



Brussels, 29.11.2016
C(2016) 7607 final

COMMISSION IMPLEMENTING DECISION

of 29.11.2016

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

(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 therefore subject to the authorisation requirement referred to in Article 56(1) of that Regulation.
- (2) An application for authorisation was submitted by the company RAG Aktiengesellschaft and RAG Anthrazit Ibbenbüren GmbH ('the applicants') on 30 September 2014 in accordance with Article 62 of Regulation (EC) No 1907/2006 for the use of trichloroethylene-containing vulcanising and bonding agents for endless connections and repair of chloroprene rubber coated conveyor belts in underground hard coal mining.
- (3) On 8 June 2015 the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency adopted their opinions² on the application. The Commission received those opinions on 18 June 2015.
- (4) In its opinion, the RAC confirmed that it is not possible to determine a DNEL (Derived No Effect Level) for the carcinogenic (category 1A) properties of TCE in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and therefore 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/10162/4a563f6f-098f-4c72-be19-140a81580172>

- (5) In its opinion the RAC also confirmed 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 be potentially exposed via the environment.
- (6) In its opinion the SEAC confirmed the applicants' conclusion that the overall socio-economic benefits arising from the use of TCE 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 for the applicants.
- (7) 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 applied for, provided that the risk management measures and operational conditions described in the application and in particular in the chemical safety report 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 four years. The recommended review period takes into account that the holders of the authorisation are bound by German legislation containing a phase-out plan for the mines where TCE is used by the holders of the authorisation. That phase-out plan contains an obligation of the holders of the authorisation to continue production in those mines until their closure in 2015 and 2018, followed by a two year-decommissioning period. The SEAC also took into account the fact that the costs of the remaining risk are very low and the socio-economic benefits are in comparison high.
- (9) It is therefore appropriate to set the review period for the use of TCE at four years as from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006, so that the holders of the authorisation are able to fulfil their legally binding obligations until 2020.
- (10) In its opinion, the RAC recommended the authorisation to be subject to monitoring arrangements, by way of a periodical assessment of individual worker exposure using passive samplers in order to better assess the exposure during the hot vulcanization and cold bonding. It is therefore appropriate to require such monitoring arrangements.
- (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) 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), subject to the full application of the risk management measures and operational conditions

described in the chemical safety report³ submitted pursuant to Article 62(4)(d) of that Regulation.

The authorised use is identified by the following authorisation numbers:

REACH/16/5/0	RAG Aktiengesellschaft	Use of trichloroethylene-containing vulcanising and bonding agents for endless connections and repair of chloroprene rubber coated conveyor belts in underground hard coal mining
REACH/16/5/1	RAG Anthrazit Ibbenbüren GmbH	

Article 2

The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 April, 2020.

Article 3

The following monitoring arrangements referred to in Article 60(9)(f) of Regulation (EC) No 1907/2006 shall apply:

- (a) The holders of the authorisation shall periodically assess and document the individual worker exposure using passive samplers in order to better assess the exposure during the hot vulcanization and cold bonding. On request of the competent authority of the Member State where the authorised use takes place, the holders of the authorisation shall submit to that authority all results of the periodical exposure assessments.
- (b) On request of the competent authority of the Member State where the authorised use takes place, the holders 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.

³

<http://ec.europa.eu/DocsRoom/documents/10925/attachments/1/translations/en/renditions/native>

Article 4

This Decision is addressed to:

RAG Aktiengesellschaft, Shamrockring 1, 44623 Herne, Germany

RAG Anthrazit Ibbenbüren GmbH, Osnabrücker Straße 112, 49477 Ibbenbüren, Germany

Done at Brussels, 29.11.2016

For the Commission

Elżbieta BIEŃKOWSKA

Member of the Commission

