EUROPEAN
COMMISSION

Brussels, 17.5.2018
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COMMISSION IMPLEMENTING DECISION

of 17.5.2018

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)

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

(2) On 18 February 2016, Lanxess Deutschland GmbH ('the applicant') submitted in accordance with Article 62 of Regulation (EC) No 1907/2006 an application for authorisation for 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 ('use 1') and as a swelling agent and reaction medium during the phthalimidomethylation reaction of polystyrene-divinylbenzene copolymer beads in the manufacturing of anion exchange and chelating resins ('use 2').

(3) On 1 February 2017, the Commission received the opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency on the application[2], pursuant to the second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.

(4) In its opinions, RAC confirmed that it is not possible to determine a derived no-effect level (DNEL) 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 non-threshold substance. In accordance with Article 60(3)(a) of Regulation (EC) No 1907/2006, Article 60(2) of that Regulation does not apply to that substance, and

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

[2] https://echa.europa.eu/documents/10162/5b61e51e-5827-e47e-ce04-3a07c8bb951e
https://echa.europa.eu/documents/10162/3705d47c-3554-e629-c6ec-d02492645f09

therefore an authorisation may only be granted on the basis of Article 60(4) of that Regulation.

(5) In its opinions, RAC concluded that the risk management measures and operational conditions as described in the application are appropriate and effective in limiting the risks to workers and the general population that could potentially be exposed via the environment.

(6) In its opinions, SEAC concluded that the overall socio-economic benefits arising from each of the two uses of EDC applied for outweigh the risk to human health or the environment arising from each of those uses and that there are no suitable alternative substances or technologies in terms of their technical and economic feasibility for the applicant. The Commission, having evaluated SEAC's assessments, concurs with those conclusions.

(7) Therefore, in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the two uses of EDC applied for, provided that the risk management measures and operational conditions described in the application and in particular in the chemical safety report[3] are fully applied.

(8) In its opinions, SEAC recommended the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 to be set at four years for use 1 and at twelve years for use 2. With regard to use 1, the recommended review period takes into account RAC's assessment of the risk arising from the continued use of the substance and its conclusion that the implemented risk management measures and operational conditions are appropriate and effective in limiting this risk, the lack of suitable alternatives by the sunset date, the time necessary to implement the identified potentially technically feasible alternative process, the time necessary for qualification of the products, as well as the fact that the socio-economic benefits of continued use, in the order of millions of euros, clearly outweigh the risk to human health. With regard to use 2, the recommended review period takes into account RAC's assessment of the risk of the continued use of the substance and conclusion that the implemented risk management measures and operational conditions are appropriate and effective in limiting the risks, the lack of suitable alternatives by the sunset date, the time necessary for research and development and for implementation of the identified potentially technically feasible alternative process, the time necessary for qualification of the products, as well as the fact that the socio-economic benefits of continued use, in the order of hundreds of millions of euros, clearly outweigh the monetised risk to human health.

(9) In view of RAC's and SEAC's opinions, the Commission considers appropriate that, as regards the two uses of EDC applied for, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 is set at four years for use 1 and at twelve years for use 2 as from the sunset date set out in Annex XIV to that Regulation.

(10) The language used for the description of the risk management measures and operational conditions included in the application for authorisation may be different from the official language(s) of the Member State(s) where the use(s) take(s) place. Therefore, in order to facilitate the enforcement of the authorisation, it is appropriate to include a monitoring arrangement requiring the authorisation holder to submit, upon request, a succinct summary of those risk management measures and operational conditions in an official language of the Member State(s) concerned.

[3] http://ec.europa.eu/DocsRoom/documents/21701/

(11) This Decision does not affect the obligation of the authorisation holder to ensure that the use does not adversely affect human health or the environment pursuant to Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, it does not affect either the obligation of the authorisation holder to ensure that the exposure to the substance is reduced to as low a level as is technically and practically possible pursuant to Article 60(10) of Regulation (EC) No 1907/2006 or the obligation of the employer 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 in accordance with Article 4(1) of Directive 2004/37/EC of the European Parliament and of the Council[4], or to prevent and reduce exposure in accordance with Article 5 of that Directive. Furthermore, this Decision is without prejudice to the application of the Union Directives in the area of health and safety at work, in particular Council Directive 89/391/EEC[5], Council Directive 98/24[6], Directive 2004/37, Council Directive 92/85/EEC[7] and Council Directive 94/33/EC[8].

(12) This Decision is without prejudice to any obligation to comply with emission limit values set in accordance with Directive 2010/75/EU of the European Parliament and of the Council[9] and Directive 2008/50/EC of the European Parliament and of the Council[10], as well as with emission limit values set to achieve compliance with the environmental quality standards established both in Directive 2008/105/EC of the European Parliament and of the Council[11] and by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[12]. Compliance with the provisions of this Decision should not necessarily result in compliance with emission limit values or environmental quality standards under other Union legislation, which may include separate or more onerous requirements.

(13) The measures provided for in this Decision are in accordance with the opinion of the Committee established under 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 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).

7 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).

8 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).

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 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).

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).

12 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).

HAS ADOPTED THIS DECISION:

Article 1

An authorisation is granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following uses of 1,2-dichloroethane (EC No 203-458-1; CAS No 107-06-2), provided that the risk management measures and operational conditions described in the chemical safety report submitted pursuant to Article 62(4)(d) of that Regulation are fully applied:

Authorisation number	Authorised use
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
REACH/18/2/1	Industrial use of 1,2-dichloroethane as a swelling agent and reaction medium during the phthalimidomethylation reaction of polystyrene-divinylbenzene copolymer beads in the manufacturing of anion exchange and chelating resins

Article 2

1. As regards the authorised uses of 1,2-dichloroethane, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 22 November 2021 for the use with authorisation number REACH/18/2/0 and on 22 November 2029 for the use with authorisation number REACH/18/2/1.

2. The authorisation for the use with authorisation number REACH/18/2/0 shall cease to be valid on 22 November 2021 in case the review report referred to in Article 61(1) has not been submitted by 22 May 2020, unless a decision to withdraw the authorisation is adopted earlier in application of Article 61(2) and (3) of Regulation (EC) No 1907/2006.

3. The authorisation for the use with authorisation number REACH/18/2/1 shall cease to be valid on 22 November 2029 in case the review report referred to in Article 61(1) has not been submitted by 22 May 2028, unless a decision to withdraw the authorisation is adopted earlier in application of Article 61(2) and (3) of Regulation (EC) No 1907/2006.

Article 3

The following monitoring arrangements shall apply:

(a) the authorisation holder shall submit, upon request, to the competent authority of the Member State where the authorised use takes place a succinct summary of the applicable risk management measures and operational conditions described in the chemical safety report in an official language of that Member State;

(b) the authorisation holder shall conduct regular occupational exposure measurements related to the uses described in Article 1. Those measurements shall:

(i) take place at least annually;

(ii) be based on relevant standard sampling procedures and analytical methods ;

(iii) be representative of the range of tasks with possible exposure to 1,2-dichloroethane and of the total number of workers that are potentially exposed;

(iv) include contextual information about the tasks with possible exposure to 1,2-dichloroethane;

(c) the authorisation holder shall regularly measure emissions of 1,2-dichloroethane to the air (including from fugitive emissions);

(d) the authorisation holder shall use the results of the measurements referred to in point (b) and (c) to regularly review the effectiveness of the risk management measures and operational conditions and to take action, as appropriate, to further reduce exposure and emissions to the air (including fugitive emissions);

(e) the results of the measurements referred to in points (b) and (c), as well as the outcome and conclusions of the review referred to in point (d), shall be included in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 and, upon request, be submitted to the competent authority of the Member State where the authorised use takes place.

Article 4

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

Done at Brussels, 17.5.2018

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION