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COMMISSION IMPLEMENTING DECISION

of 20.1.2025

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Haas Group International sp. z.o.o. and Henkel Global Supply Chain B.V. 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 14 February 2023, Haas Group International sp. z.o.o. and Henkel Global Supply Chain B.V. ('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 authorisation was sought is pre-treatments: deoxidising, pickling, etching and/or desmutting in aerospace and defence industry and its supply chains.

(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), third subparagraph, of Regulation (EC) No 1907/2006. On 28 September 2024, 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 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://ec.europa.eu/docsroom/documents/61980

(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 for workers. However, RAC concluded that they are appropriate and effective in limiting the risk to human health for the general population posed by the use of chromium trioxide described in the application. In particular, as regards workers' exposure, RAC highlighted some major concerns about the inconsistent implementation of operational conditions and risk management measures across the downstream users, the manual nature of certain tasks, the absence of physical segregation between different work areas, and the lack or inappropriate use of respiratory protective equipment.

(6) Therefore, and in order to contribute to the improvement of the risk management measures with the aim of minimising exposure of workers to hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide, RAC recommended imposing additional conditions for authorisation. Among the recommended measures, RAC included the implementation of appropriate technical improvements. Such improvements depend on the specificity of the workplace, and potentially consist of automated or closed systems to perform the dipping of the parts, redesigning to remove loading and unloading from the treatment area, bath coverage, using mist suppressants and physical segregation or removal of the workers from the treatment area through remote operation of hoists.

(7) Moreover, RAC expressed moderate concerns about the representativeness of the information provided by the applicants on the risk management measures and operational conditions applied by their downstream users, and of the provided exposure and risk data. Nevertheless, RAC concluded that the estimates of cancer risk as presented by the applicants allow to carry out a health impact assessment, also for the purpose of the further SEAC assessment. RAC considered it important that the applicants and their downstream users continue their monitoring programmes on occupational exposure to and environmental release of Cr(VI), increasing their frequency, if applicable, and that they carry out specific measurements of the workers' exposure, per worker contributing scenario, and for environmental releases, as specified in the monitoring arrangements recommended by RAC.

(8) 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 are higher than as regards other comparable applications for authorisation for the use of Cr(VI) substances. 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. However, and also taking into account the concerns related to the representativeness of the reported exposure estimates, it considers it appropriate to set out the measures concerning occupational exposure, recommended by RAC as monitoring arrangements, as conditions for authorisation.

(9) 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 described in the application. 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.

(10) 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.

(11) 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.

(12) In its opinion, SEAC concluded that there were no technically feasible alternative substances or technologies available for the applicants or their downstream users but that there were technically feasible alternatives in the Union at the time of adoption of the opinion. The Commission, having evaluated SEAC's assessment and the relevant information available, acknowledges that some of the identified alternatives are in use in the Union for a limited number of components and substrates subject to pre-treatment in the aerospace and defence sector and, therefore, can be considered to provide the overall functionality for at least some components and substrates covered by the use applied for. However, the Commission also notes that the alternatives identified cannot be implemented for the entire use applied for as they are not suitable for all types of substrates and for all part geometries and they do not achieve the level of performance required for a number of functionalities, such as adequate corrosion protection, as required by the stringent regulatory framework of the aerospace and defence sector to ensure safety and airworthiness. Therefore, the Commission considers that the applicants have demonstrated that they are not yet able to accommodate such loss of performance and would need more time to further develop and implement an alternative. Thus, 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 and their downstream users.

(13) In its opinion, SEAC concluded that the substitution plan submitted by the applicants is credible and is representative of the downstream users' situation. 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.

(14) 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.

(15) 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.

(16) 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 12 years. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments. In particular, the Commission takes into account RAC's conclusion that the risk management measures are appropriate and effective in limiting the risk to human health for the general population, as well as the recommended 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 for workers. The Commission also takes into account SEAC's conclusion on the applicants' commitment to the substitution of chromium trioxide, the current technical limitations of the identified alternatives, the stringent safety requirements in the aerospace and defence sector, as well as both the socio-economic benefits, including the contribution to the Union strategic autonomy, and the risk associated with the continued use of the substance.

(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 use takes place. Therefore, in order to facilitate supervision and enforcement of compliance with the authorisation, it is appropriate to require the authorisation holders and their downstream users 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 and their downstream users 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[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

[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).

2004/37/EC, or any 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[8] or Directive 2010/75/EU[9] of the European Parliament and of the Council, nor any obligation to comply with emission limit values set to achieve compliance with the environmental quality standards established by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[10] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[11]. Compliance with the provisions of this Decision does not necessarily imply compliance with any emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.

(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/24/58/0	Haas Group International sp. z.o.o.	Pre-treatments: deoxidising, pickling, etching or desmutting, in aerospace and defence industry and its supply chains

5 Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 348, 28.11.1992, p. 1, ELI: http://data.europa.eu/eli/dir/1992/85/oj).

6 Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work (OJ L 216, 20.8.1994, p. 12, ELI: http://data.europa.eu/eli/dir/1994/33/oj).

7 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11, ELI: http://data.europa.eu/eli/dir/1998/24/oj).

8 Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1, ELI: http://data.europa.eu/eli/dir/2008/50/oj).

9 Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17, ELI: http://data.europa.eu/eli/dir/2010/75/oj).

10 Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1, ELI: http://data.europa.eu/eli/dir/2000/60/oj).

11 Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84, ELI: http://data.europa.eu/eli/dir/2008/105/oj).

REACH/24/58/1	Henkel Global Supply Chain B.V.

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 9.

2. Without delay, and at the latest by 20 January 2026, the authorisation holders and their downstream users shall:

   (a) implement the necessary technical improvements to the risk management measures and operational conditions to ensure that occupational exposure to hexavalent chromium (Cr(VI)) is at a level as low as technically and practically possible at all downstream users' sites. Such measures shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC ;

   (b) ensure that manual handling of solid and liquid Cr(VI) substances for measuring, weighing and solution preparation is performed in dedicated work areas under local exhaust ventilation ('LEV') with high containment;

3. The authorisation holders and their downstream users shall:

   (a) until adequate technical improvements referred to in paragraph 2(a) are implemented, and until exposure data pursuant to the measurements referred to in paragraph 4 or 6 allow for a conclusion that exposure to Cr(VI) is at a level as low as technically and practically possible, ensure that workers manually performing the tasks related to dipping of parts into treatment baths, bath sampling, bath make-ups and concentration adjustment use appropriate respiratory protective equipment ('RPE'), taking into account the duration of the tasks and the comfort of the workers during its use;

   (b) ensure that the relevant workers:

      (i) are provided with adequate RPE, which is subjected to a fit test prior to its first use;

      (ii) always perform a fit check of the seal of their RPE before starting a relevant task; and

      (iii) are adequately supported to undergo the fit tests referred to in point (i) and trained to undertake the fit check referred to in point (ii).

4. The authorisation holders and their downstream users 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 technically and practically possible.

[12] https://ec.europa.eu/docsroom/documents/61960

5. By 20 January 2026 and afterwards each time when new relevant information becomes available, the authorisation holders and their downstream users shall carry out and document studies to assess the feasibility of implementing the following measures:

   (a) the substitution of solid Cr(VI) substances 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;

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

   (c) the installation of a system that continuously controls the LEV and automatically triggers an alarm in case the LEV is not functioning properly and the implementation of appropriate and effective measures to reduce the exposures to workers in case the LEV is not functioning properly;

   (d) the installation of an air abatement system at those sites where such a system is not yet in place, even if the authorisation holder or downstream user expects a low Cr(VI) emission.

   The authorisation holders and their downstream users shall act in accordance with the outcome of those studies.

6. The authorisation holders and their downstream users shall carry out a monitoring programme measuring occupational exposure to Cr(VI) at all sites. 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 and their downstream users that already conduct a biomonitoring programme at their site shall continue that programme and shall ensure that it covers a representative number of the workers potentially exposed to Cr(VI).

8. The authorisation holders and their downstream users shall use the information gathered in accordance with 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 authorisation holders and their downstream users shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. If needed, based on the outcome of this

review, the authorisation holders and their downstream users shall introduce measures to further reduce to a level as low as technically and practically possible occupational exposure to Cr(VI). Such measures shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

9. The authorisation holders and their downstream users shall document and maintain the information from the monitoring programmes referred to in paragraphs 6 and 7, and the control measurements 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 2, 4, 5 and 8, and shall make that information available, including pseudonymised or aggregated biomonitoring results, where relevant, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 3

The review period shall expire on 14 February 2035.

The authorisation shall cease to be valid on 14 February 2035 in relation to any authorisation holder who has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 14 August 2033.

Article 4

1. The monitoring arrangements set out in paragraphs 2 to 5 shall apply.

2. The authorisation holders and their downstream users shall carry out a monitoring programme measuring the environmental releases of Cr(VI) to the air and wastewater at all sites. 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 use takes place;

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

3. The authorisation holders and their downstream users shall use the information gathered in accordance with 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 holders and their downstream users 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 this review, the authorisation holders and the downstream users 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 and their downstream users 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 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 holders and their downstream users shall document the steps taken to substitute chromium trioxide in accordance with the substitution plan, including information on the technical difficulties to meet the required standards in the aerospace and defence sectors. Any deviations from the initial substitution plan and information on any contingency measures taken shall also be documented. The authorisation holders and their downstream users 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(9) and Article 4(4) and (5).

Article 6

Upon request, the authorisation holders and their downstream users 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) Haas Group International sp. z. o.o., ul. Ryszarda Chomicza 13E, 55 - 080 Nowa Wieś Wrocławska, Poland;

(2) Henkel Global Supply Chain B.V., Gustav Mahlerlaan 2970, 1081 LA Amsterdam, Netherlands (the).

Done at Brussels, 20.1.2025

For the Commission
Stéphane SÉJOURNÉ
Executive Vice-President

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION