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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 Lanxess Deutschland GmbH for a use of 1,2-dichloroethane ('EDC') in the context of a review and amending Implementing Decision C(2018) 2881

(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 Lanxess Deutschland GmbH for a use of 1,2-dichloroethane ('EDC') in the context of a review and amending Implementing Decision C(2018) 2881

(Only the English text is authentic)

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 17 May 2018, by Commission Implementing Decision C(2018) 2881[2] an authorisation was granted to Lanxess Deutschland GmbH for certain uses of EDC, including the industrial use as a swelling agent during the sulphonation reaction of polystyrene-divinylbenzene copolymer beads in the manufacturing of strong acid cation exchange resins (authorisation number REACH/18/2/0). The time-limited review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 for that authorised use expired on 22 November 2021.

(3) On 18 May 2020, Lanxess Deutschland GmbH 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 swelling agent during the sulphonation reaction of polystyrene-divinylbenzene copolymer beads in the manufacturing of strong acid cation exchange resins.

(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

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

[2] Commission Implementing Decision C(2018) 2881 of 17 May 2018 granting an authorisation for certain uses of 1,2-dichloroethane under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Lanxess Deutschland GmbH).

Analysis (SEAC)[3] of the Agency to the Commission pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006. On 2 September 2021, 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, RAC concluded that the risk management measures and operational conditions as described in the review report are 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. However, RAC pointed at the frequent malfunctions of the thermal exhaust air purification ('TAR') of the incinerating plant, which is the main cause of air emission, although Lanxess Deutschland GmbH planned improvements of the recovery of EDC from the exhaust gas before it reaches the TAR. Therefore, RAC recommended certain conditions and monitoring arrangements to further limit the risk. Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations.

(7) In its opinion, SEAC concluded that it has no substantial reservations on the quantitative and qualitative elements of Lanxess Deutschland GmbH's assessment of the socio-economic benefits and of the risk to human health resulting from the continued use of EDC. 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 of EDC in the order of hundreds of euro per year, the estimated monetised socio-economic benefits of the continued use of that substance due to avoided loss of profits at minimum in the order of between hundreds of thousands of euro and millions of euro over the review period, the qualitatively assessed additional socio-economic benefits of the continued use of EDC due to impacts on the supply chain, as well as any additional negative distributional impact, the Commission concludes that Lanxess Deutschland GmbH 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.

(8) 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 applicant 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. 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

[3] https://echa.europa.eu/documents/10162/ebc37897-6414-5ff6-6639-85f302213442

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.

(9) In its opinion, SEAC concluded that there were no suitable alternative substances or technologies available by the end of the review period set out in Decision . The Commission, having evaluated SEAC's assessment and all relevant information available, notes that further development, testing and validation of the solventless sulphonation technique is required to achieve the necessary level of performance, the full implementation of the alternative and to meet customers' requirements, in particular regarding the quality of the final strong acid cation exchange resins in terms of bead integrity and bead process stability. Thus, the Commission considers that it cannot be deemed that the identified alternative allows the functionality needed for the use applied for. Therefore, the Commission agrees with SEAC's conclusion and considers that Lanxess Deutschland GmbH has discharged its burden of proof in demonstrating the absence of suitable alternatives both in the Union and for Lanxess Deutschland GmbH.

(10) 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.

(11) 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 that additional information on exposure and emission be generated.

(12) SEAC recommended in its opinion that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 should be set at 7 years. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, the socio-economic benefits and risk of the continued use of the substance, as well as the additional time needed for development, validation and full implementation of the alternative technology in a number of remaining products still requiring transition to that alternative.

(13) The language used to describe the risk management measures and operational conditions in the review report may be different from the official language(s) 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.

(14) 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 does not affect the obligation of the authorisation holder under Article 60(10) of that Regulation or of its downstream users under Article 56(2) 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[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], 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 Union limit values.

(15) 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.

(16) The authorisation should therefore be granted in the context of the review referred to in Article 61(1) of Regulation (EC) No 1907/2006. Implementing Decision C(2018) 2881 should therefore be amended as provided for in Article 61(1) of Regulation (EC) No 1907/2006 regarding the authorisation bearing number REACH/18/2/0.

(17) 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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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 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).

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/23/39/0/R1	Industrial use as a swelling agent during the sulphonation reaction of polystyrene-divinylbenzene copolymer beads in the manufacturing of strong acid cation exchange resins.

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 shall be subject to the conditions set out in paragraphs 2 to 6.
2. The authorisation holder shall ensure that the entire unit is shut down, if the on-site thermal exhaust air purification unit (TAR) is out of operation for more than one hour or for a shorter period if such a situation can be envisaged at an earlier stage.
3. The authorisation holder shall ensure that the exhaust air ducts are washed on a weekly basis to remove possible condensation of EDC and, by 15 June 2024, ensure that the resulting wastewater is collected at the on-site treatment plant.
4. The authorisation holder shall investigate the reasons for malfunction of the thermal exhaust air purification and put in place measures to limit the number of instances and duration of such malfunctions.
5. The authorisation holder shall document the duration of the malfunctions of the thermal exhaust air purification, the flow rate of the vent gases and the concentration of EDC before the TAR and in the vent gases emitted to the environment.
6. The authorisation holder shall keep the documentation referred to in paragraphs 2 to 5 and shall make it available, upon request, to the competent authority of the Member State where the where the authorised use takes place.

Article 3

1. The review period shall expire on 22 November 2028.
2. The authorisation shall cease to be valid on 22 November 2028 if the review report has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 22 May 2027.

[12] https://ec.europa.eu/docsroom/documents/21701

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 of occupational exposure to EDC. The measurements shall:

   (a) take place at least annually;

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

   (c) ensure a sufficiently low limit of quantification;

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

   (e) be representative of all the tasks with possible exposure to EDC, the operational conditions and risk management measures for each of those tasks 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 performed during sampling.

3. 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 more frequently if a significant increase of EDC consumption takes place on site. The frequency of the measurements shall be sufficient to capture any potential increase in emissions of EDC;

   (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.

4. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraphs 2 and 3 and related contextual information to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions and, if needed, to introduce measures to further reduce the exposure and emissions to a level as low as technically and practically possible and in accordance with hierarchy of control principles.

5. The authorisation holder shall document and maintain the results of the measurements referred to in paragraphs 2 and 3, the related contextual information as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 4, 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 5

Where the authorisation holder submits a review report, it shall include the information referred to in Articles 2(5) and 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 uses take place in an official language of that Member State.

Article 7

Implementing Decision C(2018) 2881 is amended as follows:

(1) in Article 1, the following reference is deleted:

'REACH/18/2/0	Industrial use of 1,2-dichloroethane as a swelling agent during the sulphonation reaction of polystyrene-divinylbenzene copolymer beads in the manufacturing of strong acid cation exchange resins';

(2) Article 2 is amended as follows:

(a) paragraph 1 is replaced by the following:

'The review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 shall expire on 22 November 2029.';

(b) paragraph 2 is deleted.

Article 8

This Decision is addressed to Lanxess Deutschland GmbH, Kennedyplatz 1, 50569, Köln, Germany.

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