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**COMMISSION IMPLEMENTING DECISION**

**of 7.6.2017**

**granting an authorisation for a use of 1,2-dichloroethane (EDC) under Regulation (EC)  
No 1907/2006 of the European Parliament and of the Council (BASF SE)**

(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) 1,2-dichloroethane (EDC) is listed in Annex XIV to Regulation (EC) No 1907/2006 and is therefore subject to the authorisation requirement referred to in Article 56(1)(a) of that Regulation.
- (2) On 8 December 2015, BASF SE ('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 recyclable solvent and extraction agent in a closed system for purification of 1,3,5-trioxane.
- (3) On 20 September 2016, 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<sup>2</sup> on the application pursuant to the second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.
- (4) In its opinion, the 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 that Regulation, Article 60(2) of that Regulation does not apply to that substance, and therefore an authorisation may only be granted on the basis of Article 60(4) of that Regulation.
- (5) In its opinion, the RAC concluded that the risk management measures and operational conditions as described in the application are appropriate and effective in limiting the risk to workers and the general population that could potentially be exposed via the environment.

<sup>1</sup> OJ L 396, 30.12.2006, p. 1.

<sup>2</sup> <https://echa.europa.eu/documents/10162/675fb9c4-c5d4-4a4a-9e2f-5e34e5ef4808>

- (6) In its opinion, the SEAC concluded that the overall socio-economic benefits arising from the use of EDC applied for outweigh the risks to human health and the environment arising from that use and that there are no suitable alternative substances or technologies in terms of their technical and economic feasibility for the applicant.
- (7) Based on the RAC and SEAC opinions, and in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is therefore appropriate to authorise the use 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<sup>3</sup>, are fully applied.
- (8) In its opinion, the SEAC recommended the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 to be set at seven years. The recommended review period takes into account RAC's conclusion that the risk management measures and operational conditions are appropriate and effective in limiting the risks, the high benefits associated with the continued use of the substance in comparison to the negligible health impacts, the lack of suitable alternatives, and the requalification of the final polymer for certain applications, namely in safety-critical automotive components, that potential changes in the production process would require. Furthermore, the SEAC took into account the information provided by the applicant about a planned closure of the concerned production facility, the uncertainties associated with the exact timing of the closure, as well as the time that the applicant would need for submitting, if necessary, a review report.
- (9) Therefore, as regards the use of EDC applied for, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 should be set at seven years as from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006.
- (10) In their opinions, the RAC and the SEAC considered that additional conditions and monitoring arrangements for the use of EDC as described in the application were not necessary.
- (11) The language used for description of the risk management measures and operational conditions included in the application for authorisation is different from the official language of the Member State where the use of EDC applied for takes 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 that Member State.
- (12) 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 that Regulation 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<sup>4</sup> 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 EU Directives in the area of health and safety at

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<sup>3</sup> <http://ec.europa.eu/DocsRoom/documents/19103>

<sup>4</sup> OJ L 158, 30.4.2004, p. 50.

work, in particular Council Directive 89/391/EEC<sup>5</sup>, Council Directive 98/24<sup>6</sup>, Directive 2004/37 of the European Parliament and of the Council<sup>7</sup>, Council Directive 92/85/EEC<sup>8</sup> and Council Directive 94/33/EC<sup>9</sup>.

- (13) 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<sup>10</sup> and Directive 2008/50/EC of the European Parliament and of the Council<sup>11</sup>, 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<sup>12</sup> and by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council<sup>13</sup>. 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.
- (14) 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,

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 use of 1,2-dichloroethane (EDC) (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

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<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, 29.06.1989, p. 1).

<sup>6</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, 05.05.1998, p. 11).

<sup>7</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 or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.04.2004).

<sup>8</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).

<sup>9</sup> Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work (OJ L 216, 20.08.1994, p. 12).

<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).

<sup>11</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).

<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).

<sup>13</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).

REACH/17/9/0

Industrial use of EDC as a recyclable solvent and extraction agent in a closed system for purification of 1,3,5-trioxane

*Article 2*

As regards the authorised use of EDC, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 22 November 2024.

*Article 3*

The following monitoring arrangement shall apply:

- 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.

*Article 4*

This Decision is addressed to BASF SE, Carl-Bosch-Str. 38, 67056 Ludwigshafen am Rhein, Rheinland-Pfalz, Germany.

Done at Brussels, 7.6.2017

*For the Commission*  
*Elżbieta BIEŃKOWSKA*  
*Member of the Commission*

