

**COMMISSION IMPLEMENTING REGULATION (EU) 2022/800****of 20 May 2022****amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3****(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 <sup>(1)</sup>, and in particular Article 13(2)(c) thereof,

Whereas:

- (1) Council Directive 2009/116/EC <sup>(2)</sup> included paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 as active substances in Annex I to Council Directive 91/414/EEC <sup>(3)</sup>.
- (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 <sup>(4)</sup>.
- (3) The approval of the active substances paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, allows for their use as an insecticide and acaricide only.
- (4) In accordance with Article 7(1) of Regulation (EC) No 1107/2009, on 30 September 2014, Total Fluids submitted an application to Greece, the rapporteur Member State, seeking an amendment to the conditions of approval of paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 in order to allow for their use as a fungicide. The application was found to be admissible by the rapporteur Member State.
- (5) The rapporteur Member State assessed the new use of paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 applied for in 2014 in relation to the potential effects on human and animal health and the environment in accordance with Article 4 of Regulation (EC) No 1107/2009, and prepared a draft assessment report which was submitted to the European Food Safety Authority ('the Authority') and the Commission on 6 February 2018.
- (6) In accordance with Article 12(1) of Regulation (EC) No 1107/2009, the Authority circulated the revised assessment report to the applicant and to the Member States for comments and made it available to the public. In accordance with Article 12(3) of Regulation (EC) No 1107/2009, additional information was requested from the applicant.

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1.

<sup>(2)</sup> Council Directive 2009/116/EC of 25 June 2009 amending Directive 91/414/EEC to include paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 as active substances (OJ L 237, 9.9.2009, p. 7).

<sup>(3)</sup> 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).

<sup>(4)</sup> 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).

- (7) On 23 September 2021, the Authority communicated to the Commission its conclusion <sup>(7)</sup> on whether the new use of paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (8) The Commission presented an addendum to the review report for paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 27 January 2022.
- (9) The Commission invited the applicant to submit comments on the addendum to the review report, which have been carefully examined.
- (10) It has been established with respect to one or more representative uses of at least one plant protection product containing paraffin oils CAS No 64742-46-7, CAS-No-72623-86-0 and CAS No 97862-82-3 that, when used as a fungicide, the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to amend the specific provisions as laid down in the approval of paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS-No-97862-82-3 to include the use as a fungicide in addition to the uses as an insecticide and acaricide.
- (11) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Amendment to Implementing Regulation (EU) No 540/2011**

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

*Article 2*

**Entry into force**

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

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

Done at Brussels, 20 May 2022.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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<sup>(7)</sup> EFSA (European Food Safety Authority), 2021. Peer review of the efficacy as a fungicide of the active substances paraffin oils (CAS 64742-46-7 chain lengths C11–C25, CAS 72623-86-0 chain lengths C15–C30 and CAS 97862-82-3 chain lengths C11–C30); EFSA Journal 2021;19(10)6876doi: 10.2903/j.efs.2021.6876.

## ANNEX

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, the entry in the column 'Specific provisions' of row 294, paraffin oils CAS No 64742-46-7, CAS-No-72623-86-0 and CAS No 97862-82-3, is replaced by the following:

## Part A

Only uses as insecticide, acaricide and fungicide may be authorised.

## Part B

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3, including its addendum, and in particular Appendices I and II thereof, shall be taken into account.

Conditions of use shall include risk mitigation measures, where appropriate.'

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