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**COMMISSION IMPLEMENTING DECISION**

**of 12.6.2024**

**partially granting an authorisation under Regulation (EC) No 1907/2006 of the  
European Parliament and of the Council to Robur S.p.A for a use of sodium 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<sup>1</sup>, and in particular Article 64(8) thereof,

Whereas:

- (1) Sodium 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 9 April 2021, Robur S.p.A ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for a use of sodium dichromate. The use for which authorisation was sought is as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances up to 1,05 % w/w (corresponding to 0,42 % w/w as Cr(VI)) in the refrigerant solution.
- (3) The European Chemicals Agency sent the opinions<sup>2</sup> 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 June 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 carcinogenicity of sodium dichromate in accordance with Section 1.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore sodium 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 sodium dichromate and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.

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<sup>1</sup> OJ L 396, 30.12.2006, p. 1, ELI: <http://data.europa.eu/eli/reg/2006/1907/oj>.

<sup>2</sup> <https://echa.europa.eu/documents/10162/0b7300ac-45f2-842b-47fe-d4aef8f71949>

- (5) In its opinion, RAC concluded that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to human health posed by the use of sodium dichromate described in the application.
- (6) Nevertheless, in order to also minimise the exposure of professionals, who maintain and repair gas absorption appliances installed at end-users sites, to hexavalent chromium (Cr(VI)), the toxic component of sodium dichromate, RAC recommended as a condition for authorisation that the authorisation holder ensures that the professionals performing the maintenance and repair tasks described in worker contributing scenario 1 of exposure scenario 3 of the chemical safety report apply the same protocol used in worker contributing scenario 4 of exposure scenario 1. Moreover, in order to address some shortcomings in exposure estimates and to provide information on the trends in exposure and emissions during the authorisation period, RAC recommended monitoring arrangements for occupational exposure and environmental emissions.
- (7) Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations.
- (8) 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 sodium dichromate. 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 outweigh the risk to human health arising from that use.
- (9) For an alternative to be suitable it needs to be safer, available, and technically and economically feasible. Where suitable alternatives are available in the Union, but not technically or economically feasible for the applicant or its downstream users, the applicant is required by Article 62(4), point (f), of Regulation (EC) No 1907/2006 to submit a substitution plan.
- (10) An alternative that provides the functionality and level of technical performance necessary for the use for which authorisation is sought should be considered to be technically feasible.
- (11) In its opinion, SEAC concluded that there were no technically and economically feasible alternative substances or technologies available for the applicant and in the Union by the date of submission of the application. The Commission, having evaluated SEAC's assessment and the relevant information available, notes that the shortlisted alternatives were rejected due either to the lack of the required performance, or to the need for extensive research and development, testing and optimisation to assess if they are feasible for the use for which authorisation is sought and to achieve the necessary technical requirements, including corrosion resistance for sealed circuits. Therefore, the Commission considers that the identified alternative substances and technologies do not allow for the functionality needed for the use for which authorisation is sought.
- (12) However, the Commission notes that the application refers to gas absorption heat pumps and gas absorption chillers and the analysis of alternatives is also limited to those type of gas absorption appliances. Therefore, the Commission agrees with SEAC's conclusion and considers that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternatives both in the Union and for the applicant only as regards gas absorption heat pumps and gas absorption chillers. Thus,

the Commission considers it necessary to limit the scope of the use accordingly from 'gas absorption appliances' to 'gas absorption heat pumps and gas absorption chillers'.

- (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 sodium dichromate described in the application, as limited in this Decision, provided that the risk management measures described in the chemical safety report are applied and that the operational conditions described therein, as well as the conditions set out in this Decision, are fulfilled.
- (14) The Commission has based its assessment on all relevant scientific evidence available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, has concluded on the basis of a sufficient amount of material and reliable information. Nevertheless, additional scientific evidence would allow the Commission to perform its assessment on a more robust or broad evidentiary basis in the future. Hence, it is appropriate to require the authorisation holder to generate and include additional information about occupational exposure and environmental 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 12 years. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, that no suitable alternative substances or technologies will likely become available to the applicant during the requested review period of 12 years.
- (16) The language used to describe the risk management measures and operational conditions in the application for authorisation may be different from the official language of the Member State where the 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.
- (17) Directive 2011/65/EU of the European Parliament and of the Council<sup>3</sup> restricts certain hazardous substances in electrical and electronic equipment (EEE), including Cr(VI). This Decision is without prejudice to any obligation to comply with that Directive. Gas absorption heat pumps and gas absorption chillers, which are EEE and contain Cr(VI), may only be placed on the market if they are not covered by Directive 2011/65/EU or are subject of a time-limited exemption from the substance restriction pursuant to that Directive.
- (18) 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

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<sup>3</sup> Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88, ELI: <http://data.europa.eu/eli/dir/2011/65/oj>).

obligation of the employer under Article 4(1) and Article 5 of Directive 2004/37/EC of the European Parliament and of the Council<sup>4</sup> 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<sup>5</sup>, 92/85/EEC<sup>6</sup>, 94/33/EC<sup>7</sup>, 98/24/EC<sup>8</sup> and Directive 2004/37/EC<sup>3</sup>, 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<sup>9</sup> or Directive 2010/75/EU<sup>10</sup> 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<sup>11</sup> or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council<sup>12</sup>. 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,

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<sup>4</sup> 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>).

<sup>5</sup> 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>).

<sup>6</sup> 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>).

<sup>7</sup> 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>).

<sup>8</sup> 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>).

<sup>9</sup> 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>).

<sup>10</sup> 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>).

<sup>11</sup> 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>).

<sup>12</sup> 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>).

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 sodium dichromate (EC No 234-190-3; CAS No 10588-01-9):

Authorisation number	Authorisation holder	Authorised use
REACH/24/23/0	Robur S.p.A	As an anticorrosion agent of the carbon steel in sealed circuit of gas absorption heat pumps and gas absorption chillers, up to 1,05 % w/w (corresponding to 0,42 % w/w as Cr(VI)) in the refrigerant solution

An authorisation is not granted for the use of sodium chromate as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances up to 1,05 % w/w (corresponding to 0,42 % w/w as Cr(VI)) in the refrigerant solution other than in heat pumps and gas absorption chillers.

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report<sup>13</sup>, and to the conditions set out in Article 2.

#### *Article 2*

1. The authorisation is subject to the condition set out in paragraph 2.
2. The authorisation holder shall ensure that all workers, including third-party workers, who perform maintenance and repair activities on gas absorption appliances installed at the end-users' sites corresponding to workers contributing scenario 1 of exposure scenario 3 of the chemical safety report, are trained to perform those activities in accordance with the provisions set out in workers contributing scenario 4 of exposure scenario 1 of the chemical safety report.

#### *Article 3*

The review period shall expire on 31 March 2033.

The authorisation shall cease to be valid on 31 March 2033 if the authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 30 September 2031.

#### *Article 4*

1. The monitoring arrangements set out in paragraphs 2 to 5 shall apply.
2. The authorisation holder shall carry out a monitoring programme measuring occupational exposure to hexavalent chromium (Cr(VI)) of workers directly or indirectly involved in exposure scenario 1 and exposure scenario 3 of the chemical safety report. The programme shall include measurements which shall:

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<sup>13</sup> <https://ec.europa.eu/docsroom/documents/50416>

- (a) take place at least annually, or more frequently if a significant increase of sodium 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 both personal and 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 occupational exposure sampling.
3. 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, or more frequently if a significant increase of sodium 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.
4. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraphs 2 and 3 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) in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC and Cr(VI) emissions to the environment.
5. The authorisation holder shall document and maintain the information from the monitoring programmes referred to in paragraphs 2 and 3, 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 4, and shall make that information 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 4(5).

*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:

Robur S.p.A, Viale Parigi, 4/6, 24040 Verdellino, Italy.

Done at Brussels, 12.6.2024

*For the Commission*

*Thierry BRETON*

*Member of the Commission*

