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COMMISSION IMPLEMENTING DECISION

of 1.3.2017

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 (Laboratoires Expanscience)

(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 2 July 2015, Laboratoires Expanscience ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the use of EDC as process and extracting solvent in the manufacture of plant-derived pharmaceutical bioactive ingredients.

(3) On 2 February 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 ('the Agency')[2] on the application.

(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 Regulation (EC) No 1907/2006, 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 be potentially exposed via the

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

[2] http://echa.europa.eu/documents/10162/8b3877e3-1fdc-45e3-a8ea-88fbc5559378

environment. However, the RAC considered that the performance of those risk management measures and operational conditions should be monitored and reviewed in order to remedy the shortcomings identified in the risk assessment, in particular those regarding the limited availability of measured data and the unaccounted fugitive emissions into the environment in conjunction with a planned increase of production volume.

(6) In its opinion, the RAC recommended additional conditions and monitoring arrangements for the authorisation. A program of plant preventive maintenance should be introduced in order to reduce uncontrolled release of EDC. The authorisation holder should conduct regular occupational exposure measurements related to the authorised use of EDC and use the results to regularly review the risk management measures and operational conditions. The outcomes of those actions should be included in the review report to be submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006.

(7) In its opinion, the SEAC concluded that the socio-economic benefits arising from the use of EDC as process and extracting solvent in the manufacture of plant-derived pharmaceutical bioactive ingredients 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.

(8) 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[3], are fully applied.

(9) 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 twelve years. The recommended review period takes into account the low risks to human health compared to the high socio-economic benefits of continued use, the fact that the applicant has identified an alternative which could potentially replace the use of EDC within a period of twelve years from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006, the validating period of the new production process required by the use of that possible alternative, the need for a regulatory approval under national medicines legislations in the countries where the final product is sold, as well as the need for the applicant to make a significant capital investment in order to design, build and test a new plant while maintaining production with the existing plant in case the use of the possible alternative solvent proves to be feasible.

(10) 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 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 of the Member State where the use takes place. Therefore, in order to facilitate the enforcement of the authorisation, it is appropriate to include a monitoring arrangement requiring the holders of the authorisation to submit, upon request, a succinct summary of those risk management measures and operational conditions in an official language of the Member State concerned.

[3] http://ec.europa.eu/DocsRoom/documents/15923/attachments/1/translations/en/renditions/native

(12) This Decision does not affect either the obligation of the holder of the authorisation 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.

(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[5] and Directive 2008/50/EC of the European Parliament and of the Council[6], 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[7] and by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[8]. 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 (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/17/6/0	Use of 1,2-dichloroethane as process and extracting solvent in the manufacture of plant-derived pharmaceutical bioactive ingredients

[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] 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).

[6] 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).

[7] 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).

[8] 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).

Article 2

The authorisation referred to in Article 1 shall be subject to the following condition:

– the authorisation holder shall introduce a programme of plant preventive maintenance in order to identify and minimise all potential sources of uncontrolled release of EDC by taking appropriate remedial actions. In this regard, the "Improvement action plan" as initially submitted by the applicant and presented in Annex 1 of the RAC opinion shall be implemented. Additionally, the authorisation holder shall implement a closed sampling system included in that plan by three months from the date of this Decision.

Article 3

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 2029.

Article 4

The following monitoring arrangements shall apply:

(a) on request of the competent authority of the Member State where the authorised use takes place, the authorisation holder shall submit to that authority a succinct summary of the applicable risk management measures and operational conditions referred to in Article 1, in an official language of that Member State;

(b) the authorisation holder shall conduct, at least once a year, occupational exposure measurements based on relevant standard reference methodologies and protocols, representative of the range of tasks undertaken where exposure to EDC is possible and of the total numbers of workers potentially exposed (including production, sampling and laboratory quality control), and targeting, in particular, tasks with the highest potential exposure;

(c) the information obtained from the measurements to be conducted in accordance with point (b) shall be documented and used by the authorisation holder to review the effectiveness of the risk management measures and operational conditions and take action as appropriate, ensuring that the hierarchy of control principles defined in Article 6 of Council Directive 98/24/EC[9] is followed in the selection of those risk management measures;

(d) when submitting the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 concerning the use referred to in Article 1 of this Decision, the authorisation holder shall provide a report summarising the outcomes and conclusions of the monitoring it is required to perform and the actions it is required to take in accordance with Article 4(b) and (c) of this Decision.

[9] 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).

Article 5

This Decision is addressed to Laboratoires Expanscience, 10 Avenue de l'Arche, Regulatory affairs, 92419 Courbevoie, France.

Done at Brussels, 1.3.2017

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION