number	Authorisation holders	Authorised use
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<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).

<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).

REACH/21/3/0

Thyssenkrupp  
Electrical Steel  
GmbH

As surface treatment for the manufacture of grain-oriented electrical steel used in magnetic cores of high-performance transformers and related electromagnetic devices

REACH/21/3/1

Thyssenkrupp  
Electrical Steel  
UGO S.A.S.

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

#### *Article 2*

1. The review period shall expire on 31 December 2029.
2. The authorisation shall cease to be valid on 31 December 2029 with regard to any holder of the authorisation who has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 30 June 2028.

#### *Article 3*

1. The monitoring arrangements set out in paragraphs 2 to 6 shall apply.
2. The authorisation holders shall implement an occupational exposure monitoring programme. These measurements shall:
  - (a) take place at least annually;
  - (b) be based on relevant standard methodologies and protocols;
  - (c) ensure a sufficiently low limit of quantification;
  - (d) be appropriate to the duration of the tasks and be representative of all the tasks with possible exposure to Cr(VI), including maintenance tasks, and of the total number of workers that are potentially exposed;
  - (e) be recorded so as to include contextual information about the tasks with possible exposure to Cr(VI).
3. The authorisation holders shall use the information gathered via the measurements referred to in paragraph 2 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 of Cr(VI) to as low a level as technically and practically possible.
4. The authorisation holders shall document and maintain the information from the monitoring programme referred to in paragraph 2, 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 3, and

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<sup>12</sup> <https://ec.europa.eu/docsroom/documents/40604>

shall make it available, upon request, to the competent authority of the Member State where the authorised use takes place.

5. The authorisation holders may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place that exposure of humans has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately.
6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The authorisation holders shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as technically and practically possible.

#### *Article 4*

In the event that an authorisation holder submits a review report as referred to in Article 61(1) of Regulation (EC) No 1907/2006, it shall include the following:

- (a) the information referred to in Article 3(4) and (6);
- (b) a refined assessment of releases to the environment and associated exposure of the general population, including separate environmental contributing scenarios for each site.

#### *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. Thyssenkrupp Electrical Steel GmbH, Kurt-Schumacher-Straße 95, 45881, Gelsenkirchen, Northrhine-Westphalia, Germany;

2. Thyssenkrupp Electrical Steel UGO S.A.S., Rue Roger Salengro, 62330 Isbergues, France.

Done at Brussels, 22.11.2021

*For the Commission*  
*Thierry BRETON*  
*Member of the Commission*

