EUROPEAN
COMMISSION

Brussels, 26.7.2024
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COMMISSION IMPLEMENTING DECISION

of 26.7.2024

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to EDF S.A. for certain uses of trixylyl phosphate (TXP)

(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) Trixylyl phosphate (TXP) 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 16 November 2021, EDF S.A. ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for certain uses of TXP. The uses for which authorisation was sought are the industrial use as a hydraulic fluid in closed systems to drive and control the steam inlet valves of turbines ('use 1') and the industrial use as a hydraulic fluid in closed systems to drive and control main steam isolation valves ('use 2').

(3) The European Chemicals Agency sent the opinions on the application for authorisation for use 1[2] and use 2[3] adopted by its Committee for Risk Assessment (RAC) and its Committee for Socio-economic Analysis (SEAC) to the Commission pursuant to Article 64(5), third subparagraph, of Regulation (EC) No 1907/2006. On 28 June 2023, the Commission received the opinions.

(4) In its opinions, RAC concluded that it is possible to determine a derived no-effect level for the reprotoxic properties of TXP in accordance with Section 1.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore TXP is a substance for which it is possible to determine a threshold.

(5) In its opinions on uses 1 and 2, RAC concluded that the risks to human health from the uses of TXP described in the application are adequately controlled as referred to in Article 60(2), first subparagraph, of Regulation (EC) No 1907/2006. RAC noted that

[1] OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj.

[2] https://www.echa.europa.eu/documents/10162/08d734d4-eba4-0190-66ae-54efcd0baf54.

[3] https://www.echa.europa.eu/documents/10162/dcff6c7a-5f4e-170d-db2d-0946808b7899.

the risk characterisation provided by the applicant has been done using appropriate methodology and the datasets submitted for both uses allow to conclude that the risks associated with the uses of TXP are adequately controlled during all activities and at all sites. Nevertheless, RAC recommended monitoring arrangements with the aim to strengthen the data on exposure estimates and to corroborate the appropriateness and effectiveness of the risk management measures and operational conditions. Having evaluated RAC's assessment, the Commission agrees with its conclusion. In order to further enhance the representativeness of the data on exposure estimates and to provide information on the trends in occupational exposure to TXP, the Commission considers that it is appropriate to require that the monitoring programmes include measurements at all of the applicant's sites.

(6) Therefore, having regard to the conditions laid down in Article 60(2) of Regulation (EC) No 1907/2006, it is appropriate to authorise the uses of TXP as described in this Decision, provided that the risk management measures described in the chemical safety report are applied and that the operational conditions described therein are fulfilled. For the sake of clarity, the description of the uses authorised by this Decision should be 'the industrial use as a hydraulic fluid in closed systems to drive and control the steam inlet valves of turbines in nuclear power plants' and 'the industrial use as a hydraulic fluid in closed systems to drive and control main steam isolation valves in nuclear power plants'.

(7) The assessment of suitability of alternatives is relevant, among others, for the determination of the review period in accordance with Article 60(9)(e) of Regulation (EC) No 1907/2006. For an alternative to be suitable it needs to be safer, available, and technically and economically feasible.

(8) In its opinions on uses 1 and 2, SEAC concluded that there were technically feasible alternative substances or technologies available for the applicant and in the Union by the sunset date, but that the applicant has demonstrated that these cannot be fully implemented before the sunset date. The Commission, having evaluated SEAC's assessment and the relevant information available, notes that, for both uses, the technically and economically feasible alternatives are available in the required quantities and that, for use 1, the two shortlisted alternatives have been partially implemented already, in equal shares, but notes as well that substitution at nuclear power plants is subject to significant constraints and specific requirements.

(9) However, the Commission also notes that the identified alternatives for use 1 include a component which has been evaluated by France for potential endocrine disrupting properties and that those properties have been confirmed during that evaluation.[4] Therefore, the Commission, while agreeing with SEAC's conclusion that there are suitable alternatives for the applicant and in the Union for use 2, considers that the use of the alternatives identified for use 1 might not substantially reduce the risk to human health and the environment compared with TXP, thus they might not be considered safer alternatives.

(10) The Commission also notes that the applicant committed to keep active research of alternative substances or technologies if the endocrine disrupting properties were confirmed. Therefore, the Commission considers that it is appropriate to set out an obligation to ensure that this commitment is properly implemented and enforced.

[4] https://echa.europa.eu/fr/ed-assessment/-/dislist/details/0b0236e181b005c9.

(11) The Commission has based its assessment on all relevant scientific evidence available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, has concluded on the basis of a sufficient amount of material and reliable information. Nevertheless, additional scientific evidence would allow the Commission to perform its assessment on a more robust or broad evidentiary basis in the future. Hence, it is appropriate to require the authorisation holder to generate and include additional information about exposure in the review report.

(12) In its opinions on uses 1 and 2, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set at seven years, until May 2030. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, that adequate control of the risk to human health from the uses of the substance is demonstrated, the socio-economic benefits of the continued use of the substance and the time needed to implement the alternatives under the specific constraints and requirements of a nuclear power plant, including the need to undertake substitution activities only during the maintenance or the inspection outages of the nuclear reactors.

(13) The language used to describe the risk management measures and operational conditions in the application for authorisation may be different from the official language of the Member State where the uses take 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 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[5] to reduce the use of carcinogens, mutagens or reprotoxic substances at the place of work, in particular by replacing those substances, 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],

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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, mutagens or reprotoxic substances 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, ELI: http://data.europa.eu/eli/dir/2004/37/oj).

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, ELI: http://data.europa.eu/eli/dir/1989/391/oj).

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, ELI: http://data.europa.eu/eli/dir/1992/85/oj).

94/33/EC[8], 98/24/EC[9] and Directive 2004/37/EC, or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

(15) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC[10] or Directive 2010/75/EU[11] 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[12] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[13]. Compliance with the provisions of this Decision does not necessarily imply compliance with any emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.

(16) 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(2) of Regulation (EC) No 1907/2006 to the following person for the following uses of trixylyl phosphate (TXP) (EC No 246-677-8; CAS No 25155-23-1):

Authorisation number	Authorisation holder	Authorised use
REACH/24/30/0	EDF S.A.	As a hydraulic fluid in closed systems to drive and control the steam inlet valves of turbines in nuclear power plants
REACH/24/30/1		As a hydraulic fluid in closed systems to drive and control main steam isolation valves in nuclear power plants

[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, ELI: http://data.europa.eu/eli/dir/1994/33/oj).

[9] 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, ELI: http://data.europa.eu/eli/dir/1998/24/oj).

[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, ELI: http://data.europa.eu/eli/dir/2008/50/oj).

[11] 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, ELI: http://data.europa.eu/eli/dir/2010/75/oj).

[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, ELI: http://data.europa.eu/eli/dir/2000/60/oj).

[13] 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, ELI: http://data.europa.eu/eli/dir/2008/105/oj).

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[14].

Article 2

1. The review period shall expire on 31 May 2030.

2. The authorisation shall cease to be valid on 31 May 2030 if the authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 30 November 2028.

Article 3

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

2. The authorisation holder shall carry out an occupational exposure monitoring programme. The programme shall include measurements which shall:

   (a) take place at least annually, or more frequently if a significant increase of TXP consumption takes place on site, and shall be sufficiently frequent to capture any potential increase in exposure of workers to TXP;

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

   (c) take place at all sites where tasks with possible exposure to TXP are performed;

   (d) ensure a sufficiently low limit of quantification;

   (e) comprise personal and static inhalation exposure sampling;

   (f) be representative of all the tasks with possible exposure to TXP, including maintenance tasks, the operational conditions and risk management measures for each of those tasks, and of the total number of workers that are potentially exposed;

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

3. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraph 2 to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions in place. While doing so, the authorisation holder shall also review and, if needed, update its assessment of the combined exposure for the different groups of workers. If needed, based on the outcome of this review, the authorisation holder shall introduce measures to further reduce to a level as low as technically and practically possible occupational exposure to TXP in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

4. The authorisation holder shall document and maintain the information from the monitoring programme referred to in paragraph 2, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the reviews and any measure taken in accordance with paragraph 3

[14] https://ec.europa.eu/docsroom/documents/55103.

and shall make that information available, upon request, to the competent authority of the Member State where the authorised uses take place.

5. The authorisation holder shall investigate the availability of the methodology for dermal exposure testing by 26 July 2025 and afterwards each time when new relevant information becomes available. If and as soon as the methodology is available, it should be used for the purpose of the monitoring in accordance with paragraph 2.

6. The authorisation holder shall investigate the feasibility to switch to safer alternatives not involving components with endocrine disrupting properties. The authorisation holder shall document that investigation and shall make that documentation available, upon request, to the competent authority of the Member State where the authorised uses take place.

Article 4

If a review report is submitted, it shall include the information referred to in Article 3(4) and (6).

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 uses take place. The brief summary shall be drafted in an official language of that Member State.

Article 6

This Decision is addressed to EDF S.A., 22 Avenue de Wagram, 75008 Paris, France.

Done at Brussels, 26.7.2024

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION