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COMMISSION IMPLEMENTING DECISION

of 12.12.2023

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to U. S. Steel Kosice, s.r.o. for certain uses of chromium trioxide and 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) Chromium trioxide and sodium dichromate are listed in Annex XIV to Regulation (EC) No 1907/2006 and uses of those substances are subject to the authorisation requirement in Article 56(1), point (a), of that Regulation.
- (2) On 25 May 2020, U. S. Steel Kosice, s.r.o. ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for a use of chromium trioxide and a use of sodium dichromate, respectively, for passivation of electrolytic tinplate.
- (3) The European Chemicals Agency sent the opinions on the application adopted by the Committee for Risk Assessment (RAC) and by the Committee for Socio-economic Analysis (SEAC)² of the Agency to the Commission pursuant to Article 64(5), third subparagraph, of Regulation (EC) No 1907/2006. On 15 December 2021, the Commission received the opinions.
- (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 and sodium dichromate in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore chromium trioxide and sodium dichromate are substances 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 those substances and an authorisation may therefore only be granted with respect to those substances under paragraph 4 of that Article.

¹ OJ L 396, 30.12.2006, p. 1.

² <https://echa.europa.eu/documents/10162/5c29b486-3e67-8bc6-d63c-876d879d5c9c>

- (5) In its opinion, 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, both to workers and to members of the general population who could potentially be exposed via the environment, posed by the uses of chromium trioxide and sodium dichromate. However, in order to provide a more comprehensive dataset on workers' exposure and environmental releases, as well as to confirm the effectiveness and appropriateness of the risk management measures, RAC recommended monitoring arrangements. Having evaluated the RAC assessment, the Commission agrees with that conclusion and recommendation. However, the Commission notes that the estimated excess cancer risk values for humans via the environment are higher than for other comparable applications for authorisation for the uses of substances containing hexavalent chromium Cr(VI), the hazardous component of chromium trioxide, and sodium dichromate. Although the Commission acknowledges that those values are conservative estimates of the most likely excess risk values, taken for the purpose of carrying out risk-benefit analysis, it considers it appropriate to set out the measures concerning environmental emissions recommended by RAC as conditions for authorisation.
- (6) In its opinion, SEAC concluded that it has no substantial reservations on the quantitative and qualitative elements of the applicant's assessment of the benefits and the monetised risk to human health associated with the continued use of the substances. Taking into account SEAC's assessments 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 risk of cancer associated with the continued use in the order of tens of thousands of euro per year, the estimated monetised socio-economic benefits of continued use due to avoided job losses and relocation costs at minimum in the order of millions of euro over the entire review period, the additional qualitatively assessed benefits due to avoided loss of profits in the applicant's supply chain, and avoided import costs and related carbon dioxide emissions, as well as any relevant distributional impact, the Commission notes that that the monetised benefits of continued use for the applicant outweigh the monetised risk by a factor of at least 30 and concludes that the applicant has demonstrated that the socio-economic benefits of the continued use of chromium trioxide and sodium dichromate 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. An alternative that provides the functionality and level of technical performance necessary for the use applied for should be considered to be technically feasible. Certain potential alternatives may provide the 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 were no suitable alternative substances or technologies available for the applicant by the time of adoption of the opinion. The Commission, having evaluated SEAC's assessment and all relevant information available, acknowledges that before commencing full-scale production, the identified alternative technology needs to complete qualification testing over the real-time shelf-life of the product to verify whether the electrolytic tinplate allows achieving the necessary stability of the oxide layer of the packaging material that ensures a sufficient level of corrosion resistance as required by the applicable regulations on food safety. Thus, the Commission considers that the applicant needs additional time for the implementation of the identified alternative. Therefore, the Commission agrees with SEAC's conclusion and considers that the applicant has discharged its 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 and the use of sodium dichromate described in the application, provided that the risk management measures and operational conditions described in the chemical safety report, as well as the conditions set out in this Decision, are fully applied.
- (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. 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 be generated.
- (11) SEAC recommended in its opinion that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 should be set until the end of 2027. 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 time needed for testing of the alternative, as well as for its implementation at full-scale production.
- (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 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.
- (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 Article 4(1) and Article 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 and 98/24/EC⁷ 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 emission limit values or other requirements set in accordance with Directive 2008/50/EC⁸ or Directive 2010/75/EU⁹ 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 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 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,

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).

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) and sodium dichromate (EC No 234-190-3; CAS No 7789-12-0, 10588-01-9):

Authorisation number	Authorised use
REACH/23/33/0	Use of chromium trioxide for passivation of electrolytic tinplate
REACH/23/33/1	Use of sodium dichromate for passivation of electrolytic tinplate

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report¹², as well as to the conditions set out in Article 2.

Article 2

1. The authorisation shall be subject to the conditions set out in paragraphs 2 to 4.
2. The authorisation holder shall carry out a monitoring programme measuring the environmental releases of hexavalent chromium (Cr(VI)). The measurements shall:
 - (a) comprise the continuation of their monitoring programmes for Cr(VI) emission to wastewater;
 - (b) comprise air emission measurements to be carried out at least annually or more frequently if a significant increase of chromium trioxide or sodium dichromate consumption takes place on site and shall be sufficiently frequent to capture any potential increase in emissions of Cr(VI);
 - (c) be based on relevant standard methodologies or protocols;
 - (d) be representative of the operational conditions and risk management measures used at the site where the authorised uses take place;
 - (e) ensure a sufficiently low limit of quantification;
 - (f) be recorded so as to include contextual information associated with each of the measurements.
3. The authorisation holder shall use the information gathered via the measurements and related contextual information referred to in paragraph 2, 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 refine the exposure assessment of humans via the environment. If needed, the authorisation holder shall introduce measures to further reduce Cr(VI) emissions to the environment, to as low a level as technically and practically possible.

¹² <https://ec.europa.eu/docsroom/documents/48478>

4. The authorisation holder 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 review and any action taken in accordance with paragraph 3. The authorisation holder shall make that information available, upon request, to the competent authority of the Member State where the authorised uses take place.

Article 3

The review period shall expire on 31 December 2027.

The authorisation shall cease to be valid on 31 December 2027 with respect to the authorised use if the review report for that use has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 30 June 2026.

Article 4

1. The monitoring arrangements set out in paragraph 2 to 4 shall apply.
2. The authorisation holder shall carry out a monitoring programme measuring occupational exposure to Cr(VI). The measurements shall:
 - (a) be conducted at least annually or more frequently if a significant increase of chromium trioxide or sodium dichromate consumption takes place on site and shall be sufficiently frequent to capture any potential increase in 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 static inhalation exposure sampling;
 - (e) be representative of all the tasks with possible 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.
3. The authorisation holder shall use the information gathered via the measurements and related contextual information referred to in paragraph 2 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 refine the assessment of the exposure for the different groups of workers. If needed, the authorisation holder shall introduce measures to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically possible and in accordance with the hierarchy of control principles.
4. The authorisation holder 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 review and any action taken in accordance with paragraph 3. The authorisation holder shall make that information available, upon request, to the competent authority of the Member State where the authorised uses take place.

Article 5

Where the authorisation holder submits a review report, it shall include the information referred to in Article 2(4) and Article 4(4).

Article 6

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 uses take place in an official language of that Member State.

Article 7

This Decision is addressed to U. S. Steel Kosice s.r.o., Vstupny areal U. S. Steel, 044 54 Kosice, Slovakia.

Done at Brussels, 12.12.2023

For the Commission

Thierry BRETON

Member of the Commission

