EUROPEAN
COMMISSION

Brussels, 23.5.2025
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COMMISSION IMPLEMENTING DECISION

of 23.5.2025

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Turdus Testers of Capacity for a use of potassium dichromate

(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) Potassium dichromate 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 30 May 2023, Turdus Testers of Capacity ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for a use of potassium dichromate. The use for which authorisation was sought is the use of a potassium dichromate-based mixture for the manufacture of single-use chemical breathalysers.

(3) The European Chemicals Agency sent the opinions[2] on the application adopted by its Committee for Risk Assessment (RAC) and its Committee for Socio-economic Analysis (SEAC) to the Commission pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006. On 8 August 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 potassium dichromate in accordance with Section 1.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore potassium dichromate 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 potassium

[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/10162/7b02a10f-07db-0f74-eb63-d424be6a4f7c

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

(5) In its opinion, RAC concluded that the risk management measures and operational conditions described in the application are not appropriate and effective in limiting the risk to human health posed by the use of potassium dichromate described in the application. However, RAC concluded that they are appropriate and effective in limiting the health risk to the general population posed by that use. In particular, as regards occupational exposure, RAC expressed concerns regarding the risk resulting from the use of potassium dichromate in powder form during reagent preparation as well as the concerns related to the overreliance on the use of respiratory protective equipment. Therefore, RAC recommended imposing additional conditions for authorisation, including technical improvements to the operational conditions and risk management measures. Moreover, in order to address some shortcomings in exposure and emissions estimates and to corroborate the appropriateness and effectiveness of the risk management measures and operational conditions in place, RAC recommended imposing additional monitoring arrangements for both the occupational exposure to hexavalent chromium (Cr(VI)), the toxic component of potassium dichromate, and the environmental release of it, as specified in the monitoring arrangements. Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations.

(6) 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 potassium dichromate described in the application. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that the applicant has demonstrated that the benefits of the continued use described in the application outweigh the risk to human health arising from that use.

(7) 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 the downstream users, the applicant is required by Article 62(4), point (f), of Regulation (EC) No 1907/2006 to submit a substitution plan.

(8) 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 the 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.

(9) In its opinion, SEAC concluded that there were no technically feasible alternative substances or technologies available for the applicant but that there were technically and economically feasible alternatives in the Union. The Commission, having evaluated SEAC's assessment and the relevant information available, notes that there are technically and economically feasible alternatives which are commercially available in the Union, providing the overall functionality of the substance for the use

applied for, but that additional research is needed to improve and adapt the most promising alternative in order to eliminate technical limitations and to minimise the loss of performance in terms of detection of ethanol at two different concentrations of blood in a human breath, as well as the colour chart to differentiate these two concentration levels. Thus, the Commission considers that the applicant has demonstrated that it is not yet able to accommodate such loss of performance and would need more time to develop and implement the most promising alternative to make it technically feasible. Therefore, the Commission agrees with SEAC's conclusion and considers that, although suitable alternatives are available in the Union, they are not yet technically feasible for the applicant.

(10) In its opinion, SEAC concluded that the substitution plan submitted by the applicant is credible and consistent with the analysis of alternatives. 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 assessed, that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternative substances or technologies.

(11) 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 potassium dichromate 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.

(12) 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 and include additional information about exposure and emissions in the review report.

(13) 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 4 years. SEAC noted that the 7 - year review period requested by the applicant was not warranted, taking into account, in particular, that the time allocated in the substitution plan for research and development, process optimisation, and certification could be shortened and that the time allocated was not fully justified, and concluded that only 4 years are warranted. 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 current risk management measures and operational conditions are not appropriate and effective in limiting the risk, SEAC's conclusion on the monetised risk to human health and on the socio-economic benefits of the continued use of the substance, as well as SEAC's conclusion on the substitution plan.

(14) Considering that the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 is to be submitted at least 18 months before the expiry of the review period, the end date of the review period recommended by SEAC would not allow the authorisation holder sufficient time to submit a review report within the time limit in the present case. It is therefore appropriate to provide for a review period of 24 months from the date of adoption of this Decision.

(15) The language used to describe the risk management measures and operational conditions in the application for authorisation may be different from the official language of the Member State where the use takes place. Therefore, in order to facilitate supervision and enforcement of compliance with the authorisation, it is appropriate to require the authorisation holder to submit, upon request, a brief summary of those risk management measures and operational conditions to the competent authority of that Member State in an official language of that Member State.

(16) 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] and Directive 2004/37/EC, or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

(17) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC[7] or Directive 2010/75/EU[8] of the European Parliament and of the Council, nor any obligation to comply with emission limit values set to achieve compliance with the environmental quality standards established by Member States in accordance with Directive

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3 Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50, ELI: http://data.europa.eu/eli/dir/2004/37/oj).

4 Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1, ELI: http://data.europa.eu/eli/dir/1989/391/oj).

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

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

7 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).

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

2000/60/EC of the European Parliament and of the Council[9] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[10]. 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.

(18) 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 use of potassium dichromate (EC No 231-906-6; CAS No 7778-50-9)*:*

Authorisation number	Authorisation holder	Authorised use
REACH/25/30/0	Turdus Testers of Capacity	Industrial use of a potassium dichromate-based mixture for the manufacture of single-use chemical breathalysers

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[11], 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 4.

2. At the latest by 23 August 2025, the authorisation holder shall implement additional risk management measures and operational conditions to ensure that exposure to hexavalent chromium (Cr(VI)) is at a level as low technically and practically possible. Such measures shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC and shall include the installation of a fume hood with glass walls in the laboratory for preparation of the reagent to ensure that exposure to Cr(VI) in the working environment is at a level as low as technically and practically possible.

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9 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).

10 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).

11 https://ec.europa.eu/docsroom/documents/63114

3. The authorisation holder 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 feasible.

4. The authorisation holder shall check, at least annually, the effectiveness of the installed local ventilation system to confirm the effectiveness of the operational conditions and risk management measures in place.

Article 3

The review period shall expire on 23 May 2027.

The authorisation shall cease to be valid on 23 May 2027 if the authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 23 November 2025.

Article 4

1. The monitoring arrangements set out in paragraphs 2 to 7 shall apply.

2. The authorisation holder 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 and for the first time by 23 October 2025, or more frequently if a significant increase of potassium dichromate 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.

3. The authorisation holder shall conduct, for the first time by 23 October 2025, a biomonitoring programme for a representative number of workers potentially exposed to Cr(VI).

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

   (a) take place at least annually and for the first time by 23 October 2025, or more frequently if a significant increase of potassium dichromate consumption takes

place on site, and shall be sufficiently frequent to capture any potential increase in emission of Cr(VI);

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

(c) ensure a sufficiently low limit of quantification;

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

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

5. The authorisation holder shall use the information gathered via the measurements referred to in paragraphs 2, 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 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.

6. The authorisation holder shall document and maintain the information from 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 reviews and any measure taken in accordance with paragraph 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.

7. The authorisation holder shall document the steps taken to substitute potassium dichromate, including information on the efforts to convince the authorisation holder's customers to accept alternative Cr(VI)-free solutions, and justification in case its customers do not accept alternative Cr(VI)-free solutions. Information on any contingency measure taken shall also be documented by the authorisation holder. The authorisation holder 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(2) to (4) and Article 4(6) and (7).

Article 6

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 use takes place. The brief summary shall be drafted in an official language of that Member State.

Article 7

This Decision is addressed to:

Turdus Testers of Capacity, Z.A Sainte Catherine, 770 Avenue de la Méridienne, 48100 Marvejols, France.

Done at Brussels, 23.5.2025

For the Commission
Stéphane SÉJOURNÉ
Executive Vice-President

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION