EUROPEAN
COMMISSION

Brussels, 16.9.2024
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COMMISSION IMPLEMENTING DECISION

of 16.9.2024

partially granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Heinrich Schulte Söhne GmbH & Co. KG and Schulte Hartchrom GmbH for certain uses of chromium trioxide

(Only the German 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 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 25 October 2021, Heinrich Schulte Söhne GmbH & Co. KG and Schulte Hartchrom GmbH ('the applicants') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for certain uses of chromium trioxide. The uses for which authorisation was sought are functional chrome plating of large components and small components with complex geometries and/or requiring special approval procedures for their application in demanding sectors such as medical, aerospace, defence and mining industry ('use 1') and functional chrome plating of small components with simple geometries not requiring special approval procedures for their application in demanding sectors such as hydraulic systems, food, paper and chemical industry ('use 2').

(3) The European Chemicals Agency sent the opinions on the application for authorisation for use 1[2] and use 2[3] 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 3 January 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 and mutagenic properties of chromium trioxide in

[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/10162/3ebc81f0-d4e0-86d1-51bd-9debdfbb3a95

[3] https://www.echa.europa.eu/documents/10162/9e2c9426-7bcf-e80d-f6d3-671e49f217f7

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 that Regulation 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.

(5) In its opinions on uses 1 and 2, 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 those uses. RAC expressed significant concerns regarding the hierarchy of control principles and, in particular, the lack of engineering controls and resulting strong reliance on personal protective equipment. Therefore, RAC recommended imposing additional conditions for authorisation, including the introduction of additional risk management measures and operational conditions such as bath coverage and physical segregation between tasks with foreseeable exposure to hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide, and other tasks. Moreover, 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 additional monitoring programmes on occupational exposure to and environmental releases of Cr(VI).

(6) Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations. Nevertheless, as regards use 1, the Commission notes that the estimated excess cancer risk values for workers and for the general population, exposed via the environment, 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 and environmental emissions, recommended by RAC as monitoring arrangements, as conditions for authorisation for that use.

(7) As regards use 2, 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 monitoring arrangements, as conditions for authorisation for that use.

(8) In its opinions on uses 1 and 2, SEAC concluded that the societal costs of not granting an authorisation are higher than the monetised risk to human health arising from the uses of chromium trioxide. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that the applicants have demonstrated that the benefits of the continued uses outweigh the risk to human health arising from those uses.

(9) 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.

(10) 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.

(11) In its opinions on uses 1 and 2, SEAC concluded that there were no technically feasible alternative substances or technologies available for the applicants and that there was no information available indicating that there were technically or economically feasible alternatives in the Union at the time of adoption of the opinions. The Commission, having evaluated SEAC's assessment and the relevant information available, notes that the identified potential alternatives require further development and testing to fulfil all the necessary functional properties, in particular crack pattern and wear resistance for one alternative and hardness and wear resistance for another alternative, required to ensure process reliability in the relevant industry sectors, service life of components, and compliance with regulatory requirements. Thus, the Commission agrees with SEAC's conclusion and considers that there are no suitable alternatives for the applicants and in the Union.

(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 uses of chromium trioxide described in this Decision, 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) Nevertheless, taking into account the information submitted in the application as assessed by SEAC, the Commission considers that the description of the uses for which the authorisation is sought is very broad. In particular, as the Commission notes that the analysis of alternatives provides a number of more detailed applications derived from the applicants' product portfolio that are covered by the uses for which the authorisation is sought, for the sake of legal clarity and to ensure that the use descriptions properly reflect SEAC's assessment, it is appropriate to limit the authorised uses to the applications as confirmed by the authorisation holders.

(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 holders to generate and include additional information about exposure and emissions in the review report.

(15) In its opinion on use 1, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set at 12 years. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, the additional authorisation conditions imposed to limit the risk based on RAC's conclusions that the current risk management measures and operational conditions are not appropriate and

effective in limiting the risk, SEAC's conclusion on the monetised risk to human health and on the socio-economic benefits of the continued use of the substance as well as the time required to transition to an alternative, including for regulatory approvals in some of the sectors supplied with the products plated by the authorisation holders.

(16) In its opinion on use 2, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set at 7 years. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, the additional authorisation conditions imposed to limit the risk based on RAC's conclusions that the current risk management measures and operational conditions are not appropriate and effective in limiting the risk, SEAC's conclusion on the risk to human health and on the socio-economic benefits of the continued use of the substance as well as the time required to transition to an alternative.

(17) 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 uses take 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.

(18) This Decision does not affect the obligation of the authorisation holders 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 holders 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[4] 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[5], 92/85/EEC[6], 94/33/EC[7], 98/24/EC[8] and Directive 2004/37/EC, or any

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4 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).

5 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).

6 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).

7 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).

8 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

national binding occupational limit values which may be stricter than the applicable limit values under Union law.

(19) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC[9] or Directive 2010/75/EU[10] 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[11] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[12]. 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.

(20) 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 uses of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0)*:*

Authorisation number	Authorisation holder	Authorised use
REACH/24/47/0	Heinrich Schulte Söhne GmbH & Co. KG	Functional chrome plating of large components and small components with complex geometries or requiring special approval procedures for the applications listed in the Annex
REACH/24/47/1	Schulte Hartchrom GmbH	

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).

9 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).

10 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).

11 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).

12 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).

REACH/24/47/2	Heinrich Schulte Söhne GmbH & Co. KG	Functional chrome plating of small components with simple geometries not requiring special approval procedures for the applications listed in the Annex
REACH/24/47/3	Schulte Hartchrom GmbH	

The authorisation is not granted for the use of chromium trioxide in functional chrome plating of components for applications other than the ones listed in the Annex.

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[13], 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.

2. At the latest by 16 September 2025, the authorisation holders shall implement additional risk management measures and operational conditions to ensure that exposure to hexavalent chromium (Cr(VI)) is at a level as low technically and practically possible. Such measures shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC and shall include at least the following measures:

   (a) the physical segregation of the chrome plating area from other work areas to ensure that workers do not need to be close to the baths during loading and unloading operations;

   (b) the installation of bath covers for all open baths or segregation of electroplating emission sources to ensure that exposure to Cr(VI) at the plating lines is at a level as low as technically and practically feasible.

3. The authorisation holders shall conduct control measurements to validate the appropriateness and effectiveness of the additional risk management measures and operational conditions implemented in accordance with paragraph 2. If necessary, additional risk management measures or operational conditions shall be implemented to further reduce exposure to Cr(VI) to a level as low as is technically and practically feasible.

4. By 16 September 2025 and afterwards each time when new relevant information becomes available, the authorisation holders shall carry out a study to assess the feasibility of implementing the following measures:

   (a) the substitution of solid chromium trioxide flakes by liquid chromium trioxide solutions;

   (b) the installation of an automated system to perform the bath adjustment and the implementation of a closed system to perform bath sampling tasks, where exposure to Cr(VI) is expected and which currently rely on the use of personal protective equipment;

[13] https://ec.europa.eu/docsroom/documents/52969

(c) the implementation of measures to reduce the potential exposure of workers to Cr(VI) during the removal of sludge from the emptied baths;

(d) the installation of a system for the remote operation of the hoists to reduce the presence of workers in proximity of the Cr(VI)-containing baths.

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

5. The authorisation holders shall ensure that, where respiratory protective equipment is needed to minimise exposure to Cr(VI), the workers:

(a) are provided with adequate respiratory equipment, which is 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;

(c) are adequately supported to undergo the fit test referred to in point (a) and trained to undertake the fit checks referred to in point (b).

6. The authorisation holders shall carry out a monitoring programme measuring occupational inhalation 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 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 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.

7. The authorisation holders shall continue conducting a biomonitoring programme for a representative number of workers potentially exposed to Cr(VI) which shall:

(a) include, as a minimum, a pre-shift urine sample at the beginning of each working week and a post-shift urine sample at the end of each working week;

(b) be based on relevant standard methodologies;

(c) be conducted in conjunction with the annual occupational inhalation exposure monitoring programme referred to in paragraph 6.

8. As regards the authorisation bearing numbers REACH/24/47/0 and REACH/24/47/1, the authorisation holders 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 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 or 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 set of measurements.

9. The authorisation holders shall use the information gathered by way of the measurements referred to in paragraphs 6, 7 and, if applicable, paragraph 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 holders shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers and, if applicable, their assessment of the exposure of the general population via the environment. If needed, based on the outcome of those reviews, the authorisation holders shall introduce measures to further reduce to a level as low as technically and practically possible occupational exposure to Cr(VI) and, if applicable, Cr(VI) emissions to the environment. Measures introduced to reduce occupational exposure shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC,

10. The authorisation holders shall document and maintain the information from the monitoring programmes referred to in paragraphs 6, 7 and, if applicable, paragraph 8, including the contextual information associated with each set of measurements, as well as the information on the outcome and conclusions of the studies and reviews and on any measure taken in accordance with paragraphs 2, 3, 4, 5 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 uses take place.

Article 3

1. As regards the authorisation bearing numbers REACH/24/47/0 and REACH/24/47/1, the review period shall expire on 31 December 2033.

   The authorisation bearing numbers REACH/24/47/0 and REACH/24/47/1 shall cease to be valid on 31 December 2033 in relation to any authorisation holder who has not submitted the review report for that use in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 30 June 2032.

2. As regards the authorisation bearing numbers REACH/24/47/2 and REACH/24/47/3, the review period shall expire on 31 December 2028.

   The authorisation bearing numbers REACH/24/47/2 and REACH/24/47/3 shall cease to be valid on 31 December 2028 in relation to any authorisation holder who has not submitted the review report for that use in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 30 June 2027.

Article 4

1. The monitoring arrangements set out in paragraphs 2, 3 and 4 shall apply to the authorisation bearing numbers REACH/24/47/2 and REACH/24/47/3.

2. The authorisation holders 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 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 or 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 set of measurements.

3. The authorisation holders shall use the information gathered by way of the measurements referred to in paragraph 2 and related contextual information to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions in place. While doing so, the authorisation holders shall also review and, if needed, update their assessment of the exposure of the general population via the environment. If needed, based on the outcome of those reviews, the authorisation holders 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 holders shall document and maintain the information from the monitoring programmes referred to in paragraph 2, including the contextual information associated with each set of measurements, as well as the information on the outcome and conclusions of the reviews and on 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.

Article 5

If a review report is submitted, it shall include the information referred to in Article 2(10) and Article 4(4).

Article 6

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

Article 7

This Decision is addressed to:

(1) Heinrich Schulte Söhne GmbH & Co. KG, Widayweg 10, 59823 Arnsberg, Germany

(2) Schulte Hartchrom GmbH, Widayweg 10, 59823 Arnsberg, Germany.

Done at Brussels, 16.9.2024

For the Commission
Margrethe VESTAGER
Executive Vice-President