EUROPEAN
COMMISSION

Brussels, 3.10.2022
C(2022) 6874 final

COMMISSION IMPLEMENTING DECISION

of 3.10.2022

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to SAFECHEM Europe GmbH for a use of trichloroethylene (TCE) in the context of a review and amending Implementing Decision C(2018) 5057

(Only the English text is authentic)

COMMISSION IMPLEMENTING DECISION

of 3.10.2022

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to SAFECHEM Europe GmbH for a use of trichloroethylene (TCE) in the context of a review and amending Implementing Decision C(2018) 5057

(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 uses of that substance are subject to the authorisation requirement in Article 56(1), point (a), of that Regulation.

(2) On 10 August 2018, by Commission Implementing Decision C(2018) 5057[2] an authorisation was granted to Blue Cube Germany Assets GmbH & Co. KG for certain uses of TCE, including industrial use as process chemical (enclosed systems) in Alcantara Material production, with authorisation number REACH/18/9/1. The review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 for that authorised use of TCE will expire on 21 April 2023.

(3) On 22 August 2019, Blue Cube Germany Assets GmbH & Co. KG submitted a review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 for authorisation for the industrial use of TCE as process chemical (enclosed systems) in Alcantara Material production. The use takes place only at the sites of Blue Cube Germany Assets GmbH & Co. KG's downstream users' sites.

(4) On 16 February 2021, the Commission received the opinions of RAC and SEAC[3] on the review report sent to it pursuant Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006.

---

1 OJ L 396, 30.12.2006, p. 1.

2 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) (C(2018) 5057).

3 https://echa.europa.eu/documents/10162/5662036b-9b37-9ca5-7592-073282ff928d

(5) On 17 December 2021, the European Chemicals Agency ('the Agency') received a notification that the review report had been transferred from the original authorisation holder Blue Cube Germany Assets GmbH & Co. KG to SAFECHEM Europe GmbH. The Agency concluded that the notified change had no implications for the opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the Agency. The Commission agrees with that conclusion.

(6) RAC confirmed in its opinion that it is not possible to determine a derived no-effect level for the carcinogenic properties of TCE in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore TCE is a substance for which it is not possible to determine a threshold for the purposes of Article 60(3), point (a), of that Regulation. As a result, Article 60(2) of Regulation (EC) No 1907/2006 does not apply to that substance and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.

(7) In its opinion, RAC concluded that the risk management measures and operational conditions described in the chemical safety report are appropriate and effective to limit the risk to human health and the environment posed by the use of TCE for which the authorisation was sought. However, in order to further optimise those risk management measures and operational conditions, as well as to address the remaining shortcomings in the chemical safety assessment, RAC recommended imposing monitoring arrangements. Having evaluated the RAC assessment, the Commission agrees with its conclusion and recommendation.

(8) In its opinion, SEAC concluded that it has no substantial reservations on the quantitative and qualitative elements of SAFECHEM Europe GmbH 's assessment of the socio-economic benefits and the monetised risks to human health associated with the continued use of TCE. Taking into account SEAC's assessment of the socio-economic analysis, RAC's conclusion that the risk management measures and operational conditions are appropriate and effective to limit the risk, the monetised excess risk of cancer associated with the continued use estimated to be in the order of hundreds of euros yearly, the monetised socio-economic benefits of continued use due to avoided loss of profits and jobs estimated to be at minimum in the order of tens of millions of euros yearly, the Commission concludes that the applicant has demonstrated that the socio-economic benefits of the continued use of TCE outweigh the risk to human health and the environment arising from that use.

(9) A suitable alternative should be safer, available, and technically and economically feasible. Where suitable alternatives are available in the Union, but not technically or economically feasible for the applicant or its downstream users, an authorisation may be granted if the applicant for authorisation submits a substitution plan. An alternative that provides the functionality and level of technical performance necessary for the use applied for should be considered to be technically feasible.

(10) In its opinion, SEAC concluded that there were no suitable alternative substances or technologies available for the authorisation holder at the time of adoption of the opinion. SEAC acknowledged that a TCE-free alternative process is available and is being implemented in several of the downstream user's sectors, which are finalising substitution in the coming years, for example in fashion and interior sectors. Conversely, SEAC noted that substitution towards this alternative process is facing technical challenges in other sectors, in particular, the automotive sector, where qualification tests are still needed for some car manufacturers. As regards the automotive sector, SEAC acknowledged that the acceptance of the alternative varies

between car manufacturers. While the identified alternative technology is being used in mass production by some car manufacturers, it does not yet provide the high technical performance required by some other car manufacturers, which are clients of SAFECHEM Europe GmbH 's downstream users. Thus, the Commission considers that the identified alternative technology cannot be considered technically feasible for SAFECHEM Europe GmbH and its downstream user. Therefore, the Commission agrees with SEAC's conclusion that there are no suitable alternatives for SAFECHEM Europe GmbH and its downstream users, but concludes that suitable alternatives are available in the Union.

(11) In its opinion, SEAC concluded that the substitution plan submitted by SAFECHEM Europe GmbH is credible and consistent with the analysis of alternatives and the socio-economic analysis, although some reservations still remain on the possibility to fully transition to the alternative within the review period requested. The Commission, having evaluated SEAC's assessment, concurs with that conclusion. The Commission therefore considers that SAFECHEM Europe GmbH has discharged its burden of proof in demonstrating the absence of suitable alternatives.

(12) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the use of TCE described in the review report, provided that the risk management measures and operational conditions described in the chemical safety report are fully applied.

(13) The Commission has based its assessment on all relevant scientific evidence currently available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, based its conclusions on a sufficient amount of material and reliable information allowing it to conclude. Nevertheless, additional scientific evidence would allow the Commission to perform its assessment on a more robust or broad evidentiary base in the future. Hence, it is appropriate to require additional information on exposure be generated.

(14) SEAC recommended in its opinion that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set at 7 years as of the end of the review period set out in Implementing Decision C(2018) 5057, namely until 31 December 2030. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, the conclusion that the risk management measures and operational conditions described in the chemical safety report are appropriate and effective to limit the risk, the likelihood that a shorter review period would put at risk the on-going substitution with the identified alternative, especially in the automotive sector, as well as the conclusion that the monetised socio-economic benefits of continued use outweigh the monetised risk to human health and to the environment by several orders of magnitude.

(15) The language used to describe the risk management measures and operational conditions in the original application for authorisation may be different from the official language of the Member State where the use takes place. Therefore, in order to facilitate supervision and enforcement of compliance with the authorisation, it is appropriate to require the authorisation holder to submit, upon request, a brief summary of those risk management measures and operational conditions to the competent authority of that Member State in an official language of that Member State.

(16) This Decision does not affect the obligation of the authorisation holder to ensure that a use of a substance does not adversely affect human health or the environment, having regard to the principle set out in Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, this Decision does not affect the obligation of the authorisation holder under Article 60(10) of that Regulation or of its downstream users under Article 56(2) of the same Regulation to ensure that the exposure is reduced to as low a level as is technically and practically possible or the obligation of the employer under Articles 4(1) and 5 of Directive 2004/37/EC of the European Parliament and of the Council[4] 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, and to prevent workers' exposure to a risk to their health or safety. This Decision does not affect the application of Union law in the area of health and safety at work, in particular Council Directives 89/391/EEC[5], 92/85/EEC[6], 94/33/EC[7], 98/24/EC[8] and Directive 2004/37/EC, nor does it affect any national binding occupational limit values which may be stricter than the applicable Union limit values.

(17) This Decision does not affect any obligation to comply emission limit values or other requirements set in accordance with Directive 2008/50/EC of the European Parliament and of the Council[9] or Directive 2010/75/EU of the European Parliament and of the Council[10], nor any obligation to comply with emission limit values set to achieve compliance with the environmental quality standards established by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[11] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[12]. Compliance with the provisions of this Decision does not necessarily imply compliance with emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.

---

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, 29.6.1989, p. 1).

6 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).

7 Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work (OJ L 216, 20.8.1994, p. 12).

8 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, 5.5.1998, p. 11).

9 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).

10 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).

11 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).

12 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).

(18) Implementing Decision C(2018) 5057 should therefore be amended as provided for in Article 61(1) of Regulation (EC) No 1907/2006 regarding the authorisation bearing number REACH/18/9/1.

(19) The measures provided for in this Decision are in accordance with the opinion of the committee established by Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS DECISION:

Article 1

An authorisation is hereby 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):

Authorisation number	Authorised use
REACH/22/31/0/R1	Industrial use as process chemical (enclosed systems) in Alcantara Material production

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[13].

Article 2

The review period shall expire on 31 December 2030.

The authorisation shall cease to be valid on 31 December 2030 if the review report has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 30 June 2029.

Article 3

1. The monitoring arrangements set out in paragraphs 2 to 6 shall apply.

2. The authorisation holder's downstream users ('downstream users') shall carry out a monitoring programme of occupational exposure to TCE. The monitoring programme shall:

   (a) take place at least annually;

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

   (c) ensure a sufficiently low limit of quantification;

   (d) comprise personal inhalation exposure and biomonitoring, as well as static inhalation exposure sampling;

   (e) 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.

   (f) be recorded so as to include contextual information about the tasks performed during sampling.

[13] https://ec.europa.eu/docsroom/documents/45344

3. The downstream users shall use the information gathered in the measurements referred to in paragraph 2 and related contextual information to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions and, if needed, to introduce measures to further reduce the exposure and emissions to as low as technically and practically possible and in accordance with hierarchy of control principles.

4. The downstream users shall document and maintain the results of the measurements referred to in paragraph 2 and the related contextual information as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 3, and shall make that information, including pseudonymised or aggregated biomonitoring results, available, upon request, to the competent authority of the Member State where the authorised use takes place.

5. The downstream users shall make available the information gathered pursuant to paragraphs 2 and 3 to the European Chemicals Agency, at the latest by 3 October 2023 and afterwards annually, for transmission to the authorisation holder for the preparation of the review report.

6. The authorisation holder shall document the steps taken to substitute TCE in accordance with the substitution plan, including information concerning any deviations from the initial substitution plan and any contingency measures taken and shall make this documentation available, upon request, to the competent authority of the Member State where the authorised use takes place.

7. Where the authorisation holder submits a review report, it shall include the information referred to in paragraphs 4 and 6.

Article 4

Upon request, the authorisation holder shall submit a brief summary of the applicable risk management measures and operational conditions described in the chemical safety report to the competent authority of the Member State where the authorised use takes place, in an official language of that Member State.

Article 5

Implementing Decision C(2018) 5057 is amended as follows:

(1) In Article 1, the following reference is deleted:

‘REACH/18/9/1	Industrial use as process chemical (enclosed systems) in Alcantara Material production’;

(2) Article 4 is amended as follows:

(a) paragraph 1 is replaced by the following:

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

(b) paragraph 2, point (b) is replaced by the following:

‘(b) 21 April 2023 for use with authorisation number 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;’.

(3) In Article 5, the introductory wording is replaced by the following:

‘The following monitoring arrangements shall apply to the authorisation referred to in Article 1 for the use with authorisation number REACH/18/9/4:’.

Article 6

This Decision is addressed to SAFECHEM Europe GmbH, Tersteegenstr. 25, 40474 Düsseldorf, Germany.

Done at Brussels, 3.10.2022

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION