



Brussels, 8.2.2017
C(2017) 660 final

COMMISSION IMPLEMENTING DECISION

of 8.2.2017

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

(Text with EEA relevance)

(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/EC¹, 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, an application for authorisation was submitted by Spolana a.s. ('the applicant') in accordance with Article 62 of Regulation (EC) No 1907/2006 for the use of TCE as an extraction solvent in caprolactam production.
- (3) On 1 September 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 Agency² 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 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 opinion, the RAC concluded that the risk management measures and operational conditions as described in the application are not appropriate and effective in limiting the risk. The RAC also noted the existence of significant uncertainties in the exposure assessment and of a relatively high excess cancer risk level for some workers.

¹ OJ L 396, 30.12.2006, p. 1.

² <http://echa.europa.eu/documents/10162/a29d8176-e0ab-4945-b31a-106fee3542c7>

Therefore, the RAC suggested granting an authorisation subject to certain conditions and monitoring arrangements.

- (6) In its opinion, the RAC recommended additional conditions and monitoring arrangements for the authorisation in order to further reduce TCE emissions to as low level as is technically and practically possible and to address uncertainties in worker's exposure assessment. It is therefore appropriate to require the authorisation holder to conduct regular occupational exposure measurements and environmental emissions monitoring related to the authorised use of TCE, to use those results to review the risk management measures and operational conditions as appropriate 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.
- (7) In its opinion, the SEAC concluded that the overall socio-economic benefits arising from the use of TCE as an extraction solvent in caprolactam production outweigh the risks to human health or 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 the SEAC opinions, and in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the use of TCE applied for, provided that the risk management measures and operational conditions described in the application and in particular in the chemical safety report³, as well as the additional conditions and monitoring arrangements set out in this Decision 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 four years. The recommended review period takes into account, on one hand, the lack of suitable alternatives at present and the applicant's research and development plan to find and implement an alternative within the period of 16-18 years and, on the other hand, the lack of sound justification for the requested review period in terms of the analysis of alternatives, the uncertainties related to the estimation of the socio-economic impacts, as well as the concerns of the RAC with regard to the estimated risk level for some workers.
- (10) Therefore, as regards the use of TCE applied for, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 should be set at four 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 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) 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

³ <http://ec.europa.eu/DocsRoom/documents/12345/attachments/1/translations/en/renditions/native>

of the Council⁴, 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 Council⁵ and Directive 2008/50/EC of the European Parliament and of the Council⁶, 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 Council⁷ and by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council⁸. 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 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 submitted pursuant to Article 62(4)(d) of that Regulation are fully applied:

Authorisation number	Authorised use
REACH/17/3/0	Use of TCE as an extraction solvent in caprolactam production

Article 2

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

- (a) the authorisation holder shall conduct regular occupational exposure measurements relating to the use referred to in Article 1. Those measurements shall:
- (i) take place at least annually (sampling);

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).

- (ii) be based on relevant standard methodologies or protocols;
 - (iii) comprise personal inhalation exposure and biomonitoring consisting of measurement of the TCE metabolite trichloroacetic acid in urine;
 - (iv) be representative of the range of tasks with possible exposure to TCE and of the total number of workers that are potentially exposed, including process maintenance and laboratory workers;
- (b) the authorisation holder shall conduct regular environmental monitoring (with sampling done at least annually) relating to the use referred to in Article 1, to quantify the release factors and emissions of TCE to all environmental compartments;
 - (c) the information obtained from the measurements referred to in points (a) and (b) shall be documented and used to regularly review the effectiveness of the risk management measures and operational conditions and to take action as appropriate to further reduce workers' exposure to TCE and its emissions to the environment;
 - (d) the authorisation holder shall submit the information gathered in accordance with points (a) and (b), as well as documentation on the outcomes and conclusions of the review referred to in point (c), as part of the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 as well as, upon request, to the competent authority of the Member State where the use takes place.

Article 3

As regards the authorised use of TCE, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 April 2020.

Article 4

The following monitoring arrangement shall apply:

- 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 described in the chemical safety report in an official language of that Member State.

Article 5

This Decision is addressed to Spolana a.s., Ul. Práce 657, 277 11 Neratovice, Czech Republic.

Done at Brussels, 8.2.2017

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

