EUROPEAN
COMMISSION

Brussels, 29.11.2016
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COMMISSION IMPLEMENTING DECISION

of 29.11.2016

granting an authorisation for a use of trichloroethylene under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Roquette Frères)

(Text with EEA relevance)

(ONLY THE TEXT IN ENGLISH 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) Trichloroethylene (TCE) is listed in Annex XIV to Regulation (EC) No 1907/2006 and therefore subject to the authorisation requirement referred to in Article 56(1) of that Regulation.

(2) An application for authorisation was submitted by the company Roquette Frères ('the applicant') on 29 August 2014 in accordance with Article 62 of Regulation (EC) No 1907/2006 for the industrial use of trichloroethylene as a processing aid in the biotransformation of starch to obtain betacyclodextrin.

(3) On 30 April 2015 the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency sent their opinions[2] on the application to the Commission 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 TCE in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and therefore TCE 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 also confirmed that the risk management measures and operational conditions as described in the application are appropriate and effective in

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

[2] http://echa.europa.eu/documents/10162/49eeb200-c772-4714-9124-fbb51bfba95a

limiting the risk to workers and to the general population that could be potentially exposed via the environment.

(6) In its opinion the SEAC confirmed the applicant's conclusion that the overall socio-economic benefits arising from the use 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.

(7) Based on the RAC and the SEAC opinions, and in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the use applied for, provided that the risk management measures and operational conditions described in the application and in particular in the chemical safety report 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 twelve years. The recommended review period takes into account the applicant's past and current research and development efforts to substitute TCE, the time period necessary to implement a new process if an appropriate enzyme/solvent system is found, the low remaining risk and the high socio-economic benefits of continued use.

(9) It is therefore appropriate to set the review period for the use of TCE at twelve years as from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006.

(10) In its opinion, the RAC recommended monitoring arrangements for the authorisation in order to address the remaining uncertainties related to the worker exposure data. Therefore, it is appropriate to require such monitoring arrangements.

(11) The language used for the 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 applied for takes place. Therefore, in order to facilitate the enforcement of the authorisation, it is appropriate to include a monitoring arrangement requiring the holder 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.

(12) 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 trichloroethylene (EC No. 201-167-4; CAS No. 79-01-6) subject to the full application of the risk management measures and operational conditions described in the chemical safety report[3] submitted pursuant to Article 62(4)(d) of that Regulation.

The authorised use is identified by the following authorisation number:

REACH/16/4/0	Use as a processing aid in the biotransformation of starch to obtain betacyclodextrin

[3] http://ec.europa.eu/DocsRoom/documents/10790/attachments/1/translations/en/renditions/native

Article 2

The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 April 2028.

Article 3

The following monitoring arrangements referred to in Article 60(9)(f) of Regulation (EC) No 1907/2006 shall apply:

(a) the holder of the authorisation shall implement regular monitoring programmes of occupational exposure measurements relating to the use described in Article 1. Those monitoring programmes shall:

(i) take place at least annually;

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

(iii) comprise personal inhalation exposure as well as biomonitoring (measurement of the trichloroethylene metabolite trichloroacetic acid in urine);

(iv) be representative of the range of tasks with possible exposure to trichloroethylene and of the total number of workers that are potentially exposed;

(b) the results of the monitoring as described in point (a) shall be documented and included in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 and, upon request, submitted to the competent authority of the Member State where the authorised use takes place;

(c) on request of the competent authority of the Member State where an authorised use takes place, the holder of the authorisation 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.

Article 4

This Decision is addressed to Roquette Frères, 1 rue Haute Loge, 62136 Lestrem, France.

Done at Brussels, 29.11.2016

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION