EUROPEAN
COMMISSION

Brussels, 10.4.2024
C(2024) 2095 final

COMMISSION IMPLEMENTING DECISION

of 10.4.2024

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Liberty Galati for a use 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/EC[1], 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 24 August 2022, Liberty Galati SA ('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 sodium dichromate. The use for which authorisation was sought is the use of chromium(VI) trioxide and sodium dichromate for passivation of electrolytic tinplate.

(3) The European Chemicals Agency sent the opinions on the application for authorisation[2] adopted by its Committee for Risk Assessment (RAC) and its Committee for Socio-economic Analysis (SEAC) to the Commission pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006. On 12 December 2023, the Commission received the opinions.

(4) In its opinions, RAC concluded 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 chromium trioxide and sodium dichromate 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, ELI: http://data.europa.eu/eli/reg/2006/1907/oj.

[2] https://www.echa.europa.eu/documents/10162/4ec04d4b-9f87-eacc-53ec-3b46589aeb00

(5) In its opinion, RAC concluded that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to human health as regards the carcinogenic hazards posed by the uses of chromium trioxide and sodium dichromate described in the application.

(6) Nevertheless, RAC expressed moderate concerns related to the sampling of bath concentrations and the use of respiratory protective equipment. Therefore, RAC recommended imposing additional conditions. Moreover, to provide reliable further information on the effectiveness of operational conditions and risk management measures implemented as a result of additional conditions and on associated trends in exposure to hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide and sodium dichromate, during the review period, RAC recommended imposing monitoring arrangements. Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations.

(7) In its opinion, SEAC concluded that the societal costs of not granting an authorisation are higher than the monetised risk to human health arising from the use of chromium trioxide and sodium dichromate described in the application. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that the applicant has demonstrated that the benefits of the continued use outweigh the risk to human health and the environment arising from that use.

(8) For an alternative to be suitable it needs to 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 by Article 62(4), point (f), of Regulation (EC) No 1907/2006 to submit a substitution plan.

(9) 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. Certain potential alternatives may provide the functionality, but at some loss of 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 of performance or technical compromises by applying a reasonable additional effort, taking into account the circumstances of the case.

(10) In its opinion, SEAC concluded that there were no technically and economically feasible alternative substances or technologies available for the applicant, but that there were technically and economically feasible alternatives available in the Union. In particular, SEAC noted that the identified alternative is already commercially available today, but either in insufficient quantities, or adaptations to achieve full industrial production are still necessary for the applicant to fully transition to the identified alternative. The Commission, having evaluated SEAC's assessment and the relevant information available, notes that further qualification and long-term pack testing of products are required to ensure the levels of performance and compliance with the requirements of the food contact materials legislation in the Union, including Regulation (EC) No 1935/2004 of the European Parliament and of the Council, as well as relevant national specific rules, before full implementation of the alternatives can be achieved. Therefore, the Commission agrees with SEAC's conclusion and considers

that, although suitable alternatives are available in the Union, they are not yet technically feasible for the applicant.

(11) In its opinion, SEAC concluded that the substitution plan submitted by the applicant is credible for the review period requested and consistent with the analysis of the alternatives. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and, taking into account the availability of suitable alternatives in the Union for the use for which authorisation is sought, the substitution plan submitted by the applicant and its commitment to substitute the substances, considers that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternative substances or technologies.

(12) 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 sodium dichromate described in the application, provided that the risk management measures described in the chemical safety report are applied, and that the operational conditions described therein, as well as the conditions set out in this Decision, are fulfilled.

(13) The Commission has based its assessment on all relevant scientific evidence available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, has concluded on the basis of a sufficient amount of material and reliable information. 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 the authorisation holder to generate and include additional information about exposure and emissions in the review report.

(14) In its opinion, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set until the end of 2027. The Commission agrees with that recommendation, taking into account relevant elements from RAC's and SEAC's assessments and, in particular, RAC's conclusion that the risk management measures are appropriate and effective in limiting the risk, SEAC's conclusion on the socio-economic benefits and costs of the continued use of the substances, as well as the time needed to achieve full implementation of the alternative.

(15) 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.

(16) This Decision does not affect the obligation of the authorisation holder to ensure that the 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[3] to reduce the use of carcinogens, mutagens or reprotoxic substances at the place of work, in particular by replacing those substances, 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, or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

(17) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC[8] or Directive 2010/75/EU[9] 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[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 any emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.

(18) 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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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, mutagens or reprotoxic substances 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, ELI: http://data.europa.eu/eli/dir/2004/37/oj).

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, ELI: http://data.europa.eu/eli/dir/1989/391/oj).

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, ELI: http://data.europa.eu/eli/dir/1992/85/oj).

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, ELI: http://data.europa.eu/eli/dir/1994/33/oj).

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, ELI: http://data.europa.eu/eli/dir/1998/24/oj).

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, ELI: http://data.europa.eu/eli/dir/2008/50/oj).

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, ELI: http://data.europa.eu/eli/dir/2010/75/oj).

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, ELI: http://data.europa.eu/eli/dir/2000/60/oj).

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, ELI: http://data.europa.eu/eli/dir/2008/105/oj).

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 person 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, 616-541-6; CAS No 7789-12-0, 10588-01-9):

Authorisation number	Authorisation holder	Authorised use
REACH/24/2/0	Liberty Galati	Use of chromium trioxide for passivation of electrolytic tinplate
REACH/24/2/1		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 report[12], and to the conditions set out in Article 2.

Article 2

1. The authorisation is subject to the conditions set out in paragraphs 2, 3 and 4.

2. The authorisation holder shall ensure that workers:

   (a) are provided with adequate respiratory equipment, subjected to a fit test prior to its first use;

   (b) always perform a fit check of the seal of their respiratory protective equipment before starting a relevant task; and

   (c) are adequately supported and trained, respectively, to undergo these fit tests and to undertake these fit checks.

3. The authorisation holder shall ensure that for any task conducted in the tinning line cellar, including bath sampling, appropriate respiratory protective equipment is worn, as long as the exposure measured in the cellar is higher than the value used for the exposure assessment of the sampling task (worker contributing scenario 2).

4. By 10 April 2025 and afterwards each time when new information becomes available, the authorisation holder shall carry out a study to assess the feasibility of the implementation of a closed or an automated system to perform passivation tank sampling tasks, where exposure to Cr(VI) is foreseen, and shall act in accordance with the outcome of those studies. The results of those studies and the actions taken shall be made available, upon request, to the competent authority of the Member State where the authorised uses take place.

Article 3

1. The review period shall expire on 31 December 2027.

[12] https://echa.europa.eu/documents/10162/76b4b3a3-9b88-7c04-c4ba-8f2f2ce87149

2. The authorisation shall cease to be valid on 31 December 2027 with regard to an authorised use if the authorisation holder has not submitted the review report for that use 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 paragraphs 2 to 7 shall apply.

2. The authorisation holder shall carry out a monitoring programme measuring occupational exposure to Cr(VI). The programme shall include measurements which shall:

   (a) take place 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 or static inhalation exposure sampling;

   (e) be representative of all the tasks with possible exposure to Cr(VI), including maintenance tasks, of the operational conditions and risk management measures for each of these tasks, and of the total number of workers that are potentially exposed;

   (f) be recorded so as to include contextual information about the tasks with possible exposure to Cr(VI).

3. The authorisation holder shall continue conducting an annual biomonitoring programme for a representative number of workers potentially exposed to Cr(VI).

4. The authorisation holder shall carry out a monitoring programme measuring the environmental releases of Cr(VI) to the air and wastewater. The programme shall include measurements which shall:

   (a) take place 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 emission of Cr(VI);

   (b) be based on relevant standard methodologies and protocols;

   (c) ensure a sufficiently low limit of quantification;

   (d) be representative of the operational conditions and risk management measures used at the sites where the authorised uses take place;

   (e) be recorded so as to include contextual information associated with each of the measurements.

5. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraphs 2, 3 and 4 to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions in place. The authorisation holder shall also review and, if needed, update its assessment of the combined exposure for the different groups of workers and its

assessment of the exposure of the general population via the environment. If needed, the authorisation holder shall introduce measures to further reduce to a level as low as technically and practically possible both workplace exposure to Cr(VI) in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/3/EC and Cr(VI) emissions to the environment.

6. The authorisation holder shall document and maintain the information from the monitoring programmes referred to in paragraphs 2, 3 and 4, 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 5. The authorisation holder shall make that information, including pseudonymised or aggregated biomonitoring results, available, upon request, to the competent authority of the Member State where the authorised uses take place.

7. The authorisation holder shall document the steps taken to substitute chromium trioxide and sodium dichromate in accordance with the substitution plan, including information on the efforts to convince the authorisation holder's customers to accept alternative Cr(VI)-free solutions and justification in case its customers do not accept alternative solutions. Any deviations from the initial substitution plan and information on contingency measures taken shall also be documented. The authorisation holder shall make such documentation available, upon request, to the competent authority of the Member State where the authorised uses take place.

Article 5

If a review report is submitted, it shall include the information referred to in Article 2(4) and in Article 4(6) and (7).

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. The brief summary shall be drafted in an official language of that Member State.

Article 7

This Decision is addressed to Liberty Galati SA, 1 Smardan Street, 800698 Galati County, Romania.

Done at Brussels, 10.4.2024

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION