EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING DECISION

of XXX

granting an authorisation for a use of trichloroethylene under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Chimcomplex S.A. Borzesti)

(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[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 17 October 2014, Chimcomplex S.A. Borzesti ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the industrial use of trichloroethylene as a solvent as a degreasing agent in closed systems.

(3) On 16 July 2015, The Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency ('the Agency') adopted their opinions[2] on the application, together with the applicant's comment on these opinions, 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 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.

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

[2] http://echa.europa.eu/documents/10162/bb35cbbf-60cf-46bd-967f-073400bf0490

(5) In its opinion, the RAC concluded that the exposure assessment made by the applicant does not allow for a reliable assessment of the risks due to the fact that the exposure assessment for workers relies only on modelled data and covers many different workplaces with many and variable exposure determinants, as well as to the fact that the application did not include a risk assessment for man via the environment. Therefore, the RAC concluded that the risk management measures and operational conditions as described in the application are not appropriate and effective to limit the risk to workers and the general population that could be potentially exposed via the environment.

(6) In its opinion, the RAC recommended additional conditions and monitoring arrangements for the authorisation in order to addres the uncertainties and to further limit the exposure. It is therefore appropriate to impose them on the authorisation holder and its downstream users.

(7) In its opinion, the SEAC concluded that, although there is a number of uncertainties on both sides of the costs and benefits assessment, and given the apparent underestimation in the application of all the overall economic impacts, the socio-economic benefits arising from the industrial use of TCE as a solvent as a degreasing agent in closed systems outweigh the risks to human health and the environment arising from that use. The SEAC could not confirm the applicant's conclusions on technical and economic feasibility of alternatives for downstream users across the different sectors and uses affected, and noted that suitability of alternatives from the perspective of the applicant was not addressed in the application. However, on the basis of information already in the SEAC's possession, it concluded that there are no suitable alternative substances or technologies in terms of their technical and economic feasibility for the applicant for the use applied for.

(8) 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 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 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 26 months. The recommended review period takes into account the uncertainties related to the exposure assessment and the RAC's concerns related to the estimated individual risk for the workers concerned by the use, the need for the applicant to continue examining the opportunities for substitution and that the insufficient information in the application does not allow to validate the conclusion on the feasibility of alternatives across the broad scope of the use. In its opinion, SEAC also took note of the potential risks of reduced competion on the market associated with granting of authorisation of different review periods among competitors seeking authorisation for the same or similar uses leading to potential problems of scarcity rents and monopoly profits.

(10) However, considering that the deadline to submit a review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 should allow the applicant to properly and effectively collect the required data on the downstream uses from its supply chain in order to correct the uncertainties in the exposure assessment, as well as to be able to

[3] http://ec.europa.eu/DocsRoom/documents/12341/attachments/1/translations/en/renditions/native

properly assess the economic and technical feasibility of the alternatives and the impact on downstream users, it is justified to set the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 for the use of TCE applied for at twenty four months from the adoption of this Decision.

(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 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.

(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,

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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).

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[9] submitted pursuant to Article 62(4)(d) of that Regulation, as well as the conditions set out in Article 2 of this Decision and monitoring arrangements set out in Article 4 of this Decision are fully applied:

Authorisation number	Authorised use
REACH/16/9/0	Industrial use of trichloroethylene as a solvent as a degreasing agent in closed systems

Article 2

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

(a) workers shall be regularly trained for the safe use of TCE and the use of personal protection equipement;

(b) the authorisation holder's downstream users to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 shall ensure that personal protection equipement, including gloves, for which the breakthrough time for chlorinated solvents should be sufficiently long and tested according to EN374, is appropriate for the use of TCE as authorised in Article 1 of this Decision;

(c) the process referred to in Article 1should be performed under vacuum or the reasons for the impossibility of doing so should be documented;

(d) at the latest by the end of their service life, ECSA Type III machines shall be replaced with Type IV or preferably Type V machines unless it is possible to substitute TCE with an alternative;

(e) environmental releases and sources of emission, including leakage, shall be controlled;

(f) the authorisation holder's downstream users to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 shall conduct regular occupational measurements relating to the use referred to in Article 1 of this Decision. Those measurements shall:

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

  (ii) comprise both personal inhalation exposure and biomonitoring (consisting of measurement of the TCE metabolite trichloroacetic acid in urine) for the workplaces covered by this decision;

[9] http://ec.europa.eu/DocsRoom/documents/12341/attachments/1/translations/en/renditions/native

(iii) 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.

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 [*add a date – 24 months from adoption*].

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 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;

(b) the information gathered from the measurements referred to in Article 2(f) shall be used by the authorisation holder's downstream users to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 to regularly review the effectiveness of the risk management measures and operational conditions and to take action as appropriate;

(c) on request of the competent authority of the Member State where the use takes place, the holder of the authorisation's downstream users to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 shall submit to that authority the information obtained from the measurements required by Article 2 (f) of this Decision, as well as documentation on the outcomes and conclusions of the review carried out in accordance with point (b) of this Article, in an official language of that Member State;

(d) the downstream users to which this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 shall make available the information from the measurements referred to in Article 2 (f) of this Decision and the conclusions and outcomes of the review pursuant to point (b) of this Article to the European Chemicals Agency, for transmission to the authorisation holder for the purpose of the review report referred to in Article 61(1) of that Regulation;

(e) the information collected in accordance with point (d) shall be included in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006.

Article 5

This Decision is addressed to Chimcomplex S.A. Borzesti, 3 Industriilor Street, 601124, Onesti, Bacau, Romania.

Done at Brussels,

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission