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**COMMISSION IMPLEMENTING DECISION**

**of 31.10.2023**

**granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Volta Energy Solutions Hungary Kft for a use of chromium trioxide in the context of a review and amending Implementing Decision C(2020) 7**

(Only the English text is authentic)

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## **granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Volta Energy Solutions Hungary Kft for a use of chromium trioxide in the context of a review and amending Implementing Decision C(2020) 7**

(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), point (a), of that Regulation.
- (2) On 10 January 2020, by Commission Implementing Decision C(2020) 7<sup>2</sup>, an authorisation was granted to Doosan Energy Solution Kft for a use of chromium trioxide in the industrial formulation of a chromium trioxide solution below 0,1 % weight by weight (w/w) concentration for the passivation of copper foil used in the production of lithium ion batteries (LiB) for motorised vehicles (authorisation number REACH/20/13/1). The expiry of the review period referred to in Article 60(9), point (e) of Regulation (EC) No 1907/2006 for that authorised use of chromium trioxide was set at 10 January 2032.
- (3) On 22 December 2020, Volta Energy Solutions Hungary Kft<sup>3</sup> submitted a review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 for authorisation of the use of chromium trioxide in the industrial formulation of a chromium trioxide solution below 0,1 % w/w concentration for the passivation of copper foil used in the manufacture of LiB for motorised vehicles.

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

<sup>2</sup> Commission Implementing Decision C(2020) 7 of 10 January 2020 granting an authorisation for a use of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Doosan Electro-Materials Luxembourg SARL and Doosan Energy Solutions Kft).

<sup>3</sup> Doosan Energy Solution Kft had changed its corporate name to Volta Energy Solutions Hungary Kft.

- (4) The European Chemicals Agency sent the opinions on the review report, adopted by the Committee for Risk Assessment (RAC) and by the Committee for Socio-economic Analysis (SEAC) of the Agency<sup>4</sup>, to the Commission pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006. On 15 December 2021, the Commission received the opinions.
- (5) 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), point (a), of that Regulation. As a result, Article 60(2) 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.
- (6) In its opinion, RAC concluded that the risk management measures and operational conditions described in the review report, and further detailed by Volta Energy Solutions Hungary Kft at RAC's request, are appropriate and effective to limit the risk, both to workers and to members of the general population who could potentially be exposed to chromium trioxide via the environment, posed by the use of chromium trioxide described in the review report. However, in order to address some shortcomings in the representativeness of occupational exposure and environmental release measurements and to provide information on the trends in exposure and emissions during the authorisation period, as well as to ensure that the impact of the planned expansion of the plant is closely monitored, RAC recommended monitoring programmes for both occupational exposure to, and environmental release of, hexavalent chromium (Cr(VI)), which is the hazardous component of chromium trioxide. Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations.
- (7) In its opinion, SEAC concluded that it had no substantial reservations on the quantitative and qualitative elements of the Volta Energy Solutions Hungary Kft's assessment of the benefits and the risk resulting from the continued use of the substance. Taking into account SEAC's assessment, RAC's conclusion that the risk management measures and operational conditions are appropriate and effective to limit the risk, the estimated monetised risk of cancer associated with the continued use in the order of 100 euro per year, the estimated quantitatively assessed benefits due to avoided profit and job losses at minimum between tens and hundreds of millions of euro over the entire review period, the additional qualitatively assessed impacts of not granting an authorisation, as well as any relevant distributional impact, the Commission concludes that Volta Energy Solutions Hungary Kft has demonstrated that the socio-economic benefits of continued use of the substance outweigh the risk to human health or the environment arising from that use.
- (8) 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, the applicant is required to submit a substitution plan. An alternative that provides the functionality and level of technical performance necessary for the use for which authorisation is sought should be considered to be technically feasible.

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<sup>4</sup> <https://echa.europa.eu/documents/10162/bb3d460a-e977-62f3-8ccd-3be6ee35826f>

- (9) In its opinion, SEAC concluded that there were no suitable alternative substances or technologies available for Volta Energy Solutions Hungary Kft by the adoption of the opinion. The Commission, having evaluated SEAC's assessments and all relevant information available, notes that the identified alternatives do not allow achieving the necessary requirements, in particular regarding corrosion resistance, to ensure that the battery's performance is not compromised, and that extensive research and development efforts need still to be undertaken. Thus, the Commission considers that it cannot be deemed that the identified alternatives allow the functionality needed for the use applied for. Therefore, the Commission agrees with SEAC's conclusion and considers that Volta Energy Solutions Hungary Kft has discharged its burden of proof in demonstrating the absence of suitable alternatives both in the Union and for it.
- (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 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. Nevertheless, additional scientific evidence would allow the Commission to perform its assessment on a more robust or broad evidentiary basis in the future. Hence, it is appropriate to require additional exposure and emission information to be generated.
- (12) SEAC recommended in its opinion that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be until 10 January 2032. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, that the risk management measures and operational conditions are appropriate and effective to limit the risk, the high socio-economic benefits and low monetised risk to human health of the continued use of the substance, as well as Volta Energy Solutions Hungary Kft's long investment cycle.
- (13) The language used to describe the risk management measures and operational conditions in the review report 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.
- (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 Article 4(1) and Article 5, of Directive 2004/37/EC of the European Parliament and of the Council<sup>5</sup> to reduce the use of a carcinogen or mutagen at the place of work,

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<sup>5</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

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<sup>6</sup>, 92/85/EEC<sup>7</sup>, 94/33/EC<sup>8</sup> and 98/24/EC<sup>9</sup>, and Directive 2004/37/EC, or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

- (15) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC<sup>10</sup> or Directive 2010/75/EU<sup>11</sup> of the European Parliament and of the Council, 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>12</sup> or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council<sup>13</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.
- (16) The authorisation should therefore be granted in the context of the review referred to in Article 61(1) of Regulation (EC) No 1907/2006. Implementing Decision C(2020) 7 should therefore be amended as provided for in Article 61(1) of Regulation (EC) No 1907/2006 regarding the authorisation bearing number REACH/20/13/1.
- (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,

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Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC (OJ L 158, 30.4.2004, p. 50).

<sup>6</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>7</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>8</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>9</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>10</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>11</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>12</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>13</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).

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/23/26/0/R1     | Industrial formulation of a chromium trioxide solution below 0,1 % w/w concentration for the passivation of copper foil used in the manufacture of Lithium-Ion Batteries (LiB) for motorised vehicles |

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report<sup>14</sup>.

*Article 2*

1. The review period shall expire on 10 January 2032.
2. The authorisation shall cease to be valid on 10 January 2032 if the authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 10 July 2030.

*Article 3*

1. The monitoring arrangements set out in paragraphs 2 to 7 shall apply.
2. The authorisation holder shall carry out a monitoring programme measuring occupational exposure to hexavalent chromium (Cr(VI)). The measurements shall:
  - (a) be conducted at least annually or more frequently if a significant increase of chromium trioxide consumption takes place on site and the frequency of the measurements shall be sufficient to capture any potential increase in inhalation exposure of workers to Cr(VI);
  - (b) be based on relevant standard methodologies or protocols;
  - (c) ensure a sufficiently low limit of quantification;
  - (d) comprise personal and/or static inhalation exposure sampling;
  - (e) be representative of all the tasks with possible inhalation exposure to Cr(VI), the operational conditions and risk management measures for each of these tasks, and of the total number of workers who are potentially exposed;
  - (f) be recorded so as to include contextual information about the tasks performed during sampling;
  - (g) include exposure measurements for the workers involved in the on-site wastewater treatment plant activities until it can be demonstrated that the workers' exposure to Cr(VI) has been appropriately minimised.

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<sup>14</sup> <https://ec.europa.eu/docsroom/documents/48477>

3. The authorisation holder shall carry out a monitoring programme measuring the environmental releases of Cr(VI). The measurements shall:
  - (a) comprise air emission measurements to be carried out at least annually or more frequently if a significant increase of chromium trioxide consumption takes place on site and the frequency of the measurements shall be sufficient to capture any potential increase in emissions of Cr(VI);
  - (b) be based on relevant standard methodologies and protocols;
  - (c) be representative of the operational conditions and risk management measures used at the site where the authorised use takes place;
  - (d) ensure a sufficiently low limit of quantification;
  - (e) be recorded so as to include contextual information associated with each set of measurements.
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 review, at least annually, the effectiveness of operational conditions and risk management measures in place. The authorisation holder shall also review and, if needed, update its assessment of the combined exposure for the different groups of workers. If needed, the authorisation holder shall introduce measures to further reduce occupational exposure to Cr(VI), in accordance with the hierarchy of control principles, and emissions into the environment of Cr(VI), to as low a level as technically and practically possible.
5. The authorisation holder shall document and maintain the information gathered via 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 review and any action taken in accordance with paragraph 4. The authorisation holder shall make that information, including pseudonymised biomonitoring results, available, upon request, to the competent authority of the Member State where the authorised use takes place.
6. After having reached the full capacity of the plant and having ensured that the impact of the expansion is fully monitored, the authorisation holder may reduce the frequency of measurements, once it can demonstrate to the competent authority of the Member State where the use takes place that exposure of humans and emissions to the environment have 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.
7. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 6, and if there is a potential increase in emissions or exposure, the authorisation holder shall carry out without delay the monitoring programmes set out in paragraphs 2 and 3, in order to ensure that emissions and exposure continue to be reduced to as low a level as technically and practically possible. The authorisation holder shall act in accordance with the outcome of these programmes and document such actions.

#### *Article 4*

If the authorisation holder submits a review report, it shall include the information referred to in Article 3(5) and, if applicable, Article 3(6) and (7) as well as the information on the efficiencies of the air and wastewater abatement systems.

#### *Article 5*

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 6*

Implementing Decision C(2020) 7 is amended as follows:

- (1) the title is replaced by the following:  
‘COMMISSION IMPLEMENTING DECISION of 10.1.2020 granting an authorisation for a use of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Doosan Electro-Materials Luxembourg SARL)’;
- (2) In Article 1, first paragraph, the following reference is deleted:  
‘REACH/20/13/1 Doosan Energy Solution Kft’;
- (3) in Article 5, point (2) is deleted.

#### *Article 7*

This Decision is addressed to Volta Energy Solutions Hungary Kft, Váci út 76, HU-1133, Budapest, Hungary.

Done at Brussels, 31.10.2023

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

