EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING DECISION

of XXX

partially granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to STI Deutschland GmbH and Hartchrom Teikuro Automotive GmbH for a use of chromium trioxide

(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 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 20 November 2023, STI Deutschland GmbH and Hartchrom Teikuro Automotive GmbH ('the applicants') 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 an authorisation was sought is functional plating of mesh baskets, printing cylinders, rollers, valves, and other industrial applications, conforming to the definition of large-scale industrial installations.

(3) The European Chemicals Agency sent the opinions[2] 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 29 September 2025, 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 and mutagenic 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

[1] OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj.

[2] https://echa.europa.eu/documents/10162/1a3d0129-ed83-4a6a-4cb0-1ee60257453f

and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.

(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 posed by the use of chromium trioxide described in the application. However, RAC expressed concerns about the manual nature of certain tasks, the lack of fit test of respiratory protective equipment and the lack of automation. Consequently, in order to further minimise the exposure of workers to hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide, RAC recommended imposing additional conditions for authorisation. Moreover, in order to address shortcomings in exposure and emissions estimates, and to corroborate the appropriateness and effectiveness of the risk management measures and operational conditions in place, RAC recommended imposing additional monitoring arrangements for both occupational exposure to Cr(VI) and environmental release of Cr(VI).

(6) Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations. Nevertheless, 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 impose additional conditions for authorisation and to set out the measures concerning occupational exposure to Cr(VI) and environmental emissions, recommended by RAC as monitoring arrangements, 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 applicants have demonstrated that the benefits of the continued 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 an 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 feasible alternative substances or technologies available for the applicants but that there were technically and economically feasible alternatives in the Union at the time of adoption of the opinion. The Commission, having evaluated SEAC's assessments and the relevant

information available, notes that alternatives providing the overall functionality needed for the use for which an authorisation is sought are commercially available and already implemented in the Union for some of the applications covered by the use for which an authorisation is sought. The Commission, however, recognises that those alternatives imply a loss of performance in terms of requirements of functional nature, namely related to abrasion, adhesion, anti-adhesive properties, chemical resistance, corrosion resistance and hardness, and that the applicants have demonstrated that they are not yet able to accommodate such loss of performance and would need more time to develop and implement an alternative. 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 applicants.

(11) In its opinion, SEAC concluded that the substitution plan submitted by the applicants is credible and consistent with the analysis of alternatives and the socio-economic analysis. 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 an authorisation is sought and the substitution plan submitted by the applicants, that the applicants have discharged their 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 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 by the applicants as assessed by SEAC, the Commission considers that the description of the use for which the authorisation is sought is very broad. The Commission notes that the analysis of alternatives provides more detailed information on the product groups and sectors covered by the use for which the authorisation is sought. Therefore, for the sake of legal clarity and to ensure that the use description properly reflects SEAC's assessment, it is appropriate to limit and reword the authorised use accordingly.

(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, based its conclusions on 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 additional information about exposure and emission to be included 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 twelve years. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, the estimated excess cancer risk values, the additional authorisation conditions imposed to limit the risk based on RAC's conclusion that the existing risk management measures and operational conditions are appropriate and effective in limiting the risk for workers, SEAC's conclusion on the risk to human health and on the socio-economic benefits of the use of the substance, as well as SEAC's conclusion on the substitution plan.

(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 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], and 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.

(18) 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

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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).

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.

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

Authorisation number	Authorisation holder	Authorised use
REACH/26/X/0	STI Deutschland GmbH	Functional plating of the applications listed in the Annex
REACH/26/X/1	Hartchrom Teikuro Automotive GmbH	

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 to 13.

2. The authorisation holders shall ensure that workers:

   (a) are provided with adequate respiratory protective 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 tests referred to in point (a) and trained to undertake the fit checks in point (b).

3. Without delay, and at the latest by [*please insert the date = 12 months from the date of adoption of this Decision*], the authorisation holders shall implement the necessary

[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://webgate.ec.europa.eu/circabc-ewpp/ui/group/cf89c883-2efd-452b-a037-de271c1a703c/library/3cf2acdf-e3e2-454c-9b3f-8a6bc359309f/details

technical improvements to the risk management measures and operational conditions to ensure that occupational exposure to hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide, is at a level as low as technically and practically possible. Such measures shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

4. No later than 3 months after implementation of technical improvements to the risk management measures and operational conditions in accordance with paragraph 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 3. 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 technically and practically possible. Such measures shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

5. Without delay, and at the latest by *[please insert the date – 3 months from the date of adoption of this Decision]*, the authorisation holders shall conduct a specific measurement campaign and measure the environmental releases of Cr(VI) to the air at all emission points pursuant to paragraph 10 to validate and review the appropriateness and effectiveness of risk management measures and operational conditions implemented at the site and, if needed, update their assessment of the exposure of the general population via the environment. If necessary, at the latest by *[please insert the date = 18 months from the date of adoption of this Decision]*, technical improvements to the risk management measures and operational conditions shall be implemented to ensure that the emissions of Cr(VI) to the environment from the authorisation holders' site is at a level as low as technically and practically possible. The authorisation holders shall ensure that all the appropriate preventive measures are taken to reduce emissions from the authorisation holders' site and the best available techniques are applied.

6. By *[please insert the date = 3 months from the date of adoption of this Decision]* the authorisation holders shall conduct a specific exposure monitoring programme to assess accurately the exposure to Cr(VI) of workers loading and unloading the jigs and to validate the appropriateness and effectiveness of separation of the automatic plating line and the loading and unloading area. If necessary, without delay, and at the latest by *[please insert the date = 12 months from the date of adoption of this Decision]*, additional risk management measures or operational conditions shall be implemented to ensure that exposure to Cr(VI) of workers who are not performing activities directly associated with operating the electroplating lines, is reduced to as low a level as is technically and practically possible. Such measures shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

7. By [*please insert the date = 12 months from the date of adoption of this Decision*] and afterwards each time that new relevant information becomes available, the authorisation holders shall carry out a study to assess the feasibility of implementing the following measures:

   (a) implementation of a closed or automatic system to perform bath sampling tasks, where exposure to Cr(VI) is expected;

   (b) the substitution of solid Cr(VI) substances with liquid solutions and the implementation of a closed or automatic system to perform the bath concentration adjustment including the preparation of functional Cr(VI)

solutions and any subsequent (re-)filling of the baths with liquid solutions or the implementation of a closed or automatic system to perform the dissolution of solid Cr(VI) substances and any subsequent (re-)filling of the baths with liquid solutions;

(c) the possibility of minimising or eliminating the direct exposure to Cr(VI) when performing sludge removal from the plating baths by implementing alternative methods or additional control measures for sludge removal from the plating baths. Such measures shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC;

(d) implementing full or partial segregation of the loading and unloading areas from the manual plating lines;

(e) automation of the manual plating line referred to in workers contributing scenario 4e;

(f) any additional operational conditions and risk management measures to further reduce workplace exposure to Cr(VI) and environmental emissions of Cr(VI).

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

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

(a) take place at least once before adequate technical improvements referred to in paragraph 3 are in place, and afterwards 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.

9. The authorisation holders shall conduct a biomonitoring programme for a representative number of workers potentially exposed to Cr(VI), which shall:

(a) take place at least annually;

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

(c) be based on relevant standard methodologies;

(d) be conducted in conjunction with the monitoring programme measuring occupational exposure to Cr(VI) referred to in paragraph 8.

10. The authorisation holders shall, at least annually, conduct a biomonitoring programme for a representative number of workers potentially exposed to Cr(VI).

11. The authorisation holders shall carry out a monitoring programme measuring the environmental releases of Cr(VI) to the air. 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 site where the authorised use takes place;

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

12. The authorisation holders shall use the information gathered by way of the measurements referred to in paragraphs 9, 10 and 11 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 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 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.

13. The authorisation holders shall document and maintain the information from the monitoring programmes referred to in paragraphs 9, 10 and 11, and from the measurements referred to in paragraphs 4, 5 and 6, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the reviews and study and any measure taken in accordance with paragraphs 2 to 8 and 12. The authorisation holders 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

The review period shall expire on 20 November 2035.

The authorisation shall cease to be valid on 20 November 2035 if an authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 20 May 2034.

Article 4

The following monitoring arrangement shall apply: the authorisation holders shall document the steps taken to substitute chromium trioxide, including information on the efforts to convince the authorisation holders' customers to accept alternative Cr(VI)-free solutions, and justification in case its customers do not accept alternative Cr(VI)-free solutions. Information on any contingency measure taken shall also be documented by the authorisation holders. The

authorisation holders 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 information referred to in Article 2(13) and Article 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 use takes place. The brief summary shall be drafted in an official language of that Member State.

Article 7

This Decision is addressed to:

(1) STI Deutschland GmbH, Mühlackerstraße 10, 75447 Sternenfels-Diefenbach, Deutschland;

(2) Hartchrom Teikuro Automotive GmbH, Mühlackerstraße 10, 75447 Sternenfels-Diefenbach, Deutschland.

Done at Brussels,

For the Commission
Stéphane Séjourné
Executive Vice-President