EUROPEAN
COMMISSION

Brussels, 29.7.2024
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COMMISSION IMPLEMENTING DECISION

of 29.7.2024

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to KYB Suspensions Europe, S.A.U. and KYB Manufacturing Czech s.r.o. 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 9 February 2022, KYB Suspensions Europe, S.A.U. and KYB Manufacturing Czech s.r.o. ('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 functional chrome plating of piston rods for shock absorbers for automotive applications.

(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 26 September 2023, 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://echa.europa.eu/documents/10162/27562fb3-7258-945c-ffcb-51d40f0effcf

(5) The chemical safety report provided in the application includes only one exposure scenario. However, since the risk management measures and operational conditions differ at the two sites where the use of chromium trioxide described in the application takes place, for legal clarity, it is appropriate to reflect that differentiation by providing two exposure scenarios to be covered by this Decision. Therefore, the site of KYB Suspensions Europe, S.A.U. should be referred to as exposure scenario 1 ('ES1') and the site of KYB Manufacturing Czech s.r.o. as exposure scenario 2 ('ES2').

(6) In its opinion, RAC concluded that the risk management measures and operational conditions in ES1 are appropriate and effective in limiting the risk posed by the use of chromium trioxide described in the application to workers but not appropriate and effective in limiting the health risk posed by that use to the general population, exposed via the environment. In particular, RAC noted that, despite the clear description of the risk management measures in place to minimise the emissions to the air compartment, as well as the maintenance routine to ensure their correct functioning, the actual efficiency of the abatement system in place is unknown, and possibly not optimal, and consequently, recommended imposing additional conditions for authorisation. Moreover, in order to address some shortcomings in exposure estimates and to provide information on the trends in exposure and emissions during the review period, RAC recommended imposing additional monitoring arrangements for both occupational exposure to and environmental release of hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide.

(7) As regards ES2, RAC concluded that the risk management measures and operational conditions in place are appropriate and effective in limiting the risk to human health posed by the use of chromium trioxide described in the application. Nevertheless, in order to further minimise the exposure of workers to Cr(VI), RAC recommended imposing additional conditions for authorisation. Moreover, in order to address some minor shortcomings in exposure estimates and to provide information on the trends in exposure and emissions during the authorisation period, RAC recommended imposing additional monitoring arrangements for both occupational exposure to and environmental release of Cr(VI).

(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 as regards ES1 and ES2, and for the general population, exposed via the environment, as regards ES1, are higher than as regards other comparable applications for authorisation for the use of Cr(VI) substances. Although the Commission acknowledges that those values are conservative estimates of the most likely excess risk values taken for the purpose of carrying out a risk-benefit analysis, it considers it appropriate to set out the measures concerning occupational exposure, recommended by RAC as monitoring arrangements, as a condition for authorisation for both ES1 and ES2, and to set out the measures concerning environmental emissions, recommended by RAC as monitoring arrangements, as a condition for authorisation for ES1.

(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. 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 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 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 assessment and the relevant information available, notes that, although certain alternatives are already being used within the Union for similar applications, they are not applicable for the use for which an authorisation is sought due to the very specific design features of the piston rods produced by the applicants, in terms of, among others, roughness, corrosion, microcracking, or durability of the shock absorber. The Commission acknowledges 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, while agreeing with SEAC's conclusion that there are no suitable alternatives and economically for the applicants, considers that there are no suitable alternatives available 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 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.

(14) The Commission has based its assessment on all relevant scientific evidence available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, has concluded on the basis of a sufficient amount of material and reliable information. Nevertheless, additional scientific evidence would allow the Commission to perform its assessment on a more robust or broad evidentiary basis in the future. Hence, it is appropriate to require the authorisation holders to generate and include additional information about exposure and emissions in the review report.

(15) In its opinion, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set at 7 years. The Commission, while considering that substitution may take longer than 7 years in view of the current technological status concerning the identified alternatives agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, RAC's conclusion that risk management measures and operational conditions are appropriate and effective in limiting the risk in ES 2 as well

as the additional authorisation conditions imposed based on RAC's conclusions that the current risk management measures and operational conditions are not appropriate and effective in limiting the risk in ES1 and on the estimated excess cancer risk values, as well as SEAC's conclusions on the socio-economic benefits and costs of the continued use of the substance.

(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 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 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[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], 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

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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).

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.

(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/24/33/0	KYB Suspensions Europe, S.A.U.	Functional chrome plating of piston rods for shock absorbers for automotive applications
REACH/24/33/1	KYB Manufacturing Czech s.r.o.	Functional chrome plating of piston rods for shock absorbers for automotive applications

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 Articles 2 and 3.

Article 2

1. The authorisation bearing number REACH/24/33/0 is subject to the conditions set out in paragraphs 2 to 8.

2. By 29 July 2025 and afterwards each time when new relevant information becomes available, the authorisation holder shall carry out a study to assess the feasibility of

[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).

[12] https://ec.europa.eu/docsroom/documents/60037

implementing the installation of a closed or automatic system to perform bath sampling tasks and shall act in accordance with the outcome of that study.

3. The authorisation holder shall carry out a monitoring programme measuring occupational exposure to hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide. 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 performed during exposure sampling.

4. The authorisation holder shall continue to conduct a biomonitoring programme for workers potentially exposed to Cr(VI).

5. The authorisation holder 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 for the first time by 29 October 2024, on all emission points 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 of the measurements.

6. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraphs 3, 4 and 5 to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions in place. While doing so, the authorisation holder shall also review and, if needed, update its assessment of the combined exposure for the different groups of workers and its assessment of the exposure of the general population via the environment. If needed, based on the outcome of this review, the authorisation holder 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.

7. The authorisation holder shall, by 29 July 2025 ensure a release factor for the air of the same order of magnitude or lower than the one derived for the authorisation bearing number REACH/24/33/1.

If the release factor is not of the same order of magnitude or lower than the one derived for the authorisation bearing number REACH/24/33/1, the authorisation holder shall conduct a root cause analysis and, without delay, take appropriate actions for the control of the environmental releases of Cr(VI) to the air. Additional risk management measures shall be implemented to further reduce these releases to as low a level as technically and practically feasible.

The authorisation holder shall conduct control measurements to confirm the impact of any action taken. The "control measurement – analysis – action" cycle shall be continued until a release factor for the air of the same order of magnitude or lower than the one derived for the authorisation bearing number REACH/24/33/1 is achieved.

8. The authorisation holder shall document and maintain the information from the monitoring programmes referred to in paragraphs 3, 4 and 5, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the reviews and any measures taken in accordance with paragraphs 2, 6 and 7, 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/24/33/1 is subject to the conditions set out in paragraphs 2 to 6.

2. The authorisation holder shall, by 29 October 2024, ensure that the respiratory protection equipment (RPE) used at its site achieves at least the same level of effectiveness as the RPE used at the site with the authorisation bearing number REACH/24/33/0.

3. The authorisation holder shall carry out a monitoring programme for occupational exposure to Cr(VI). The programme shall include measurements which shall:

   (a) take place 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 performed during exposure sampling.

4. The authorisation holder shall conduct a biomonitoring programme for workers potentially exposed to Cr(VI).

5. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraphs 3 and 4 to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions in place. While doing so, the authorisation holder shall also review and, if needed, update its assessment of the combined exposure for the different groups of workers. If needed, based on the outcome of this review, the authorisation holder 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.

6. The authorisation holder shall document and maintain the information from the monitoring programmes referred to in paragraphs 3 and 4, 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 paragraphs 2 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 4

1. The review period shall expire on 9 February 2029.

2. The authorisation shall cease to be valid on 9 February 2029 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 9 August 2027.

Article 5

1. As regards the authorisation bearing number REACH/24/33/1, the monitoring arrangements set out in paragraphs 2, 3 and 4 shall apply.

2. The authorisation holder shall carry out a monitoring programme measuring the environmental releases of Cr(VI) to the air and wastewater. The programme shall include measurements which shall:

   (a) take place at least annually, or more frequently if a significant increase of chromium trioxide consumption takes place on site, and shall be sufficiently frequent to capture any potential increase in emission of Cr(VI);

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

   (c) ensure a sufficiently low limit of quantification;

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

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

3. The authorisation holder 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 authorisation holder shall also review and, if needed, update its assessment of the exposure of the general population via the environment. If needed, based on the outcome of this review, the authorisation holder

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 holder shall document and keep the information from the monitoring programme referred to in paragraph 2, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the review and measure taken in accordance with paragraph 3. The authorisation holder 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, as regards the authorisation bearing number REACH/24/33/0, the information referred to in Article 2(8) and, as regards the authorisation bearing number REACH/24/33/1, the information referred to in Articles 3(6) and 5(4).

Article 7

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 8

This Decision is addressed to:

1. KYB Suspensions Europe, S.A.U. Ctra. Irurzun, 6, 31171 Ororbia, Navarra, Spain;
2. KYB Manufacturing Czech s.r.o. U Panasonicu, 53006 Stare Civice, Czech Republic.

Done at Brussels, 29.7.2024

For the Commission
Thierry BRETON
Member of the Commission