EUROPEAN
COMMISSION

Brussels, 22.11.2023
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COMMISSION IMPLEMENTING DECISION

of 22.11.2023

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Eaton S.R.L. and Eaton Automotive Systems sp.zoo 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 23 November 2020, Eaton S.R.L. and Eaton Automotive Systems sp.zoo ('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 the functional chrome plating of engine valves and valve actuation ('lash adjusters').

(3) The European Chemicals Agency sent the opinions on the application adopted by the Committee for Risk Assessment (RAC) and by the Committee for Socio-economic Analysis (SEAC)[2] of the Agency to the Commission pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006. On 3 January 2022, the Commission received the opinions.

(4) In its opinion, RAC concluded that it is not possible to determine a derived no-effect level for the carcinogenic properties of chromium trioxide in accordance with Section 6.4 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.

[2] https://echa.europa.eu/documents/10162/8301e643-0ca9-0af4-fb5a-8d4b0763682e

(5) In its opinion, RAC concluded that the risk management measures and operational conditions described in the application, as further detailed by the applicants at RAC's request, are appropriate and effective to limit the risk to human health posed by the use of chromium trioxide described in the application. Nevertheless, in order to ensure that the risk management measures, in particular as regards workers' exposure, are implemented and function appropriately, RAC recommended certain conditions for authorisation. Moreover, RAC recommended monitoring arrangements with the aim to address some shortcomings in exposure estimates and to provide information on the trends in exposure and emissions during the authorisation period, for both occupational exposure and environmental release of Cr(VI), the hazardous component of chromium trioxide. Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations. Nevertheless, the Commission notes that the estimated excess cancer risk value for workers for one of the three sites is 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 appropriate to set out the measures concerning occupational exposure, recommended by RAC, as a condition for authorisation, for that site.

(6) In its opinion, SEAC concluded that it has no substantial reservations on the quantitative and qualitative elements of the applicants' assessment of the benefits and the monetised risk to human health associated with the continued use of the substance. Taking into account SEAC's assessment of the socio-economic analysis, RAC's conclusion that the risk management measures and operational conditions are appropriate and effective to limit the risk, the estimated monetised risk of cancer associated with the continued use in the order of hundreds of thousands of euro and the estimated monetised socio-economic benefits of continued use due to avoided profit losses, job losses, and avoided decommissioning costs in the order of between tens of millions to hundreds of millions of euro over the same period, the additional qualitatively assessed impacts of not granting an authorisation, as well as any distributional impact, the Commission concludes that the applicants have demonstrated that the socio-economic benefits of continued use of chromium trioxide outweigh the risk to human health or the environment arising from that use.

(7) A suitable alternative should 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 to submit a substitution plan. 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 they or their downstream users are not able to accommodate such losses to performance or technical compromises by applying a reasonable additional effort, taking into account the circumstances of the case.

(8) In its opinion, SEAC concluded that there were no suitable alternative substances or technologies available for the applicants at the time of adoption of its opinion. The Commission, having evaluated SEAC's assessment and all relevant information

available, notes that the identified alternatives still require further development and extensive testing to achieve the necessary hardness, layer thickness, wear resistance and adhesive strength to manufacture engine parts at industrial scale allowing a long engine life for both passenger cars and heavy-duty trucks. Thus, the Commission considers that the identified alternatives are not yet technically feasible as they do not achieve the level of performance needed for the use applied for. Therefore, the Commission agrees with SEAC's conclusion and considers that the applicants have discharged their burden of proof in demonstrating the absence of suitable alternatives both in the Union and for the applicant.

(9) 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 and operational conditions described in the chemical safety report, as well as the conditions set out in this Decision, are fully applied.

(10) The Commission has based its assessment on all relevant scientific evidence currently 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 allowing it to conclude. 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 additional exposure and emission information to be generated.

(11) In its opinion, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 should be set at 10 years, until the end of 2030. 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 and operational conditions are appropriate and effective to limit the risk, the remaining risk and the socio-economic benefits of the use of the substance, the applicants' ongoing efforts to develop an alternative to chromium trioxide, the time needed for the full implementation of any of the identified alternatives, as well as the applicants' obligation to provide their customers with spare engine parts for old and existing engine models.

(12) 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 States 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 to submit, upon request, a brief summary of those risk management measures and operational conditions to the competent authority of those Member States in an official language of those Member States.

(13) This Decision does not affect the obligation of the authorisation holders 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 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 a carcinogen or mutagen at the place of work, in particular by replacing it, 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.

(14) 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.

(15) 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):

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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 or mutagens 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).

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).

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).

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).

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).

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).

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).

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).

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).

Authorisation number	Authorisation holder	Authorised use
REACH/23/25/0	Eaton S.R.L.	Functional chrome plating of engine valves and valve actuation (‘lash adjusters’)
REACH/23/25/1	Eaton Automotive Systems sp.zoo	

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 shall be subject to the conditions set out in paragraphs 2 to 7.

2. The authorisation holders 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 undertake that test adequately.

3. The authorisation holders shall finalise by 22 November 2024 and afterwards when new information becomes available, the following studies assessing the feasibility of:

   (a) using a liquid chromium trioxide solution instead of solid chromium trioxide to fill the solution tank of the hard chrome plating line, as regards the authorisation bearing number REACH/23/25/0;

   (b) replacing the plastic curtains that give access to the hard chrome plating lines by doors with an electric lock;

   (c) installing devices that measure continuously the function of the local exhaust ventilation systems, connected with a system of alarm or shutdown of the plating operation, in case the local exhaust ventilation is not functioning properly.

   The authorisation holders shall act in accordance with the outcome of those studies.

4. As regards the authorisation bearing number REACH/23/X/1, the authorisation holder shall carry out a monitoring programme measuring the occupational inhalation exposure to Cr(VI). The measurements 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 cleaning and maintenance tasks, the operational conditions and risk management measures for each of those tasks, and of the total number of workers who are potentially exposed;

[12] https://ec.europa.eu/docsroom/documents/48476

(f) be recorded so as to include contextual information about the tasks performed during sampling.

5. As regards the authorisation bearing number REACH/23/25/1, the authorisation holder shall carry out a biomonitoring programme for a representative number of workers potentially exposed to Cr(VI).

6. The authorisation holders shall use the information gathered via the measurements and related contextual information referred to in paragraphs 4 and 5, to confirm and review, at least annually, the effectiveness of risk management measures and operational conditions in place. The authorisation holders shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. If needed, the authorisation holders shall introduce measures to further reduce occupational exposure to Cr(VI) to as low a level as technically and practically possible, in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

7. The authorisation holders shall document and keep the information gathered via the monitoring programmes referred to in paragraphs 4 and 5, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the review and studies and any measure taken in accordance with paragraph 3 and paragraph 6. The authorisation holders shall make that information, including pseudonymised or aggregated biomonitoring results, available, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 3

1. The review period shall expire on 31 December 2030.

2. The authorisation shall cease to be valid on 31 December 2030 with regard to any authorisation holder who has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 30 June 2029.

Article 4

1. The monitoring arrangements set out in paragraphs 2 to 6 shall apply.

2. The authorisation holders shall carry out a monitoring programme measuring environmental releases of Cr(VI). The measurements shall:

(a) comprise air emission measurements, to be carried out 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 emissions of Cr(VI);

(b) comprise wastewater emission measurements, to be carried out 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 emissions of Cr(VI);

(c) be based on relevant standard methodologies or protocols;

(d) be representative of the operational conditions and risk management measures used at the site where the authorised use takes place;

(e) ensure a sufficiently low limit of quantification;

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

3. As regards the authorisation bearing number REACH/23/25/0, the authorisation holder shall carry out a monitoring programme measuring occupational inhalation exposure to Cr(VI). The measurements 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 cleaning and maintenance tasks, the operational conditions and risk management measures for each of those tasks, and of the total number of workers who are potentially exposed;

(f) be recorded so as to include contextual information about the tasks performed during sampling.

4. As regards the authorisation bearing number REACH/23/25/0, the authorisation holder shall continue to carry out a biomonitoring programme for a representative number of the workers potentially exposed to Cr(VI).

5. The authorisation holders shall use the information gathered via the measurements and related contextual information referred to in paragraphs 2, 3 and 4, to review, at least annually, the effectiveness of the risk management measures and operational conditions in place. If needed, the authorisation holders shall introduce measures to further reduce environmental emissions of Cr(VI) to as low a level as technically and practically possible.

As regards the authorisation bearing number REACH/23/25/0, the authorisation holder shall also review and, if needed, update its assessment of the combined exposure for the different groups of workers. If needed, the authorisation holder shall introduce measures to further reduce occupational exposure to Cr(VI) to as low a level as technically and practically possible, in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

6. The authorisation holders shall document and keep the information gathered via the monitoring programmes referred to in paragraphs 2, 3 and 4, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the review in accordance with paragraph 5. The authorisation holders shall make that information, available, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 5

Where an authorisation holder submits a review report, it shall include the information referred to in Article 2(7) and Article 4(6), as well as clear information that supports the reported efficiency values of the air and wastewater abatement systems.

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 in an official language of that Member State.

Article 7

This Decision is addressed to:

1. Eaton S.R.L., Corso Francesco Ferrucci 112, 10138, Torino, Italy;

2. Eaton Automotive Systems sp.zoo, Rudawka 83, 43-382 Bielsko-Biala, Poland.

Done at Brussels, 22.11.2023

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION