EUROPEAN
COMMISSION

Brussels, 4.3.2021
C(2021) 1385 final

# COMMISSION IMPLEMENTING DECISION

**of 4.3.2021**

**granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to SPOLANA s.r.o. for a use of trichloroethylene in the context of a review**

(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)(a) of that Regulation.

(2) On 8 February 2017, by Commission Implementing Decision C(2017) 660[2] an authorisation was granted to Spolana a.s. for the use of TCE as an extraction solvent in caprolactam production. The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 for that authorised use of TCE expired on 21 April 2020.

(3) On 16 August 2018, Spolana a.s. submitted a review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 for authorisation for the use of TCE as an extraction solvent in caprolactam production.

(4) On 4 December 2018, the European Chemicals Agency (‘the Agency’) received a notification that Spolana a.s. had changed its corporate name to Spolana s.r.o. In its assessment, 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). The Commission accepts that conclusion.

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

[2] Commission Implementing Decision of 8.2.2017 granting an authorisation for a use of trichloroethylene under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Spolana a.s.) (C(2017) 660 final).

(5) On 11 June 2019, the Commission received the opinions on the review report adopted by RAC and SEAC[3] and sent to it pursuant to the second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.

(6) RAC confirmed in its opinion 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 that therefore TCE is a substance for which it is not possible to determine a threshold for the purposes of Article 60(3)(a) of that Regulation. As a result, paragraph 2 of Article 60 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) 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. RAC noted that fugitive emissions of TCE have been reduced due to the improvements in the risk management measures and operational conditions introduced by the authorisation holder but further reduction should be expected as a result of the implementation of risk management measures that were planned for 2019. However, in order to further optimise the risk management measures and operational conditions already in place, 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 the socio-economic benefits arising from the use of TCE as an extraction solvent in caprolactam production outweigh the risk to human health and the environment arising from that use. Having evaluated the SEAC assessment, the Commission agrees with that conclusion.

(9) An authorisation may be granted under Article 60(4) of Regulation (EC) No 1907/2006 if there are no suitable alternative substances or technologies. A suitable alternative should be safer, available, and technically and economically feasible.

(10) In order to be considered technically feasible, an alternative to the substance should be capable of providing the level of technical performance functionally necessary for the use for which the authorisation is sought. Some potential alternatives may provide this functionality but at some loss to performance or in a manner that involves technical compromises. The Commission considers that, given the economic and other incentives towards substitution that already arise from inclusion in the authorisation system, and in the light of the objective of progressive substitution, as a starting point, the Commission should not consider a potential alternative to be technically viable where such losses to performance or technical compromises are not minor.

(11) Furthermore, a potential alternative should not be considered economically feasible for the applicant or its downstream users where it would lead to an increase in net costs related to the use of the substance, including the initial investment, that is likely to lead to: (i) the shut-down of the operator's facilities; (ii) job losses or other adverse social implications that are disproportionate to the human health or environmental risk associated with the use of the substance; or (iii) a loss of market share or a loss of profits or other negative economic impact of a magnitude that would jeopardise the economic viability of the operations related to the use. In order to be considered economically viable, the changes in net costs caused by switching to an alternative

[3] https://echa.europa.eu/documents/10162/18584504/afa_fo_tce_0129-01_en.pdf/b6cc5ecb-3684-7723-fa1d-84449cde5c55

should still allow the operator to cover the production cost and make a reasonable profit margin[4].

(12) Nevertheless, the Commission considers that it must be possible to depart from the standard economic or technical feasibility criteria set out above where justified by particular circumstances, including the specific function of the substance for the use for which an authorisation is sought, the public interests at stake, or a low net difference between the socio-economic benefits and the risk to human health or the environment. The Commission considers that no particular factors justify less strict technical or economic feasibility requirements in this case.

(13) In its opinion, SEAC also concluded that there are no suitable alternative substances or technologies. In particular, SEAC concluded that the two potentially technically feasible alternatives, toluene and benzene, would not lead to reduced overall risks to human health and the environment, and that those alternatives are not economically feasible for the authorisation holder, since they require extensive modifications of the existing plant and significant investments. Having evaluated the SEAC assessment, the Commission agrees with that conclusion and considers that the authorisation holder has discharged its burden of proof in demonstrating the absence of suitable alternatives available for the use for which an authorisation is sought.

(14) Therefore, an authorisation for the use of TCE described in the review report should be granted under Article 60(4) of Regulation (EC) No 1907/2006 on condition that the authorisation holder complies with the risk management measures and operational conditions described in the chemical safety report submitted by the authorisation holder and further detailed by the authorisation holder at RAC's request.

(15) The Commission has based its assessment on all relevant scientific evidence currently available, as assessed by RAC, and based its conclusions on the existence of a sufficient weight of evidence allowing it to conclude. Nevertheless, additional scientific evidence would allow the Commission to perform its assessments on a more robust or broad evidentiary base in the future. Hence, it is appropriate to require the generation of additional exposure and emission information in the monitoring arrangements.

(16) SEAC recommended in its opinion that the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 should be set at 12 years. 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 no suitable alternative would become available within a shorter timeframe, the extensive and continued research and development activities by the authorisation holder to substitute TCE, the time necessary to implement a suitable alternative once one becomes available, as well as the conclusion that the monetised benefits of continued use outweigh the monetised risk to human health by several orders of magnitude.

(17) It is therefore appropriate to provide for a review period of 12 years from the expiry date of the previous review period.

(18) The language used to describe the risk management measures and operational conditions in the original application for authorisation may be different from the

[4] A reasonable profit margin is established based on evidence submitted in respect of the industry sector related to the use or, in the absence of such evidence, determined by the Commission.

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.

(19) 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[5] 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[6], 92/85/EEC[7], 94/33/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.

(20) 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 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

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5 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).

6 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).

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, 20.8.1994, p. 12).

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).

compliance with emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.

(21) The authorisation granted by Implementing Decision C(2017) 660 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) 660 should be repealed and replaced by this Decision.

(22) 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/21/2/0/R1 | Extraction solvent in caprolactam production |

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

*Article 2*

1. The review period shall expire on 21 April 2032.

2. The authorisation shall cease to be valid on 21 April 2032 if the review report has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 21 October 2030.

*Article 3*

1. The monitoring arrangements set out in paragraphs 2 to 7 shall apply.

2. The authorisation holder shall carry out at least annual measurements of occupational exposure to TCE. Those measurements shall comprise personal inhalation exposure and biomonitoring.

3. The authorisation holder shall carry out at least annual environmental monitoring to quantify the release factors and emissions of TCE to all environmental compartments.

4. The authorisation holder shall use the information gathered via the measurements referred to in paragraph 2 and 3 and related contextual information to further optimise the risk management measures and operational conditions in place in order to minimise releases and exposure, in particular with regard to fugitive emissions of

[13] https://ec.europa.eu/docsroom/documents/36021

TCE. This shall include the improvement of the TCE unloading station as described in the review report concerning the authorisation granted by Implementing Decision C(2017) 660, and the review of the working practices for the installation of new equipment.

5. The authorisation holder shall document the results of the measurements referred to in paragraphs 2 and 3 and the related contextual information as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 4, and shall make them available, upon request, to the competent authority of the Member State where the authorised use takes place.

6. The authorisation holder may reduce the frequency of measurements referred to paragraphs 2 and 3, once it can clearly demonstrate to the competent authority of the Member State where the use takes place that exposure to humans and releases to the environment have been reduced to as low level as technically and practically possible.

7. Where the authorisation holder submits a review report, it shall include the information in accordance with paragraph 4.

*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(2017) 660 is repealed.

*Article 6*

This Decision is addressed to SPOLANA s.r.o., ul. Práce 657, 277 11 Neratovice, Czechia.

Done at Brussels, 4.3.2021

*For the Commission*
*Thierry BRETON*
*Member of the Commission*

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION