EUROPEAN
COMMISSION

Brussels, 14.12.2023
C(2023) 8397 final

COMMISSION IMPLEMENTING DECISION

of 14.12.2023

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to DOMO Caproleuna GmbH for a use of trichloroethylene (TCE) in the context of a review and repealing Implementing Decision C(2017) 69

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

(2) On 17 January 2017, by Commission Implementing Decision C(2017)69[2], an authorisation was granted to DOMO Caproleuna GmbH for certain uses of TCE, including the industrial use of TCE as an extraction solvent for the purification of caprolactam from caprolactam oil, with authorisation number REACH/16/8/0. The review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 for that authorised use expired on 21 April 2023.

(3) On 17 August 2021, DOMO Caproleuna GmbH submitted a review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 for authorisation of the industrial use of TCE as an extraction solvent for the purification of caprolactam from caprolactam oil.

(4) The European Chemicals Agency sent the opinions on the review report adopted by the Committee for Risk Assessment (RAC) and by the Committee for Socio-economic Analysis (SEAC)[3] of the Agency to the Commission pursuant to Article 64(5), second

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

[2] Commission Implementing Decision C(2017)69 final of 17 January 2017 granting an authorisation for a use of trichloroethylene under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Domo Caproleuna GmbH).

[3] https://echa.europa.eu/documents/10162/966f0b7b-4261-de7a-5d16-5c6d9e343f3e

subparagraph, of Regulation (EC) No 1907/2006. On 7 December 2022, the Commission received the opinions.

(5) In its opinion, RAC confirmed 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 therefore that 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 that Regulation does not apply to that substance, and therefore an authorisation may only be granted under paragraph 4 of that Article.

(6) In its opinion, RAC concluded that the risk management measures and operational conditions as described in the review report are appropriate and effective in limiting the risks to workers and the general population that could potentially be exposed via the environment. Nevertheless, to achieve further improvement of the risk management measures and operational conditions in place, so as to reduce exposure to workers and general population via the environment to as low a level as technically and practically possible, in particular addressing fugitive emissions, RAC recommended certain conditions for authorisation. Moreover, RAC noted minor uncertainties regarding the effectiveness of the recently implemented risk management measures and therefore recommended monitoring arrangements, also with a view to optimising risk management measures and operational conditions. Having evaluated the RAC assessment, the Commission agrees with its conclusion and recommendations.

(7) In its opinion, SEAC concluded that the societal costs of not granting an authorisation are higher than the monetised risks to human health and the environment arising from the use of TCE. The Commission, having evaluated SEAC's assessment, agrees with that conclusion and considers that DOMO Caproleuna GmbH has demonstrated that the socio-economic benefits of the continued use of TCE described in the application outweigh the risk to human health or the environment arising from that use.

(8) 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 applicants 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 for which authorisation is sought should be considered to be technically feasible. Unless justified by particular circumstances, the Commission should not consider an alternative to be economically feasible where its use leads to a negative economic impact of a magnitude that would jeopardise the economic viability of the operations related to the use for which an authorisation is sought.

(9) In its opinion, SEAC concluded that there were no technically or economically feasible alternative substances or technologies available for DOMO Caproleuna GmbH but there were technically and economically feasible alternative substances or technologies in the Union by the end of the review period set out in Decision C(2017)69. SEAC identified two substances, benzene and toluene, that are technically feasible and are used commercially in the caprolactam extraction process by other operators in the Union. The Commission, having evaluated SEAC's assessment and all relevant information available, notes that, due to the hazard properties of those substances, their use may not substantially reduce the risks to human health and the environment compared with TCE. Thus, the Commission concludes that those

substances may not be considered safer alternatives and that there are no suitable alternatives in the Union.

(10) DOMO Caproleuna GmbH assessed and shortlisted four alternative solvents, including toluene. As regards the suitability of alternatives for DOMO Caproleuna GmbH, SEAC considered that, for an efficient recovery of caprolactam from the caprolactam oil, the identified alternative solvents have major technical limitations and do not meet the DOMO Caproleuna GmbH's requirements, including immiscibility with water, solubility of caprolactam, purity, extractive capacity, no solvent mixtures, chemical inertness, and thermal stability. Moreover, one of the alternatives cannot be considered economically feasible due to its high investment and production costs. The Commission, having evaluated SEAC's assessment and all relevant information available, considers that the identified alternatives are not yet technically or economically feasible for the applicant. Therefore, the Commission agrees with SEAC's conclusion and considers that DOMO Caproleuna GmbH has discharged its burden of proof in demonstrating the absence of suitable alternatives both in the Union and for the applicant.

(11) 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, as well as the conditions set out in this Decision, are fully applied.

(12) 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 and emission be submitted.

(13) SEAC recommended in its opinion that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 should be set until the end of 2033. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, the improvement of risk management measures achieved by DOMO Caproleuna GmbH, the significant reduction of TCE volumes used, the socio-economic benefits and risk of the continued use of the substance, as well as the time needed for the identification and implementation of a new suitable alternative.

(14) 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(s) 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.

(15) 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 that 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 Article 4(1), and Article 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] 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.

(16) This Decision does not affect any obligation to comply with other regulatory provisions including emission limit values set in accordance with Directive 2008/50/EC[8] or Directive 2010/75/EU[9] of the European Parliament and of the Council, 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[10] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[11]. 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.

(17) Implementing Decision C(2017)69 should therefore be amended as provided for in Article 61(1) of Regulation (EC) No 1907/2006. For reasons of clarity and legal certainty, Implementing Decision C(2017)69 should be repealed and replaced by this Decision.

(18) 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,

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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, 29.6.1989, 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 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).

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 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).

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).

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/23/36/0/R1	As an extraction solvent for the purification of caprolactam from caprolactam oil

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[12], as well as to the conditions set out in Article 2.

Article 2

1. The authorisation shall be subject to the conditions set out in paragraphs 2 to 4.
2. The authorisation holder shall implement the extension and sealing of the vent system with integration of vessel B636 a/b.
3. The authorisation holder shall finalise by 14 December 2024, and afterwards when new information becomes available, a detailed study to assess the feasibility to further limit fugitive emissions and shall act without delay in accordance with the outcome of that study.
4. The authorisation holder shall document and keep the information obtained in accordance with paragraphs 2 and 3 and make it available, upon request, to the competent authority of the Member State where the use takes place.

Article 3

1. The review period shall expire on 31 December 2033.
2. The authorisation shall cease to be valid on 31 December 2033 if the authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006, by 30 June 2032.

Article 4

1. The monitoring arrangements set out in paragraphs 2 to 7 shall apply.
2. The authorisation holder shall carry out a monitoring programme measuring occupational exposure to TCE. Those measurements shall:
   (a) take place at least annually or more frequently if a significant increase in exposure to TCE takes place. The frequency of the measurements shall be sufficient to capture any potential increase in exposure of workers to TCE;
   (b) be based on relevant standard methodologies or protocols;

[12] https://ec.europa.eu/docsroom/documents/52535

(c) ensure a sufficiently low limit of quantification;

(d) comprise personal and static inhalation exposure sampling;

(e) be representative of the range of tasks undertaken, the operational conditions and risk management measures for each of these tasks 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.

3. The authorisation holder shall continue to conduct the annual biomonitoring programme for workers with potential exposure to TCE.

4. The authorisation holder shall carry out a monitoring programme measuring the releases of TCE to air and wastewater. The measurements shall:

(a) take place at least annually or more frequently following any possible changes in the process;

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

(c) ensure a sufficiently low limit of quantification;

(d) be representative of the operational conditions and risk management measures used at the site where the authorised use takes place;

(e) as regards wastewater, be carried out before discharge to the on-site wastewater treatment plant;

(f) be recorded with contextual information associated with each set of measurements.

5. The authorisation holder shall use the information gathered in accordance with paragraphs 2 to 4 and related contextual information to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions. If needed, the authorisation holder shall introduce measures to further reduce the exposure and emissions to as low a level as technically and practically possible, and in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

6. The authorisation holder shall review and, if needed, update the assessment of the combined exposure for the different groups of workers.

7. The authorisation holder shall document and maintain the results of the measurements obtained in accordance with paragraphs 2 to 4, the related contextual information as well as the outcome and conclusions of the review and any action taken in accordance with paragraphs 5 and 6, 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.

Article 5

Where the authorisation holder submits a review report, it shall include the information referred to in Articles 2(4), and 4(7).

Article 6

Implementing Decision C(2017)69 is repealed.

Article 7

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 8

This Decision is addressed to DOMO Caproleuna GmbH, Am Haupttor Bau 3101, 06237 Leuna, Germany.

Done at Brussels, 14.12.2023

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION