EUROPEAN
COMMISSION

Brussels, XXX
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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 (Parker Hannifin Manufacturing Netherlands (Filtration & Separation) BV)

(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 20 August 2014, Parker Hannifin Manufacturing Netherlands (Filtration & Separation) BV ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the use of TCE as a process solvent for the manufacturing of modules containing hollow fibre gas separation membranes.

(3) On 22 May 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 on the application[2].

(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

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

[2] http://echa.europa.eu/documents/10162/c6f8890e-c17d-4912-86d3-0ea40a1490e4

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

(6) In its opinion, the SEAC concluded 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 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.

(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 activities so far searching to substitute TCE with a suitable solvent or to switch to a new polymer and his plans for the development of and a transition to a promising alternative using a new type of polymer within a period of 18 years, the long investment cycle in this sector, the very high costs and long implementation time of switching to an alternative, the qualification requirements for the use of possible alternatives in the aviation industry, the low remaining risks to human health and the fact that the benefits of continued use exceed the risks to human health and the environment by a very significant margin. The SEAC concluded that, although the applicant has provided arguments for an 18 years review period, he would have to show that there is an exceptional case for justifying a longer than twelve years review period. In SEAC's opinion, producing for the aviation industry, as presented in the application, under certain requirements imposed by the authorities (airworthiness certificate) does not constitute an exceptional case.

(9) 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 twelve years as from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006.

(10) In their opinions, the RAC and the SEAC considered that additional conditions and monitoring arrangements for the use as described in the application were not necessary. However, with respect to the expansion plans mentioned in the application, any increase in the annual quantity of TCE used in the manufacturing process should include the implementation of risk management measures to limit exposure to workers and humans via the environment to at least the currently described levels and preferably reduce them further. Should changes in the manufacturing process take place requiring modifications in the risk management measures, the applicant should update the chemical safety report accordingly and submit it to the Agency so that it

[3] http://echa.europa.eu/documents/10162/b625fe60-fba5-4e43-95bc-057decbc80c5

can be assessed whether the authorisation should be reviewed in accordance with Article 61(2) of 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 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) 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, 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[4] and Directive 2008/50/EC of the European Parliament and of the Council[5], 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[6] and by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[7]. 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

1. An authorisation is granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following use of trichloroethylene (TCE) (EC No: 201-167-4; CAS No: 79-01-6) provided that the risk management measures and operational

[4] 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).

[5] 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).

[6] 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).

[7] 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).

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/16/7/0	Industrial use of TCE as a process solvent for the manufacturing of modules containing hollow fibre gas separation membranes

2. The authorisation referred to in paragraph 1 shall be subject to the condition that any changes to the manufacturing process referred to in paragraph 1, resulting from an increase in the annual quantity of TCE used, include risk management measures to ensure that the exposure to workers and humans via the environment is limited to at least the levels described in the chemical safety report referred to in paragraph 1.

Article 2

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 2028.

Article 3

The following monitoring arrangements shall apply:

(a) any changes to the manufacturing process referred to in Article 1(2) caused by an expansion of the production requiring a change in the risk management measures referred to in that Article shall be reported without delay to the European Chemicals Agency by means of an updated chemical safety report;

(b) 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 Parker Hannifin Manufacturing Netherlands (Filtration & Separation) BV, Oude Kerkstraat 4**,** 4870 AG Etten-Leur, Netherlands.

Done at Brussels,

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission