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COMMISSION IMPLEMENTING DECISION

of 10.8.2018

granting an authorisation for certain uses of trichloroethylene under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Blue Cube Germany Assets GmbH & Co. KG)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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 therefore subject to the authorisation requirement referred to in Article 56(1)(a) of that Regulation.

(2) On 18 August 2014, Dow Deutschland Anlagengesellschaft mbH ('the applicant') submitted an application for authorisation in accordance with Article 62 of Regulation (EC) No 1907/2006 for five uses of TCE, namely its use in industrial parts cleaning by vapour degreasing in closed systems where specific requirements (system of use-parameters) exist ('use 1'), industrial use of TCE as process chemical (enclosed systems) in Alcantara Material production ('use 2'), use of TCE in packaging ('use 3'), its use in formulation ('use 4') and use of TCE as extraction solvent for bitumen in asphalt analysis ('use 5').

(3) On 18 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 Agency (ECHA)[2] on the application, together with the applicant's comment regarding use 1, pursuant to the second and third subparagraphs of Article 64(5) of Regulation (EC) No 1907/2006. On 20 December 2016, the Commission received an Addendum to the opinion for use 1.

(4) In its opinion, 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

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

[2] http://echa.europa.eu/documents/10162/18a240f5-d83d-40ff-bde9-d4ae1f5e9904
http://echa.europa.eu/documents/10162/61ef19a7-bb3e-40dc-8b48-64826d294039
http://echa.europa.eu/documents/10162/99062bfd-e7b8-4991-acc0-f463ff5c310c
http://echa.europa.eu/documents/10162/2bad29cd-d933-4aca-aff2-6d6ed266ea45
http://echa.europa.eu/documents/10162/1201a108-4cc7-44b6-abd3-19575b27ff90

of Annex I to Regulation (EC) No 1907/2006 and that 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.

(5) In its opinion on use 1, RAC concluded that the risk management measures and operational conditions as described in the application are not appropriate and effective in limiting the risk to workers. RAC considered that the information provided by the applicant to describe the exposures in general appears to be sufficient for the assessment of the use applied for. However, with respect to workers exposure RAC identified uncertainties on the representativeness of the measured data - data were measured in eleven companies in two Member States, while a higher number of companies would benefit from the authorisation. Additionally, RAC noted and further clarified in the addendum to its opinion that the risk management measures and operational conditions are not appropriate in limiting the risk for workers. RAC considered that its concerns could be addressed by the development of more specific exposure scenarios validated with representative exposure monitoring data. For those reasons, RAC recommended additional conditions for the authorisation.

(6) In its opinion on uses 3 and 5, RAC concluded that the risk management measures and operational conditions as described in the application are appropriate and effective in limiting the risk to indirectly exposed workers and to the general population that could potentially be exposed via the environment. However, concerning use 3, due to the fact that sealed systems are not used as a standard process for filling of containers in all workplaces, RAC recommended additional conditions.

(7) In its opinion on uses 2, and 4, RAC concluded that the risk management measures and operational conditions as described in the application are appropriate and effective in limiting the risk to both workers and to the general population that could potentially be exposed via the environment. However, concerning use 4, it noted that for some tasks further reduction of exposure and risks seemed possible by the use of closed systems.

(8) In its opinions, SEAC concluded that the overall socio-economic benefits arising from each of the five uses of TCE applied for outweigh the risk to human health or the environment arising from those uses. With regard to uses 1, 2 and 5, SEAC confirmed the applicant's conclusion that there are no suitable alternative substances or technologies in terms of their technical and economic feasibility and their risk reduction capacity. With regard to uses 3 and 4, considering that TCE has no independent function in these uses (packaging and formulation) and, consequently, an assessment of the feasibility of alternatives is not relevant for those uses, SEAC confirmed that there are no suitable alternative substances or technologies. In order to facilitate substitution of TCE with alternatives in use 1, SEAC, in its opinion, recommended additional conditions linked to the analysis of alternatives and addressed to the authorisation holder's downstream users. The Commission, having evaluated the SEAC assessment, concurs with those conclusions.

(9) Therefore, in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the five uses 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], as well as the conditions set out in this Decision, are fully applied.

(10) In its opinions, SEAC recommended the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 to be set at seven years for uses 1, 2 and 5 and at twelve years for uses 3 and 4. The recommended review period takes into account the relevant elements from the RAC and the SEAC's assessments, and in particular, concerning use 1, the uncertainties concerning the timing and the possibilities of substitution in the different sectors covered by this use, as well as the need to ensure certainty of supply and to promote substitution across the different sectors. Concerning use 2, the recommended review period takes into account the fact that the risk management measures and operational conditions are appropriate and effective in limiting the risk, the fact that the socio-economic benefits of continued use of the substance clearly outweigh the monetised risk to human health, as well as the applicant's efforts to develop an alternative and its substitution activities plan to implement one within seven years from the sunset date. Concerning uses 3 and 4, the recommended review period takes into account the negligible costs associated with the health impacts of the continued use of the substance, that the socio-economic benefits of continued use of the substance clearly outweigh the monetised risk to human health and the fact that TCE has no independent function in the two uses (packaging and formulation). Concerning use 5, the recommended review period takes into account the negligible costs associated with the health impacts of the continued use of the substance, the applicant's activities to identify and implement a safer alternative within a period of seven years from the sunset date, as well as the RAC's concerns related to the estimated risk level for directly exposed workers. The Commission concurs with the SEAC recommendations. However, regarding use 1, and taking into account the concerns of Member States with regard to the time needed to substitute, the Commission considers a shorter review period to be more appropriate.

(11) Therefore, as regards the uses of TCE applied for, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 for use 1 is set at 54 months from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006, for uses 2 and 5 at seven years as from the sunset date and for uses 3 and 4 at twelve years as from the sunset date.

(12) On 3 March 2016 a legal entity change was notified to ECHA pursuant to which the application was transferred from the original applicant Dow Deutschland Anlagengesellschaft mbH to Blue Cube Germany Assets GmbH & Co. KG. In its assessment ECHA concluded that the notified change has no implications on the opinions of RAC and SEAC. The Commission acknowledges that conclusion.

(13) 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(s) of the Member State(s) where the use(s) take(s) place. Therefore, in order to facilitate the enforcement of the authorisation, it is appropriate to include a monitoring arrangement requiring the authorisation holder to submit, upon request, a succinct summary of those risk management measures and operational conditions in an official language of the Member State(s) concerned.

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[3] http://ec.europa.eu/DocsRoom/documents/21681
http://ec.europa.eu/DocsRoom/documents/21682
http://ec.europa.eu/DocsRoom/documents/21683
http://ec.europa.eu/DocsRoom/documents/21684
http://ec.europa.eu/DocsRoom/documents/21685

(14) This Decision does not affect the obligation of the authorisation holder to ensure that the use does not adversely affect human health or the environment pursuant to Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, it does not affect either the obligation of the authorisation holder 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. Furthermore, this Decision is without prejudice to the application of the Union Directives in the area of health and safety at work, in particular Council Directive 89/391/EEC[5], Council Directive 98/24[6], Directive 2004/37, Council Directive 92/85/EEC[7] and Council Directive 94/33/EC[8].

(15) 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[9] and Directive 2008/50/EC of the European Parliament and of the Council[10], 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[11] and by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[12]. 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.

(16) 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 Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.06.1989, p. 1).

6 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 05.05.1998, p. 11).

7 Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/ 391 / EEC) (OJ L 348, 28.11.1992, p. 1).

8 Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work (OJ L 216, 20.08.1994, p. 12).

9 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).

10 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).

11 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).

12 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 uses of trichloroethylene (EC No. 201-167-4, CAS No. 79-01-6), provided that the risk management measures and operational conditions as described in the chemical safety report submitted pursuant to Article 62(4)(d) of that Regulation and as reviewed in accordance with the conditions set out in Articles 2 and 3 of this Decision, are fully applied:

Authorisation number	Authorised use
REACH/18/9/0	Use of trichloroethylene in industrial parts cleaning by vapour degreasing in closed systems where specific requirements (system of use-parameters) exist
REACH/18/9/1	Industrial use as process chemical (enclosed systems) in Alcantara Material production
REACH/18/9/2	Use of trichloroethylene in packaging
REACH/18/9/3	Use of trichloroethylene in formulation
REACH/18/9/4	Use of trichloroethylene as extraction solvent for bitumen in asphalt analysis

Article 2

The authorisation referred to in Article 1 for use with authorisation number REACH/18/9/0 shall be subject to the following conditions:

(a) the use shall be performed under vacuum and, where this is not possible, an alternative method to vacuum, such as local exhaust ventilation, shall be implemented and documented;

(b) ECSA Type III machines shall be replaced with Type IV or preferably Type V machines at the latest by the end of their service life and in any event by 3 February 2020, unless it is possible to substitute trichloroethylene with an alternative;

(c) the authorisation holder and/or 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 exposure measurements of trichloroethylene. Those measurements shall:

  (i) take place at least annually. The first measurements shall be performed without delay and at the latest by 3 February 2019;

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

  (iii) comprise both personal and static inhalation exposure sampling and biomonitoring (consisting of measurement of the trichloroethylene metabolite trichloroacetic acid in urine) and be representative of the range of tasks undertaken and of the total number of workers that are potentially exposed (including process, maintenance and other types of workers involved);

  (iv) information shall be recorded about the relevant exposure determinants in the work places when measurements are taken, such as the ECSA Type of

degreaser used, size of the machine, number of machines per room, relevant process parameters and cleaned part types;

(d) the authorisation holder and his downstream users shall use the information gathered via the measurements referred to in point (c) including the contextual information to regularly review the effectiveness of the risk management measures and operational conditions and to introduce measures to reduce worker's exposure to trichloroethylene;

(e) the results of the measurements referred to in point (c), as well as the outcome and conclusions of the review and any actions taken in accordance with point (d), shall be documented and, upon request, be submitted to the competent authority of the Member State where the authorised use takes place, in an official language of that Member State.

(f) the authorisation holder's downstream users shall make available the information from the measurements referred to in point (c) and the conclusions and outcomes of the review referred to in point (d) 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;

(g) the information collected in accordance with point (f) shall be included in the case of a review report referred to in Article 61(1) of Regulation (EC) No 1907/2006;

(h) as from the adoption of this Decision, the authorisation holder's downstream users shall provide to the European Chemicals Agency, for transmission to the authorisation holder, a written declaration that they have assessed that no suitable alternatives exist for their use on the basis of the Suitability Selection Grid[13] provided in the analysis of alternatives submitted as part of the application. This assessment shall be documented. Additionally, in the written declaration, the authorisation holder's downstream users shall confirm that they have put in place the risk management measures as indicated in the exposure scenarios for this use. The Agency shall grant access to this information to the competent authorities of the Member State(s) where the use(s) take(s) place;

(i) within 30 months after the sunset date, the authorisation holder shall ensure that his downstream users receive training on alternative cleaning solutions and on methodologies to assess the suitability of alternatives for their use on the basis of the Suitability Selection Grid provided in the analysis of alternatives submitted as part of the application;

(j) the written declaration and the assessment of the suitability of alternatives for their use on the basis of the Suitability Selection Grid provided in the analysis of alternatives submitted as part of the application referred to in point (h) shall be renewed three years as from the adoption of this Decision, to take into account technological developments;

(k) in the written declaration referred to in point (h), the authorisation holder's downstream users shall confirm the use of trichloroethylene exclusively in ECSA type IV or V machines at the latest by the end of the service life of the ECSA Type III machines and in any event by 3 February 2020.

[13] https://echa.europa.eu/documents/10162/063fb0a1-52b6-45fc-9572-56d91e43c98a, Annex II

Article 3

The authorisation referred to in Article 1 for use with authorisation number REACH/18/9/2 shall be subject to the following conditions:

(a) the authorisation holder and/or the authorisation holder's downstream users shall conduct regular occupational exposure measurements of trichloroethylene. Those measurements shall:

  (i) take place at least annually;

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

  (iii) comprise both personal and static inhalation exposure sampling and biomonitoring (consisting of measurement of the trichloroethylene metabolite trichloroacetic acid in urine) and be representative of the range of tasks undertaken and of the total number of workers that are potentially exposed (including process, maintenance and other types of workers involved);

(b) the authorisation holder and his downstream users shall use the information gathered via the measurements referred to in point (a) including the contextual information to regularly review the effectiveness of the risk management measures and operational conditions and to introduce measures to reduce worker's exposure to trichloroethylene, especially in tasks related to filling of containers in semi-closed systems;

(c) the results of the measurements referred to in point (a), as well as the outcome and conclusions of the review and any actions taken in accordance with point (b), shall be documented and, upon request, be submitted to the competent authority of the Member State where the authorised use takes place, in an official language of that Member State;

(d) the authorisation holder’s downstream users shall make available the information from the measurements referred to in point (a) 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 4

1. The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 October 2020 for use REACH/18/9/0, on 21 April 2023 for uses with authorisation numbers, REACH/18/9/1 and REACH/18/9/4 and on 21 April 2028 for uses with authorisation numbers REACH/18/9/2 and REACH/18/9/3.

2. Unless a decision to withdraw the authorisation is adopted earlier in application of Article 61(2) and (3) of Regulation (EC) No 1907/2006, the present authorisation shall cease to be valid:

  (a) on 21 October 2020 for use REACH/18/9/0 should the holder of the authorisation referred to in Article 1 not submit the review report foreseen in Article 61(1) of Regulation (EC) No 1907/2006 by 21 April 2019;

(b) 21 April 2023 for uses with authorisation numbers REACH/18/9/1 and REACH/18/9/4 should the holder of the authorisation referred to in Article 1 not submit the review report foreseen in Article 61(1) of Regulation (EC) No 1907/2006 by 21 October 2021;

(c) on 21 April 2028 for uses with authorisation numbers REACH/18/9/2 and REACH/18/9/3 should the holder of the authorisation referred to in Article 1 not submit the review report foreseen in Article 61(1) of Regulation (EC) No 1907/2006 by 21 October 2026.

Article 5

The following monitoring arrangements shall apply to the authorisations referred to in Article 1 with authorisation numbers REACH/18/9/1 and REACH/18/9/4:

(a) the authorisation holder and/or his downstream users shall conduct regular occupational exposure measurements of trichloroethylene. Those measurements shall:

(i) take place at least annually;

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

(iii) comprise both personal and static inhalation exposure sampling and biomonitoring (consisting of measurement of the trichloroethylene metabolite trichloroacetic acid in urine) and be representative of the range of tasks undertaken and of the total number of workers that are potentially exposed (including process, maintenance and other types of workers involved);

(b) the authorisation holder and his downstream users shall use the information gathered via the measurements referred to in point (a) including the contextual information to regularly review the effectiveness of the risk management measures and operational conditions and to introduce measures to reduce worker's exposure to trichloroethylene;

(c) the results of the measurements referred to in point (a), as well as the outcome and conclusions of the review and any actions taken in accordance with point (b), shall be documented and, upon request, be submitted to the competent authority of the Member State where the authorised use takes place;

(d) the authorisation holder’s downstream users shall make available the information from the measurements referred to in point (a) and the conclusions and outcomes of the review pursuant to point (b) 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 6

The following monitoring arrangement shall apply to the authorisation referred to in Article 1 with authorisation number REACH/18/9/3:

– closed systems shall be used in all tasks and where this is not possible, the reasons for not doing so shall be documented.

Article 7

The authorisation holder shall submit, upon request, to the competent authority of the Member State where the authorised use takes place 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 8

This Decision is addressed to Blue Cube Germany Assets GmbH&Co. KG, Buetzflether Sand 2, 21683 Stade, Germany.

Done at Brussels, 10.8.2018

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION