



Brussels, 24.11.2015  
C(2015) 8093 final

**COMMISSION IMPLEMENTING DECISION**

**of 24.11.2015**

**granting an authorisation for some uses of trichloroethylene under Regulation (EC) No 1907/2006 of the European Parliament and of the Council**

(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/EC<sup>1</sup>, 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 Vlisco Netherlands BV ('the applicant') on 30 May 2014 for two uses of TCE ('uses applied for') in accordance with Article 62 of Regulation (EC) No 1907/2006. The uses applied for are the use of TCE as a solvent for the removal and recovery of resin from dyed cloth and the use of TCE as a solvent in a process to recover and purify resin from process water.
- (3) The Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency adopted their opinions on the application on 9 January 2015. The Commission received those opinions on 13 January 2015.
- (4) In its two opinions, the RAC confirmed that it is not possible to determine a DNEL (Derived No Effect Level) for the carcinogenic (category 1A) properties of trichloroethylene and that it is a non-threshold substance. Therefore, it meets the criteria in Article 60(3)(a) of Regulation (EC) No 1907/2006 and authorisation cannot be granted for the use of that substance in accordance with Article 60(2) of that Regulation.
- (5) In its two opinions, the RAC concluded that the risk management measures and operational conditions described in the application with regard to both uses applied for are appropriate and effective in limiting the risk to workers and the general population

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<sup>1</sup> OJ L 396, 30.12.2006, p. 1.

to the levels reported in the application. For workers, the full application of such measures and conditions has been confirmed by the biological monitoring data presented in the application.

- (6) In its two opinions, the SEAC confirmed that the overall benefits arising from the uses applied for outweigh the risks to human health resulting from those uses and that there are no suitable alternatives to TCE for the two uses applied for in terms of their technical and economic feasibility for the applicant and their risk reduction capacity.
- (7) Based on the RAC and the SEAC opinions, and in accordance with the provisions in Article 60(4) of Regulation (EC) No 1907/2006, it is therefore appropriate to authorise the uses of TCE applied for, provided that the risk management measures and operational conditions described in the application, in particular in the chemical safety report, are fully applied.
- (8) In its two opinions, the SEAC recommended the time-limited review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 to be set at twelve years. The SEAC based its recommendations on the very low risk to human health from the two uses as compared to the very high socio-economic benefits arising from the uses applied for, the considerable efforts undertaken in the past and at present by the applicant in searching for alternatives, the lack of technically and economically feasible alternatives that would result in a reduced overall risk to human health and environment, and the unlikelihood that suitable alternatives will become available in that timeframe. The SEAC considered that the recommended review period would enable the applicant to carry out its proposed 12-year research and development plan on a new solvent-based technology with the potential to develop a sustainable suitable alternative to TCE without incurring excessive costs. It is therefore appropriate to set the review period for both uses at twelve years.
- (9) In their opinions, the RAC and SEAC did not recommend any additional conditions or additional monitoring arrangements. However, in order to facilitate the enforcement of this decision, it is appropriate to include a monitoring arrangement requiring the holder of the authorisation to submit, upon request, to the competent authority of the Member State where the use takes place a succinct summary of the risk management measures and operational conditions of the relevant parts of the above mentioned chemical safety report in an official language of that Member State.
- (10) 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 submitted pursuant to Article 62(4)(d) of that Regulation corresponding to the uses<sup>2</sup> are fully applied. The authorised uses shall be identified by the following authorisation numbers:

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<sup>2</sup> <http://echa.europa.eu/documents/10162/9055ee0e-4307-4cc3-86e8-92ac29040385>  
<http://echa.europa.eu/documents/10162/dafcf691-8ca2-4b0f-a1b3-c8f1639e7ac8>

[REACH/15/5/0]

Use: use of TCE as a solvent for the removal and recovery of resin from dyed cloth

[REACH/15/5/1]

Use: use of TCE as a solvent in a process to recover and purify resin from process water

#### *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 arrangement shall apply:

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 Vlisco Netherlands BV, Binnen Parallelweg 27, 5701 PH, Helmond, Netherlands.

Done at Brussels, 24.11.2015

*For the Commission*  
*Elzbieta BIENKOWSKA*  
*Member of the Commission*

