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**COMMISSION IMPLEMENTING DECISION**

**of 8.9.2025**

**granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Shell Nederland Raffinaderij B.V., for a use of tetraethyl lead**

(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<sup>1</sup>, and in particular Article 64(8) thereof,

Whereas:

- (1) Tetraethyl lead 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 27 June 2023, Shell Nederland Raffinaderij B.V., ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for a use of tetraethyl lead (TEL). The use for which authorisation was sought is in the formulation of aviation fuel.
- (3) The European Chemicals Agency sent the opinions<sup>2</sup> on the application adopted by its Committee for Risk Assessment (RAC) and its Committee for Socio-economic Analysis (SEAC) to the Commission pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006. On 10 September 2024, the Commission received the opinions.
- (4) In its opinion, RAC concluded that it is not possible to determine a derived no-effect level for the toxic to reproduction properties of tetraethyl lead in accordance with Section 1.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore tetraethyl lead 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 tetraethyl lead and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.

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

<sup>2</sup> <https://www.echa.europa.eu/documents/10162/0f4b5afd-3ab2-58cd-0d61-a6100824c923>

- (5) In its opinion, RAC concluded that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to workers and the general population posed by the use of tetraethyl lead described in the application. However, RAC expressed moderate concerns regarding the operational conditions during the coupling and decoupling of the hose at the time of transfer of the substance between the TEL solution storage tank and ships, barges or trucks. Consequently, in order to improve further the current risk management measures and operational conditions, RAC recommended additional conditions for authorisation. Moreover, to improve the exposure and emissions data, RAC recommended monitoring arrangements for both occupational exposure to TEL and environmental release of it. Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations.
- (6) In its opinion, SEAC concluded that the applicant has provided convincing evidence that the benefits of continued use of tetraethyl lead are higher than the monetised human health costs. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that the applicant has demonstrated that the benefits of the continued use outweigh the risk to human health arising from that use.
- (7) For an alternative to be suitable it needs to 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, the applicant is required by Article 62(4), point (f), of Regulation (EC) No 1907/2006 to submit a substitution plan.
- (8) 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.
- (9) In its opinion, SEAC concluded that there are no technically feasible alternative substances or technologies available for the applicant nor in the Union before the sunset date. The Commission, having evaluated SEAC's assessment and the relevant information available notes that there is no function *per se* provided by the substance in the use applied for (formulation of aviation gasoline). The Commission further notes that, despite this, the applicant is actively researching alternatives that can replace the use of tetraethyl lead in the formulation of aviation gasoline for use in aircrafts powered by piston engines and has provided an assessment of the most promising alternatives, also detailing why those alternatives are currently not technically feasible. The Commission, taking into consideration the applicant's efforts to find an alternative to tetraethyl lead, agrees with the conclusion by SEAC that there are no suitable alternatives available for the applicant and in the Union before the sunset date.
- (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 tetraethyl lead described in the application, provided that the risk management measures described in the chemical safety report are applied, and that the operational conditions described therein, as well as the conditions set out in this Decision, are fulfilled.
- (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 and emissions in the review report.

- (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 April 2032. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, RAC's conclusion that the risk management measures are appropriate and effective in limiting the risk, SEAC's conclusion on the socio-economic benefits and costs of the continued use of the substance, as well as the time needed to find an appropriate unleaded fuel substitute for piston engine aircrafts and obtaining the relevant EU certification.
- (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 States 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 holders 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 the 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<sup>3</sup> 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<sup>4</sup>, 92/85/EEC<sup>5</sup>, 94/33/EC<sup>6</sup>, 98/24/EC<sup>7</sup> and Directive 2004/37/EC, or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

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<sup>3</sup> 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>).

<sup>4</sup> 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>).

<sup>5</sup> 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>).

<sup>6</sup> 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>).

<sup>7</sup> 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>).

- (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<sup>8</sup> or Directive 2010/75/EU<sup>9</sup> 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<sup>10</sup> or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council<sup>11</sup>. 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(4) of Regulation (EC) No 1907/2006 to the following person for the following use of tetraethyl lead (EC No 201-075-4; CAS No 78-00-2) ('TEL'):

| Authorisation number | Authorisation holder              | Authorised use                      |
|----------------------|-----------------------------------|-------------------------------------|
| REACH/25/37/0        | Shell Nederland Raffinaderij B.V. | In the formulation of aviation fuel |

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report<sup>12</sup>, and to the conditions set out in Article 2.

#### *Article 2*

1. The authorisation is subject to the conditions set out in paragraphs 2 and 3.

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<sup>8</sup> 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>).

<sup>9</sup> 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>).

<sup>10</sup> 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>).

<sup>11</sup> 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>).

<sup>12</sup> <https://ec.europa.eu/docsroom/documents/61775>

2. By 8 September 2026 and afterwards each time that new relevant information becomes available, the authorisation holder shall carry out a study to assess the feasibility of implementing the following measures:

- (a) a vapour recovery system for the unloading of TEL solutions from the containers to the storage tank;
- (b) additional technical measures to prevent the occurrence of spills or drips during disconnection of the hose after the transfer operations of the TEL solution.

The authorisation holder shall act in accordance with the outcome of that study. The results of the study and documentation on the actions taken shall be made available, upon request, to the competent authority of the Member State where the authorised use takes place.

3. The authorisation holder shall, for the first time by 8 March 2026 and regularly afterwards, provide adequate training to the workers involved in the transfer tasks to ensure that the risk of spillage of TEL solution during disconnection of the hose is further minimised.

### *Article 3*

The review period shall expire on 30 April 2032.

The authorisation shall cease to be valid on 30 April 2032 in relation to any authorisation holder who has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 31 October 2030.

### *Article 4*

1. The monitoring arrangements set out in paragraphs 2 to 6 shall apply.
2. The authorisation holder shall carry out a monitoring programme measuring the environmental releases of TEL to air. The programme shall:
  - (a) take place at least annually or more frequently following if a significant increase of TEL consumption takes place on site in the process;
  - (b) be based on relevant standard methodologies or protocols;
  - (c) be representative for the operational conditions and risk management measures used at the site where the authorised use takes place;
  - (d) ensure a sufficiently low limit of quantification;
3. The authorisation holder shall conduct a monitoring programme measuring the occupational exposure to TEL. The programme shall:
  - (a) be conducted at least annually for the workers exposed to TEL. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to TEL;
  - (b) be based on relevant standard methodologies or protocols;
  - (c) ensure a sufficiently low limit of quantification;
  - (d) comprise personal or static inhalation exposure sampling;
  - (e) be representative of:

- (i) the full range and duration of tasks undertaken where exposure to TEL is possible;
    - (ii) the operational conditions and risk management measures typical for each of these tasks;
    - (iii) the number of workers potentially exposed;
  - (f) include contextual information about the tasks performed during sampling.
4. The authorisation holder shall conduct a biomonitoring programme for a representative number of workers potentially exposed to TEL.
  5. The authorisation holder shall use the information gathered via the measurements referred to in paragraphs 2 to 4 to confirm the effectiveness of the operational conditions and risk management measures in place and, if needed, introduce measures to further reduce occupational exposure to TEL and emissions to the environment to a level as low as technically and practically feasible. Measures introduced to reduce occupational exposure shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC. 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.
  6. The authorisation holder shall document and maintain the information gathered via the monitoring programmes referred to in paragraphs 2 to 4, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 5, and shall make that information available including pseudonymised or aggregated biomonitoring results, upon request, to the competent authority of the Member State where the authorised use takes place.

#### *Article 5*

If a review report is submitted, it shall include the information referred to in Article 2(2), and Article 4(6).

#### *Article 6*

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 7*

This Decision is addressed to:

Shell Nederland Raffinaderij B.V., Vondelingenweg 601, Postbus 3000, 3190 GA Rotterdam, the Netherlands.

Done at Brussels, 8.9.2025

*For the Commission*  
*Stéphane SÉJOURNÉ*  
*Executive Vice-President*

