



2026/870

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COMMISSION IMPLEMENTING REGULATION (EU) 2026/870

of 21 April 2026

renewing the approval of the active substance paraffin oil (CAS 8042-47-5) in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009, of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 20(1) thereof,

Whereas:

- (1) Council Directive 2009/117/EC ⁽²⁾ included paraffin oil (CAS 8042-47-5) as an active substance in Annex I to Council Directive 91/414/EEC ⁽³⁾.
- (2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁴⁾.
- (3) The approval of the active substance paraffin oil (CAS 8042-47-5), as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 November 2026.
- (4) An application for the renewal of the approval of the active substance paraffin oil (CAS 8042-47-5) was submitted to Greece, the rapporteur Member State, and France, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ⁽⁵⁾ and within the time period provided for in that Article.
- (5) The applicant submitted the supplementary dossier required to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority') in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be admissible by the rapporteur Member State.
- (6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the Authority and the Commission on 1 February 2021. In its draft renewal assessment report, the rapporteur Member State proposed to renew the approval of paraffin oil (CAS 8042-47-5).

⁽¹⁾ OJ L 309, 24.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1107/oj>.

⁽²⁾ Council Directive 2009/117/EC of 25 June 2009 amending Directive 91/414/EEC to include paraffin oil CAS No 8042-47-5 as an active substance (OJ L 237, 9.9.2009, p. 11, ELI: <http://data.europa.eu/eli/dir/2009/117/oj>).

⁽³⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1, ELI: <http://data.europa.eu/eli/dir/1991/414/oj>).

⁽⁴⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2011/540/oj).

⁽⁵⁾ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26, ELI: http://data.europa.eu/eli/reg_impl/2012/844/oj).

- (7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the draft renewal assessment report to the applicant and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.
- (8) On 1 July 2024, the Authority communicated to the Commission its conclusion. An updated version of this conclusion was communicated on 17 June 2025 ⁽⁶⁾. The Authority indicated that, taking into account the approval criteria laid down in Annex II to Regulation (EC) No 1107/2009, plant protection products containing paraffin oil (CAS 8042-47-5) can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) The Commission presented a renewal report on 1 October 2025 and a draft of this Regulation on 20 January 2026 to the Standing Committee on Plants, Animals, Food and Feed.
- (10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments, which have been carefully examined and taken into consideration.
- (11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance paraffin oil (CAS 8042-47-5) that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (12) Although the risk assessment for the renewal of the approval of the active substance paraffin oil (CAS 8042-47-5) is based on a limited number of representative uses, this does not restrict the uses for which plant protection products containing paraffin oil (CAS 8042-47-5) may be authorised. It is therefore appropriate not to maintain its restriction for use as insecticide and acaricide.
- (13) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge and the outcome of the risk assessment, it is, however, necessary to provide for certain conditions. It is, in particular, appropriate to require further confirmatory information on the contents of the impurity polycyclic aromatic hydrocarbons (PAHs), in order to address the new technical developments regarding the limit for PAHs in the European Pharmacopoeia and to increase confidence in the conclusion that the potential exposure from PAH is low and that there is no indication of consumer concern.
- (14) Implementing Regulation (EU) No 540/2011 should be amended accordingly.
- (15) Commission Implementing Regulation (EU) 2025/787 ⁽⁷⁾ extended the approval period of paraffin oil (CAS 8042-47-5) to 30 November 2026 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply earlier than that date.
- (16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽⁶⁾ Conclusion on pesticides peer review of the pesticide risk assessment of the active substance paraffin oil (CAS 8042-47-5, chain lengths C17–C31), *EFSA Journal* 2024; 22:e8913, available online: <https://doi.org/10.2903/j.efsa.2024.8913>.

⁽⁷⁾ Commission Implementing Regulation (EU) 2025/787 of 24 April 2025 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1,4-dimethylnaphthalene, amidosulfuron, bentazone, bixafen, clomazone, fenoxaprop-P, fludioxonil, fluoxastrobin, flutolanil, fluxapyroxad, gibberellic acid, gibberellins, halauxifen-methyl, mecoprop-P, paraffin oil, penthiopyrad, pirimiphos-methyl, propamocarb, propyzamide, prothioconazole, rimsulfuron, sedaxane and sulfoxaflor (OJ L, 2025/787, 25.4.2025, ELI: http://data.europa.eu/eli/reg_impl/2025/787/oj).

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance

The approval of the active substance paraffin oil (CAS 8042-47-5), as specified in Annex I to this Regulation, is renewed, subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and date of application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 July 2026.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 21 April 2026.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Paraffin oil (Not ISO) Paraffin, light liquid 'Paraffinum Perliquidum' (European Pharmacopoeia, EurPharm) CAS No: 8042-47-5 CIPAC No: 898	White mineral oil (petroleum) (Not IUPAC)	1 000 g/kg The impurity Polycyclic Aromatic Hydrocarbons (PAHs) shall not exceed 0,3 mg/kg in the technical material in accordance with the European Pharmacopoeia.	1 July 2026	30 June 2041	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on paraffin oil (CAS 8042-47-5), and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the consumer risk assessment, in particular to ensure compliance with maximum levels that are set in Union law for total mineral oil aromatic hydrocarbon (MOAH); — the protection of aquatic organisms, non-target arthropods in off field area and bees. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information to: (1) demonstrate the compliance of technical grade paraffin oil with the maximum level of PAH (PAH4- benzo(a)pyrene, benz(a)anthracene, benzo(b) fluoranthene and chrysene and PAH8) in the technical specification (0,3 mg/kg), with validated analytical methods for the determination of those PAHs in the technical paraffin oil and the formulations for the representative uses as proposed by the applicant; (2) complete the consumer risk assessment, where exposure to PAH residues shall be estimated using an approach based on application rate and yield rate for the representative uses as proposed by the applicant. This risk assessment shall be carried out based on that estimated exposure. The applicant shall submit to the Commission, the Member States and the Authority the information referred to in points 1 and 2 by 12 May 2027.

⁽¹⁾ Further details on the identity and specification of the active substance are provided in the renewal report.

ANNEX II

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

- (1) in Part A, entry 295 on paraffin oil (CAS 8042-47-5) is deleted;
- (2) in Part B, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
'180	Paraffin oil (Not ISO) Paraffin, light liquid "Paraffinum Perliquidum" (European Pharmacopoeia, EurPharm) CAS No: 8042-47-5 CIPAC No: 898	White mineral oil (petroleum) (Not IUPAC)	1 000 g/kg The impurity Polycyclic Aromatic Hydrocarbons (PAHs) shall not exceed 0,3 mg/kg in the technical material in accordance with the European Pharmacopoeia.	1 July 2026	30 June 2041	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on paraffin oil (CAS 8042-47-5), and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the consumer risk assessment, in particular to ensure compliance with maximum levels that are set in Union law for total mineral oil aromatic hydrocarbon (MOAH); — the protection of aquatic organisms, non-target arthropods in off field area and bees. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information to: (1) demonstrate the compliance of technical grade paraffin oil with the maximum level of PAH (PAH4- benzo(a)pyrene, benz(a)anthracene, benzo(b) fluoranthene and chrysene and PAH8) in the technical specification (0,3 mg/kg) with validated analytical methods for the determination of those PAHs in the technical paraffin oil and the formulations for the representative uses as proposed by the applicant; (2) complete the consumer risk assessment, where exposure to PAH residues shall be estimated using an approach based on application rate and yield rate for the representative uses as proposed by the applicant. This risk assessment shall be carried out based on that estimated exposure. The applicant shall submit to the Commission, the Member States and the Authority the information referred to in points 1 and 2 by 12 May 2027.'

⁽¹⁾ Further details on the identity and specification of the active substance are provided in the renewal report.