EUROPEAN
COMMISSION

Brussels, 8.5.2024
C(2024) 2880 final

COMMISSION IMPLEMENTING DECISION

of 8.5.2024

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Maschinenfabrik Kaspar Walter GmbH & Co KG for certain uses 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 15 February 2021, Maschinenfabrik Kaspar Walter GmbH & Co KG ('the applicant') 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 formulation of chromium trioxide-based electrolyte for electroplating process ('use 1'), and chromium trioxide-based functional chrome plating of cylinders used in the rotogravure printing and embossing industry ('use 2'). Use 1 is carried out by one downstream user, the formulator, use 2 is carried out by a large group (more than 100) of downstream users, either manufacturers of printing cylinders or printing companies.

(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 14 March 2022, 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 in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore 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/10162/2b9387a0-5805-5b5a-5ecd-1c7669d14a91

[3] https://echa.europa.eu/documents/10162/61fbc576-3b52-04af-71b6-28f03e8793d8

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.

(5) In its opinions, 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 uses 1 and 2.

(6) However, in view of a few inherent uncertainties in the survey of the downstream users and in determining if all the risk management measures and operational conditions form part of the minimum requirements for all downstream users, as well as to facilitate enforcement, RAC recommended imposing additional conditions for uses 1 and 2. Moreover, to obtain 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 during the review period, RAC also recommended imposing monitoring arrangements for uses 1 and 2.

(7) Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations. In this regard, the Commission notes the large number of downstream users and the potential future inclusion of additional downstream users for use 2 and considers it appropriate to set out detailed additional conditions for that use. Nevertheless, the Commission notes that the estimated excess cancer risk values for workers as regards uses 1 and 2, and for the general population, exposed via the environment, as regards use 2, are higher than as regards other comparable applications for authorisation for the use of hexavalent (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 corresponding measures concerning occupational exposure and environmental emissions, recommended by RAC, as conditions for authorisation.

(8) In its opinions, 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 applicant has 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 opinion on use 1, SEAC noted that chromium trioxide has no separate function at the formulation stage. Therefore, SEAC concluded that the assessment of alternatives is not relevant for this use. Having evaluated SEAC's assessment, the Commission agrees with that conclusion and considers that the analysis of alternatives for use 1 needs to rely on the analysis carried out for use 2.

(12) In its opinion on use 2, SEAC concluded that there were no suitable alternative substances or technologies available for the applicant and in the Union at the time of adoption of the opinion. The Commission, having evaluated SEAC's assessment and the relevant information available, notes that further development and testing of the identified potential alternatives is necessary to achieve the required layer homogeneity, surface morphology/density of microcracks and wear resistance. The Commission therefore agrees with SEAC's conclusion that there are no suitable alternatives for the applicant and in the Union.

(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 uses 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 additional information about exposure and emission to be included in the review report.

(15) In its opinions on uses 1 and 2, 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, until the end of 2032. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, RAC's conclusion that the risk management measures are appropriate and effective in limiting the risk, SEAC's conclusions on the socio-economic benefits and costs of the continued uses of the substance, as well as the time needed to replace the substance for the applicant and its downstream users.

(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 uses take 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 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[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 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[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.

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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 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).

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

Authorisation number	Authorisation holder	Authorised use
REACH/24/13/0	Maschinenfabrik Kaspar Walter GmbH & Co KG	Formulation of chromium trioxide-based electrolyte for electroplating process
REACH/24/13/1		Chromium trioxide-based functional chrome plating of cylinders used in the rotogravure printing and embossing industry

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 Articles 2 and 3.

Article 2

1. The authorisation bearing number REACH/24/13/0 is subject to the conditions set out in paragraphs 2 to 6.

2. The downstream user shall ensure that workers perform a fit check of the seal of their respiratory protective equipment before taking on relevant tasks and that they are trained to properly undertake that test.

3. By 8 May 2025 and afterwards each time when new relevant information becomes available, the downstream user shall carry out a study to assess the feasibility to enclose the area around the filling point of the mixing tank to guarantee the maximum possible effectiveness of the local exhaust ventilation system and shall act in accordance with the outcome of that study.

4. The downstream user shall carry out a monitoring programme measuring occupational exposure to hexavalent chromium (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;

[13] https://echa.europa.eu/documents/10162/8d7c4d48-2018-9af9-7427-c1485e79961a

(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 occupational exposure sampling.

5. The downstream user shall use the information gathered by way of the measurements referred to in paragraph 4 to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions in place. While doing so, the downstream user shall also review and, if needed, update its assessment of the combined exposure for the different groups of workers. If needed, the downstream user shall introduce measures to further reduce to a level as low as technically and practically possible workplace exposure to Cr(VI) in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

6. The downstream user shall document and maintain the information from the monitoring programme referred to in paragraph 4, 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 3 and 5, 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 authorisation bearing number REACH/24/13/1 is subject to the conditions set out in paragraphs 2 to 9.

2. The downstream users shall at least implement the following risk management measures and operational conditions to minimise the workers' exposure to Cr(VI) and the emission of Cr(VI) to the environment:

(a) chromium trioxide shall be used in liquid mixtures only;

(b) as regards worker contributing scenario 2, electroplating units and dechroming units shall be closed-loop systems equipped with fixed capturing hoods and shall run fully automated during chrome-plating while monitored by a software system, with the possible exception of loading and unloading operations;

(c) in relation to the dechroming activity of worker contributing scenario 2, any wastewater that could contain Cr(VI) shall be disposed of separately;

(d) mist suppressants shall be used;

(e) the electrolyte of the dechroming bath shall contain a reducing agent to scavenge any Cr(VI)-containing compounds directly as they are formed by reducing them to trivalent chromium (Cr(III)). The reducing agent shall be present in such a concentration that Cr(VI) cannot accumulate in the electrolyte of the dechroming bath at any time. The concentration of the reducing agent shall be monitored regularly;

(f) the exhaust air system of the chrome electroplating units shall be connected to the local exhaust ventilation system and have a sensor that monitors the partial pressure difference, that is used to stop immediately the electroplating process

in the event of disturbance or malfunction. Older electroplating units in which this system is not installed shall be retrofitted without undue delay;

(g) the plating units and dechroming units shall have measures implemented to prevent unauthorised intervention. During the standard operation of the processes of electroplating and dechroming in worker contributing scenario 2, no employee shall be present within a distance of 1 m from the units;

(h) adjustment of the chromium trioxide concentration shall be done with a closed automatic dosing system;

(i) the design of the units shall be such that no contact with the chromium trioxide solution is possible during loading/unloading. Therefore, the chromium trioxide solution shall be situated in an enclosed basin below the main tank and shall only be pumped up to the main tank when the plating process is started and the unit is closed. After the plating process is finished, the solution shall flow back into the basin and the cylinder shall be rinsed with water before the unit is opened again for unloading;

(j) the access to the chrome plating unit and the chromium trioxide storage area shall be restricted to authorised and trained personnel only;

(k) the dechroming units shall always be installed in the same working area as the electroplating units, and be subject to the safety measures of that area, including the exposure measurement programme;

(l) Standard Operating Procedures, covering the tasks under worker contributing scenarios 1 to 6, shall be in place and workers shall receive regular training regarding chemical risk management and how to properly wear the personal protective equipment, including a fit check of their respiratory protective equipment before taking on relevant tasks;

(m) the workers involved in tasks potentially leading to contact with liquid Cr(VI) formulations shall use, as a minimum, protective clothing, chemical-resistant gloves, and goggles;

(n) wastewater that contains Cr(VI) shall be disposed of separately for adequate treatment;

(o) the exhaust air from the chrome baths shall be passed through wet chrome scrubbers according to the best available technique. The water from the chrome scrubber shall be redirected into the process during standard operation until the chromium solution needs to be replaced and exchange of liquids is necessary;

(p) the replacement of chromium trioxide solution shall be performed in a closed system and waste solution shall be collected in a container. The collected waste shall be disposed of for adequate treatment;

(q) remaining liquids in the electroplating / dechroming units and all rinsing water used for cleaning the equipment shall be collected and disposed of for adequate treatment;

(r) solid waste potentially containing Cr(VI) shall be stored in closed containers which are collected and disposed of for adequate treatment.

3. By 8 May 2025, the authorisation holder shall provide a detailed guidance for its downstream users for the implementation of the operational conditions and risk management measures.

4. The authorisation holder shall continue to develop connection systems that prevent contact with chromium trioxide and unintentional dripping when changing the containers, and valve and pump systems for sampling. The authorisation holder shall take action to ensure that such systems are implemented. The authorisation holder shall document and maintain the information from the developments and shall make that information available, upon request, to the competent authority of the Member States where the authorised use takes place.

5. By 8 May 2025 and afterwards each time when new relevant information becomes available, downstream users shall carry out a study to assess the feasibility to use an appropriate connection system, either developed by the authorisation holder, by the downstream user, or provided by a third party, that prevents contact to chromium trioxide and unintentional dripping when changing the containers, and of a valve and pump system for sampling and shall act in accordance with the outcome of that study.

6. The downstream users 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 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, 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 with possible exposure to Cr(VI).

7. The downstream users 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 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 use takes place;

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

8. The downstream users shall use the information gathered by way of the measurements referred to in paragraphs 6 and 7 to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational

conditions in place. While doing so, the downstream users 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, the downstream users shall introduce measures to further reduce both workplace exposure to Cr(VI) to a level as low as technically and practically possible in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC and emissions into the environment.

9. The downstream users shall document and maintain the information from the monitoring programmes referred to in paragraphs 6 and 7, 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 4, 5 and 8, and shall make that information available, upon request, to the competent authority of the Member States where the authorised use takes place.

Article 4

1. The review period shall expire on 31 December 2032.

2. The authorisation shall cease to be valid on 31 December 2032 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 2031.

Article 5

1. As regards the authorisation bearing number REACH/24/13/0 the following monitoring arrangements shall apply.

2. The downstream user 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 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 use takes place;

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

3. The downstream user 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 downstream user shall also review and, if needed, update its assessment of the exposure of the general population via the environment. If needed, the downstream user shall introduce measures to further reduce emissions of Cr(VI) into the environment, to a level as low as technically and practically possible.

4. The downstream user 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 outcome and conclusions of the reviews and any action 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 6

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

(a) the information referred to in Articles 2(6), 3(9) and 5(4);

(b) as regards the authorisation bearing number REACH/24/13/0, information concerning the air and wastewater abatement efficiencies, on the progress made on the reduction of air emissions and wastewater and on the maintenance of the local exhaust ventilation systems;

(c) as regards the authorisation bearing number REACH/24/13/1, the results of a downstream users' survey concerning the risk management measures and operational conditions in place at their sites, to be held by 31 December 2030, and that shall be designed in such a way that a maximum and representative response is obtained.

Article 7

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 8

This Decision is addressed to:

Maschinenfabrik Kaspar Walter GmbH & Co KG, Konrad-Zuse-Bogen 18, 82152, Krailling, Germany.

Done at Brussels, 8.5.2024

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION