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COMMISSION IMPLEMENTING DECISION

of 8.12.2023

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Roquette Frères for a use of trichloroethylene (TCE) in the context of a review and repealing Implementing Decision C(2017) 7581

(Only the English text is authentic)

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granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Roquette Frères for a use of trichloroethylene (TCE) in the context of a review and repealing Implementing Decision C(2017) 7581

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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 uses of that substance are subject to the authorisation requirement in Article 56(1), point (a), of that Regulation.
- (2) On 29 November 2016, by Commission Implementing Decision C(2016) 7581², an authorisation was granted to Roquette Frères for a use of TCE as a processing aid in the biotransformation of starch to obtain beta cyclodextrin (authorisation number REACH/16/4/0). The time-limited review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 for that authorised use expires on 21 April 2028.
- (3) On 7 August 2020, Roquette Frères submitted a review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 for authorisation of the use of TCE as a processing aid in the biotransformation of starch to obtain beta cyclodextrin.
- (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 subparagraph, of Regulation (EC) No 1907/2006. On 17 November 2021, 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

¹ OJ L 396, 30.12.2006, p. 1.

² Commission Implementing Decision C(2016) 7581 final of 29 November 2016 granting an authorisation for a use of trichloroethylene under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Roquette Frères).

³ <https://echa.europa.eu/documents/10162/3a00bcec-e909-fb7e-9a88-a1f1db8b394c>

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 members of the general population who could potentially be exposed via the environment. RAC noted that, as a result of the foreseen increase in production, the authorisation holder has introduced technical upgrades and changes to the risk management measures and manufacturing process. However, due to minor shortcomings in the exposure estimates for workers and general population via the environment, due to the lack of measured exposure data for the planned increased use of TCE, RAC recommended monitoring arrangements. Having evaluated the RAC assessment, the Commission agrees with its conclusion and recommendations.
- (7) In its opinion, SEAC concluded that it has no substantial reservations on the quantitative and qualitative elements of Roquette Frères' assessment of the socio-economic benefits and the monetised risk to human health resulting from 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 estimated monetised excess risk of cancer associated with the continued use of that substance in the order of less than twenty thousand euro over the review period, the monetised socio-economic benefits of continued use due to avoided profit loss, investments in a new plant and jobs estimated to be at minimum in the order of a few million euro over the review period, in addition to avoiding possible negative consequences for the production of pharmaceutical products, as well as any relevant distributional impact, the Commission concludes that Roquette Frères has demonstrated that the socio-economic benefits of the continued use of TCE 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 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 for which an 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 suitable alternative substances or technologies available for Roquette Frères at the time of submission of the review report. In particular, SEAC noted that one of the alternative substances assessed, the solvent toluene, may not lead to reduced risks to human health and the environment due to its hazardous properties. The Commission, having evaluated SEAC's assessment and all relevant information available, notes that the alternative solvent-free technology assessed is not economically feasible, due to significantly higher production costs, and that the alternative solvents, other than toluene, do not provide the necessary function and properties required by Roquette Frères for obtaining beta

cyclodextrin through the biotransformation of starch. The Commission also notes that significant research and development activities are still necessary to develop and implement a safer alternative solvent. Therefore, the Commission agrees with SEAC's conclusion that the identified alternatives are not yet technically and economically feasible and considers that Roquette Frères has discharged its burden of proof in demonstrating the absence of suitable alternatives both in the Union and for the applicant.

- (10) 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.
- (11) 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 generated.
- (12) In its opinion, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set until the end of 2031. The Commission agrees with that recommendation, taking into account the decision by the applicant to review the existing authorisation before its expiry date, mainly due to the changes to the production process and the increased volume of the substance. The Commission also takes into account the relevant elements from RAC's and SEAC's assessments and, in particular, RAC's conclusion that the risk management measures and operational conditions are appropriate and effective to limit the risk, the monetised socio-economic benefits and risk to human health of the continued use of the substance, the research and development activities undertaken during the review period, as well as the additional time needed for the identification, the validation with customers in the pharmaceutical sector and the full implementation of either a new alternative or technological developments for existing alternatives.
- (13) The language used to describe the risk management measures and operational conditions in the review report 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.
- (14) 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

Council⁴ 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/EEC⁵, 92/85/EEC⁶, 94/33/EC⁷ 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.

- (15) This Decision does not affect any obligation to comply with other regulatory provisions including emission limit values set in accordance with Directive 2008/50/EC⁸ or Directive 2010/75/EU⁹ 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 Council¹⁰ or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council¹¹. 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.
- (16) The authorisation should therefore be granted in the context of the review referred to in Article 61(1) of Regulation (EC) No 1907/2006. For reasons of clarity and legal certainty, Implementing Decision C(2016)7581 should be replaced by this Decision.
- (17) 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,

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/23/37/0/R1	As a processing aid in the biotransformation of starch to obtain betacyclodextrin

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report¹².

Article 2

1. The review period shall expire on 31 December 2031.
2. The authorisation shall cease to be valid on 31 December 2031 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 2030.

Article 3

1. The monitoring arrangements set out in paragraphs 2 to 5 shall apply.
2. The authorisation holder shall carry out a monitoring programme of occupational exposure to TCE. The 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;
 - (c) ensure a sufficiently low limit of quantification;
 - (d) comprise personal and static inhalation exposure sampling as well as biomonitoring;
 - (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 carry out a monitoring programme measuring the releases of TCE to air and wastewater. The measurements shall:

¹² <https://ec.europa.eu/docsroom/documents/47655>

- (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 into the on-site sewage treatment plant and prior to the release into surface waters;
 - (f) take into account the batch nature of the process and any changes in it;
 - (g) be recorded so as to include contextual information associated with each set of measurements.
4. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraphs 2 and 3 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 a level as low as technically and practically possible and in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.
5. The authorisation holder shall document and maintain the results of the measurements referred to in paragraphs 2 and 3, 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 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 4

Where the authorisation holder submits a review report, it shall include:

- (a) the information referred to in Article 3(5);
- (b) a revised exposure and emission assessment based on more detailed exposure data and a revised methodology as regards air emissions.

Article 5

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 6

Implementing Decision C(2016) 7581 is repealed.

Article 7

This Decision is addressed to Roquette Frères, 1 Rue de la haute loge, 62136, Lestrem Cedex, France.

Done at Brussels, 8.12.2023

For the Commission
Thierry BRETON
Member of the Commission

