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COMMISSION IMPLEMENTING DECISION

of 7.6.2024

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Newform S.P.A for a use of chromium trioxide

(Only the Italian 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 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 18 August 2021, Newform S.P.A. ('the applicant') 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 electroplating of different types of substrates using chromium trioxide to achieve functional surfaces with high durability and a bright or matt silvery appearance for sanitary applications.
- (3) The European Chemicals Agency sent the opinions² on the application 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 20 September 2022, the Commission received the opinions.
- (4) In its opinion, RAC concluded that it is not possible to determine a derived no-effect level for the carcinogenic properties of chromium trioxide in accordance with Section 1.4 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 chromium trioxide and an authorisation may therefore only be granted with respect to that substance 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/c91a97f4-0843-f479-504f-75282d325160>

- (5) In its opinion, RAC concluded that the risk management measures and operational conditions described in the application are not appropriate and effective in limiting the risk to human health posed by the use of chromium trioxide described in the application. In particular, RAC expressed major concerns regarding the risk originating from the use of a manual plating line as well as moderate concerns related to the implementation of the hierarchy of control principles onsite. Consequently, it recommended additional conditions for authorisation, including the shutdown of the manual plating line, until more appropriate risk management measures and operational conditions are in place. Moreover, RAC recommended monitoring arrangements with the aim of addressing shortcomings in exposure estimates and of providing information on the trends in exposure and emissions during the authorisation period, for both occupational exposure to and environmental release of hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide, as well as of obtaining further information on the effectiveness of operational conditions and risk management measures implemented as a result of the additional conditions.
- (6) Having evaluated RAC's assessment, the Commission agrees with its conclusions and recommendations. Nevertheless, the Commission notes that the estimated excess cancer risk values for workers are higher than as regards other comparable applications for authorisation for the use of Cr(VI) substances. Although the Commission acknowledges that those values are conservative estimates of the most likely excess risk values taken for the purpose of carrying out a risk-benefit analysis, it considers it appropriate to set out the measures concerning occupational exposure recommended by RAC as a condition for authorisation.
- (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. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that the applicant has demonstrated that the benefits of the use outweigh the risk to human health 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 at the time of the adoption of the opinions. The Commission, having evaluated SEAC's assessment and the relevant information available, notes that the applicant has

identified alternatives to substitute Cr(VI), with chromium hydroxide based electrolytes as the preferred option. However, the Commission acknowledges that additional research is needed to improve and adapt the most promising alternative process to the applicant's production process and quality requirements, especially considering the significant loss of performance in relation to corrosion protection, chemical resistance and surface appearance. In this regard, the Commission acknowledges that the applicant has demonstrated that it is not yet able to accommodate such loss of performance and would need more time to develop and implement one of the most promising alternatives to make it technically feasible for them. 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, overall, credible, in particular for the substitution phases that address the study of the production process with the alternative, scaling up the production, placing on the market the products made with the alternative and implementing a phasing out of Cr(VI) production. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers, taking into account the availability of suitable alternatives in the Union for the use for which authorisation is sought and the substitution plan submitted by the applicant, that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternative substances or technologies.
- (12) The Commission recalls that the aim of the authorisation system is to ensure that substances of very high concern are progressively replaced by suitable alternative substances or technologies where these are available and technically and economically viable. The Commission also acknowledges that, as the substitution of chromium trioxide progresses, the applicant expects to reduce the overall quantities of that substance used throughout the review period, in accordance with the figures provided by the applicant to the Commission. Therefore, the Commission considers it appropriate to set out as a condition for authorisation that the quantity of chromium trioxide used in the use for which authorisation is sought should be reduced in line with the figures provided by the applicant to the Commission, in order to ensure that the substitution strategy is duly implemented and to facilitate the enforcement of that obligation.
- (13) 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 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.
- (14) 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.
- (15) 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 at nine years, until 18 August 2030.

SEAC noted that the 12 years review period requested by the applicant was not warranted, taking into account that the substitution plan does not provide adequate and detailed justifications for the time and objectives of the substitution activities. The Commission agrees with that recommendation, considering 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 not appropriate and effective to limit the risk to human health, SEAC's conclusion on the socio-economic benefits of the continued use of the substance, as well as SEAC's conclusion on the substitution plan. More specifically, the Commission considers that the applicant's strategy to reduce the quantity of chromium trioxide used during the review period is a key factor for its agreement with SEAC's recommendation on the review period.

- (16) 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.
- (17) 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 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/EEC⁴, 92/85/EEC⁵, 94/33/EC⁶, 98/24/EC⁷ and Directive 2004/37/EC, or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

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>).

- (18) 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.
- (19) 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 person for the following use of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0):

Authorisation number	Authorisation holder	Authorised use
REACH/24/18/0	Newform S.P.A.	Electroplating of different types of substrates using chromium trioxide to achieve functional surfaces with high durability and a bright or matt silvery appearance for sanitary applications

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

Article 2

1. The authorisation is subject to the conditions set out in paragraphs 2 to 10.

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>).

¹² <https://www.echa.europa.eu/documents/10162/563c6103-4cdd-ec3a-ff19-da980aecdfb>.

2. By 31 December 2029, the authorisation holder shall reduce the total annual quantity of chromium trioxide used for the authorised use by 75% compared to the total annual quantity of that substance used in 2021.

The authorisation holder shall, upon request, provide the relevant documentation, including the reduction progress to the competent authority of the Member State where the authorised use takes place.

3. The authorisation holder shall, without delay, discontinue the use of the manual plating line until the following measures are implemented:
 - (a) the process is modified so that workers no longer stay nearby the hexavalent chromium (Cr(VI))-containing baths and manually hold the jigs during plating;
 - (b) it is ensured that the risk management measures and operational conditions are in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC and are effective in limiting the risk.

4. By 7 June 2025 and afterwards each time when new relevant information becomes available, the authorisation holder shall carry out a study to assess the feasibility of implementing the following measures:

- (a) automation of the concentration adjustment using liquid chromium trioxide within a closed system;
- (b) installation of a closed or automatic system to perform bath sampling tasks.

The authorisation holder shall act in accordance with the outcome of that study.

5. Without prejudice to the obligation set out in paragraph 4, by 7 June 2025 the authorisation holder shall implement additional risk management measures and occupational conditions to ensure that the exposure to Cr(VI) at the loading and unloading working area is at as low a level as technically and practically feasible.

6. 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.

7. 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 Cr(VI) 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/or static inhalation exposure sampling;
- (e) be representative of all the tasks with possible exposure to Cr(VI), including maintenance tasks, the operational conditions and risk management measures

for each of those tasks, and of the total number of workers that are potentially exposed;

- (f) be recorded so as to include contextual information about the tasks performed during exposure sampling with possible exposure to Cr(VI).
8. The authorisation holder shall conduct a biomonitoring programme for a representative number of workers potentially exposed to Cr(VI).
 9. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraphs 7 and 8 to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions in place. While doing so, 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 to a level as low as technically and practically possible occupational exposure to Cr(VI) in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.
 10. The authorisation holder shall document and maintain the information gathered via the monitoring programmes referred to in paragraphs 7 and 8, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the reviews and studies and any measure taken in accordance with paragraphs 3 to 6 and 9, and shall make that information available, including pseudonymised or aggregated biomonitoring results, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 3

1. The review period shall expire on 18 August 2030.
2. The authorisation shall cease to be valid on 18 August 2030 if the authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 18 February 2029.

Article 4

1. The monitoring arrangements set out in paragraphs 2 to 5 shall apply.
2. 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 the production process is modified, and shall be sufficiently frequent to capture any potential increase in emission of Cr(VI);
 - (b) be based on relevant standard methodologies or protocols;
 - (c) ensure a sufficiently low limit of quantification;
 - (d) be representative of the operational conditions and risk management measures used at the site where the authorised use takes place;
 - (e) be recorded so as to include contextual information associated with each set of measurements.

3. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraph 2 to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions in place. While doing so, the authorisation holder shall also review and, if needed, update 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 Cr(VI) emissions to the environment.
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 reviews and any measure taken in accordance with paragraph 3 and shall make that information available, upon request, to the competent authority of the Member State where the authorised use takes place.
5. The authorisation holder shall document the steps taken to substitute chromium trioxide 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 Cr(VI)-free 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 use takes place.

Article 5

If a review report is submitted, it shall include the following:

- (a) the information referred to in Article 2(10) and Article 4(4) and (5).
- (b) the figures detailing the reduction of the quantity of chromium trioxide used in the authorised use, in line with the commitments set out in the updated substitution plan.

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

Article 7

This Decision is addressed to:

Newform S.P.A., Via Marconi 25/A. Fraz. Vintebbio, 13037, Serravalle Sesia (VC), Italy.

Done at Brussels, 7.6.2024

For the Commission
Thierry BRETON
Member of the Commission