EUROPEAN
COMMISSION

Brussels, 15.1.2024
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COMMISSION IMPLEMENTING DECISION

of 15.1.2024

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Eurenco for a use of 1,2-dichloroethane ('EDC') in the context of a review and repealing Implementing Decision C(2019) 2260

(Only the English text is authentic)

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granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Eurenco for a use of 1,2-dichloroethane ('EDC') in the context of a review and repealing Implementing Decision C(2019) 2260

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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) 1,2-dichloroethane ('EDC') is listed in Annex XIV to Regulation (EC) No 1907/2006 and uses of that substance are therefore subject to the authorisation requirement referred to in Article 56(1), point (a), of that Regulation.

(2) On 28 March 2019, by Commission Implementing Decision C(2019) 2260[2] an authorisation was granted to Eurenco for the industrial use of EDC as a solvent for the synthesis of polyepichlorohydrin used as a precursor in the production of glycidyl azide polymer, an oligomer with hydroxyl terminations used to increase the energetic performance of propellants and explosives (authorisation number REACH/19/7/0). The time-limited review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 for that authorised use of EDC expired on 22 November 2021.

(3) On 15 May 2020, Eurenco submitted a review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 for authorisation of the industrial use of EDC as a solvent for the synthesis of polyepichlorohydrin used as a precursor in the production of glycidyl azide polymer, an oligomer with hydroxyl terminations used to increase the energetic performance of propellants and explosives.

(4) The European Chemicals Agency sent the opinions on the review report adopted by the Committee for Risk Assessment (RAC) and by the Committee for Socio-economic Analysis (SEAC)[3] of the Agency to the Commission pursuant to Article 64(5), third

[1] OJ L 396, 30.12.2006, p. 1.

[2] Commission Implementing Decision C(2019) 2260 final of 28 March 2019 granting an authorisation for a use of 1,2-dichloroethane under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Eurenco).

[3] https://echa.europa.eu/documents/10162/5d6a2257-7e8f-680e-cf74-56ac27c622d0

subparagraph, of Regulation (EC) No 1907/2006. On 30 March 2022, the Commission received the opinions.

(5) In its opinion, RAC confirmed that it is not possible to determine a derived no-effect level for the carcinogenic properties of EDC in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and therefore that EDC 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 that Regulation does not apply to that substance, and therefore an authorisation may only be granted under paragraph 4 of that Article.

(6) In its opinion, as regards a risk for human health, RAC concluded that the risk management measures and operational conditions as described in the review report are not appropriate and effective in limiting the risk to workers and to members of the general population who could potentially be exposed to EDC via the environment. In particular, RAC noted that although the main processes are carried out in closed systems, a significant number of tasks still include open handling, which leads to potential exposure to EDC, and certain measures do not follow the best available techniques, also taking into account that Eurenco has not complied with the conditions for authorisation set out in Commission Implementing Decision C(2019) 2260. Therefore, RAC recommended, as a condition for authorisation, to carry out a feasibility study to improve the risk management measures and operational conditions for protection of workers in line with the hierarchy of control principles to reduce the need for personal protective equipment.

(7) In its opinion, as regards emissions to the environment, RAC noted that, although the risk management measures and operational conditions have significantly improved since the submission of the original application for authorisation, releases to air, not captured by the extraction tower, may occur. Therefore, RAC recommended certain conditions and monitoring arrangements. Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations.

(8) In its opinion, SEAC concluded that it has no substantial reservations on the quantitative and qualitative elements of Eurenco's assessment of the socio-economic benefits and of the risk to human health or the environment resulting from the continued use of EDC. Taking into account SEAC's assessment of the socio-economic analysis, the estimated monetised risk of cancer associated with the continued use of that substance in the order of thousands of euro per year, the estimated monetised socio-economic benefits of the continued use of EDC due to avoided loss of profits and avoided decontamination costs, at minimum in the order of hundreds of thousands of euro over the review period, as well as the qualitative benefits from maintaining operational defence capabilities, and any distributional impact, the Commission concludes that Eurenco has demonstrated that the socio-economic benefits of the continued use of EDC outweigh the risk to human health or the environment arising from that use.

(9) A suitable alternative should be safer, available, and technically and economically feasible. Where suitable alternatives are available in the Union, but are not technically or economically feasible for the holder of the authorisation or its downstream users, an authorisation may be granted if the applicant for authorisation submits 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.

(10) In its opinion, SEAC concluded that there were no suitable alternative substances or technologies available for the Eurenco before the end of the review period set out in Decision C(2019) 2260. The Commission, having evaluated SEAC's assessment and all relevant information available, notes that further testing, validation and scaling-up is required to achieve full implementation of the identified alternatives. Thus, the Commission considers that it cannot be deemed that the shortlisted alternatives allow the functionality needed for the use for which the authorisation is sought. Therefore, the Commission agrees with SEAC's conclusion and considers that Eurenco has discharged its burden of proof in demonstrating the absence of suitable alternatives both in the Union and for it.

(11) In its opinion, SEAC noted that with a review period shorter than the requested period of 7 years, Eurenco may choose to substitute EDC with certain non-safer substances available. Therefore, in order to avoid regrettable substitution, SEAC recommended certain conditions, including the reporting of substitution progresses to the competent authority of the Member State where the authorised use takes place. The Commission, having evaluated SEAC's assessment, concurs with its conclusion and recommendations.

(12) 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 EDC described in the review report, 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.

(13) 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 base in the future. Hence, it is appropriate to require additional information on exposure and emission be generated.

(14) SEAC recommended in its opinion that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set at four years. The Commission takes into account that recommendation and the relevant elements from RAC's and SEAC's assessments and, in particular, that the risk management measures are not appropriate and effective in limiting the risk to human health, as well as the socio-economic benefits, the risk associated with the continued use of the substance and the time needed to validate, test and implement a safer alternative.

(15) However, taking into account the low efforts undertaken by Eurenco to improve the risk management measures and operational conditions as required in Implementing Decision C(2019) 2260, the Commission considers that a shorter review period is appropriate to swiftly implement the best available techniques and the hierarchy of control principles, following the finalisation of the feasibility study. Therefore, the review period should be set at 15 January 2026.

(16) The language used to describe the risk management measures and operational conditions in the review report 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) This Decision does not affect the obligation of the authorisation holder 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 neither affects the obligation of the authorisation holder under Article 60(10) of that Regulation or of its downstream users under Article 56(2) of the same Regulation to ensure that the exposure is reduced to as low a level as is technically and practically possible nor 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[4] 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[5], 92/85/EEC[6] and 94/33/EC[7], and Directive 2004/37/EC, nor does it affect 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 other regulatory provisions including emission limit values 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 emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.

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4 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).

5 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).

6 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).

7 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).

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 repealingCouncil 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).

(19) The authorisation should therefore be granted in the context of the review referred to in Article 61(1) of Regulation (EC) No 1907/2006. For reasons of clarity and legal certainty, Implementing Decision C(2019) 2260 should be replaced by this Decision.

(20) The measures provided for in this Decision are in accordance with the opinion of the committee established by Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS DECISION:

Article 1

An authorisation is hereby granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following use of 1,2-dichloroethane ('EDC') (EC No 203-458-1; CAS No 107-06-2):

Authorisation number	Authorised use
REACH/23/35/0/R1	Industrial use as a solvent for the synthesis of polyepichlorohydrin used as a precursor in the production of glycidyl azide polymer, an oligomer with hydroxyl terminations used to increase the energetic performance of propellants and explosives

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[12], as well as to the conditions set out in Article 2.

Article 2

1. The authorisation is subject to the conditions set out in paragraphs 2 to 8.

2. The authorisation holder shall finalise by 15 March 2024 a study to assess the feasibility of implementing additional risk management measures and operational conditions to reduce the use of personal protective equipment, including the implementation of an automatic transfer of EDC from the delivery trucks to the reservoir. The authorisation holder shall act in accordance with the outcome of that study and implement, as appropriate, the additional risk management measures and operational conditions by 15 July 2024.

3. The authorisation holder shall carry out a monitoring programme of occupational exposure to EDC. The measurements shall:

   (a) take place at least annually or each time EDC is used, if the frequency of the use is less than annual;

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

   (c) ensure a sufficiently low limit of quantification;

[12] https://ec.europa.eu/docsroom/documents/49456

(d) comprise personal inhalation exposure and biomonitoring, as well as static inhalation exposure sampling;

(e) be representative of the range of tasks undertaken and of the total number of workers that are potentially exposed, including process, maintenance and other types of workers;

(f) be recorded so as to include contextual information about the tasks with possible exposure to EDC.

4. The authorisation holder shall carry out a monitoring programme measuring the releases of EDC to air. The measurements shall:

(a) be carried out at least annually or each time EDC is used, if the frequency of the use is less than annual;

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

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

(d) ensure a sufficiently low limit of quantification;

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

5. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraphs 3 and 4 and related contextual information to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions, including the positioning of the extraction ventilation. If needed, the authorisation holder shall introduce measures to further reduce the exposure and emissions to EDC to as low a level as is technically and practically possible, in accordance with hierarchy of control principles.

6. The authorisation holder shall document and maintain the results of the measurements referred to in paragraphs 3 and 4, the related contextual information as well as the outcome and conclusions of the review and any action taken in accordance with paragraphs 2 and 5, and shall make that information available, upon request, to the competent authority of the Member State where the authorised use takes place.

7. The authorisation holder shall ensure that substitution of EDC is made with a safer substance or technology, avoiding substances that have carcinogenic, mutagenic or reprotoxic properties.

8. The authorisation holder shall document the substitution progress in annual reports that shall be submitted to the competent authority of the Member State where the authorised use takes place.

Article 3

1. The review period shall expire on 15 January 2026.

2. The authorisation shall cease to be valid on 15 January 2026 if the authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 15 July 2024.

Article 4

Where the authorisation holder submits a review report, it shall include the information referred to in Article 2(6).

Article 5

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, in an official language of that Member State.

Article 6

Implementing Decision C(2019) 2260 is repealed.

Article 7

This Decision is addressed to Eurenco, 1928, Avenue d'Avignon, 84700, Sorgues, France.

Done at Brussels, 15.1.2024

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION