EUROPEAN
COMMISSION

Brussels, 8.2.2017
C(2017) 658 final

COMMISSION IMPLEMENTING DECISION

of 8.2.2017

granting an authorisation for certain uses of trichloroethylene under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Richard Geiss GmbH)

(Text with EEA relevance)

(ONLY THE GERMAN TEXT IS AUTHENTIC)

COMMISSION IMPLEMENTING DECISION

of 8.2.2017

granting an authorisation for certain uses of trichloroethylene under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Richard Geiss GmbH)

(Text with EEA relevance)

(ONLY THE GERMAN TEXT IS AUTHENTIC)

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 is therefore subject to the authorisation requirement referred to in Article 56(1)(a) of that Regulation.

(2) On 21 August 2014, Richard Geiss GmbH ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for two uses of TCE, namely in formulation and in packaging.

(3) On 31 July 2015, 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') on the application[2].

(4) In its two opinions, 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 that 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 two opinions, the RAC concluded 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/d6fe944a-4f78-44ad-9e4d-64b3db39ab8e
http://echa.europa.eu/documents/10162/b1308c68-b2bc-47ec-b5b0-6d1a633ffb2c

limiting the risk to indirectly exposed workers and the general population. However, as regards directly exposed workers, the RAC concluded that there are uncertainties related to the appropriateness and effectiveness of risk management measures and operational conditions in limiting the exposure and risks related to workplaces that do not use sealed systems as a standard process. In order to address those uncertainties, the RAC recommended that regular occupational exposure measurements should be conducted in the workplaces covered by this authorisation. It is therefore appropriate to require the authorisation holder to conduct such measurements, to use those results to review the risk management measures and operational conditions and to include them in the case of a review report to be submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006.

(6) In its two opinions, the SEAC concluded that the overall socio-economic benefits arising from each of the two uses of TCE applied for outweigh the risks to human health and the environment arising from each of those uses. Considering that TCE has no independent function in the two uses applied for (packaging and formulation), the SEAC concluded that an assessment of the feasibility of alternatives is irrelevant and confirmed that there are no suitable alternative substances or technologies for the uses applied for.

(7) Based on the RAC and the SEAC opinions, and in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is therefore appropriate to authorise the two uses of TCE applied for, provided that the risk management measures and operational conditions described in the application and in particular in the respective chemical safety reports[3], as well as the monitoring arrangements suggested by RAC are fully applied.

(8) In its opinions, 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 very small risks associated with the continued use, the fact that benefits of continued use significantly outweigh the risks of such use and the fact that TCE has no independent function in the uses applied for (packaging and formulation) and as such any substitution is dependent on the downstream users rather than the applicant.

(9) Therefore, as regards both uses of TCE 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.

(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 of the Member State where the uses take 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.

(11) 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

[3] http://ec.europa.eu/DocsRoom/documents/12342/attachments/1/translations/en/renditions/native
http://ec.europa.eu/DocsRoom/documents/12343/attachments/1/translations/en/renditions/native

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.

(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[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.

(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,

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 trichloroethylene (EC No. 201-167-4, CAS No. 79-01-6) provided that the risk management measures and operational conditions described in the chemical safety report corresponding to each use and submitted pursuant to Article 62(4)(d) of that Regulation are fully applied:

Authorisation number	Authorised use
REACH/2017/1/0	Use of trichloroethylene in formulation
REACH/2017/1/1	Use of trichloroethylene in packaging

Article 2

As regards the authorised uses of trichloroethylene, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 April 2028.

---

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 3

The following monitoring arrangements shall apply:

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

  (i) take place at least annually;

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

  (iii) comprise both personal inhalation exposure and 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, including process, maintenance and other workers involved;

(b) the information obtained from the measurements to be implemented in accordance with point (a) shall be documented and used by the authorisation holder to review the effectiveness of the risk management measures and operational conditions and to take action as appropriate. This information shall also be submitted, upon request, to the competent authority of the Member State where an authorised use takes place;on request of the competent authority of the Member State where the authorised uses take place, the authorisation holder shall submit to that authority a succinct summary of the applicable risk management measures and operational conditions described in the chemical safety reports, in an official language of that Member State;

(c) when submitting the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 concerning the uses referred to in Article 1 of this Decision, the authorisation holder shall provide the results of the monitoring referred to in point (a) of this Article as well as a report resulting from the outcomes and conclusions of the review it is required to perform in accordance with point (b) of this Article.

Article 4

This Decision is addressed to Richard Geiss GmbH, Lueßhof 100, 89362 Offingen, Bayern, Germany.

Done at Brussels, 8.2.2017

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION