EUROPEAN
COMMISSION

Brussels, 10.1.2018
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COMMISSION IMPLEMENTING DECISION

of 10.1.2018

granting an authorisation for certain uses 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[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 is therefore subject to the authorisation requirement referred to in Article 56(1)(a) of that Regulation.

(2) On 3 February 2016, an application for authorisation was submitted by BASF SE ('the applicant') in accordance with Article 62 of Regulation (EC) No 1907/2006 for the industrial use of EDC as a solvent and crystallisation medium in the synthesis of the EU plant protection active substance bentazone (EC No. 246-585-8 and CAS No. 25057-89) (('use 1') and as a solvent and crystallisation medium in the synthesis of the biocidal active substance flocoumafen (EC No. 421-960-0 and CAS No. 90035-08-8) ('use 2').

(3) Regulation (EC) No 1107/2009 of the European Parliament and of the Council[2] applies to the placing on the market of bentazone. Regulation (EU) 528/2012 of the European Parliament and of the Council[3] applies to the placing on the market and use of flocoumafen.

(4) On 15 December 2016, the Commission received the opinions of the Committee for Risk Assessment ('RAC') and the Committee for Socio-economic Analysis ('SEAC') of

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

[2] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

[3] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.06.2012, p. 1).

the European Chemicals Agency[4] on the application pursuant to the second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.

(5) In its opinion, 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.

(6) In its opinion, RAC concluded, for both uses, 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.

(7) In its opinion, SEAC concluded that the overall socio-economic benefits arising from the two uses of EDC applied for outweigh the risks to human health or the environment arising from those uses and that there are no suitable alternative substances or technologies in terms of their technical and economic feasibility for the applicant before the sunset date. The Commission, having evaluated the SEAC assessment, concurs with this conclusion.

(8) Based on RAC and SEAC opinions, and in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the 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[5] are fully applied.

(9) In its opinion, SEAC recommended the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 to be set at twelve years. The recommended review period takes into account RAC's assessment of the risk of the continued use of the substance, that the socio-economic benefits of continued use outweigh the risks by a significant margin and that this is not likely to change in the near future, the non-availability of suitable alternatives, the long investment cycle of the applicant, the time required for the development of suitable alternatives, as well as the time needed for regulatory approval in case of changes in the production process in all the countries where the final products are sold.

(10) In view of RAC and SEAC 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 should be set at twelve years as from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006.

(11) 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) of EDC 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.

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[4] https://echa.europa.eu/documents/10162/9b4a261f-9c92-c562-1bec-d8cc2c321a74 https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/13549/term

[5] http://ec.europa.eu/DocsRoom/documents/20621 http://ec.europa.eu/DocsRoom/documents/20622

(12) This Decision does not affect the obligation of the authorisation holder to ensure that the authorised uses do 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[6], 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[7], Council Directive 98/24[8], Directive 2004/37, Council Directive 92/85/EEC[9] and Council Directive 94/33/EC[10].

(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[11] and Directive 2008/50/EC of the European Parliament and of the Council[12], 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[13] and by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[14]. 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,

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6 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).

7 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).

8 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).

9 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).

10 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).

11 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).

12 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).

13 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).

14 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 and 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/17/34/0	Industrial use as solvent and crystallisation medium in the synthesis of the plant protection active substance bentazone (EC No. 246-585-8 and CAS No. 25057-89)
REACH/17/34/1	Industrial use as solvent and crystallisation medium in the synthesis of the biocidal active substance flocoumafen (EC No: 421-960-0 and CAS No. 90035-08-8)

Article 2

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 2029.

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 occupational exposure measurements of 1,2-dichloroethane relating to maintenance tasks for use 1 and to the number of workers performing them. Those measurements shall be based on relevant standard methodologies or protocols;

(c) the results of the measurements referred to in point (b), as well as all sources of release to the air, including fugitive emissions, for use 2, shall be documented and included in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006.

Article 4

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

Done at Brussels, 10.1.2018

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION