



2024/1207

30.4.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/1207

of 29 April 2024

concerning the non-renewal of the approval of the active substance dimethomorph, 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) and Article 78(2) thereof,

Whereas:

- (1) Commission Directive 2007/25/EC ⁽²⁾ included dimethomorph 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 dimethomorph, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 February 2025.
- (4) An application for the renewal of the approval of the active substance dimethomorph was submitted to the Netherlands, the rapporteur Member State, and Germany, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ⁽⁵⁾ within the time period provided for in that Article.
- (5) The applicants submitted the supplementary dossiers 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 complete 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 August 2017. In its draft renewal assessment report the rapporteur Member State proposed to renew the approval of dimethomorph.

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

⁽²⁾ Commission Directive 2007/25/EC of 23 April 2007 amending Council Directive 91/414/EEC to include dimethoate, dimethomorph, glufosinate, metribuzin, phosmet and propamocarb as active substances (OJ L 106, 24.4.2007, p. 34, ELI: <http://data.europa.eu/eli/dir/2007/25/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 applicants 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 26 May 2023, the Authority communicated to the Commission its conclusion ⁽⁶⁾ on whether dimethomorph can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) In its conclusion, the Authority identified several areas of concern. In particular, dimethomorph has been classified as toxic to reproduction, category 1B. On 20 September 2019, the Committee for Risk Assessment of the European Chemicals Agency adopted an opinion ⁽⁷⁾ in accordance with Article 37(4) of Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽⁸⁾ in which it concluded that dimethomorph has been classified as toxic to reproduction, category 1B (H360F 'may damage fertility'). Commission Delegated Regulation (EU) 2021/849 ⁽⁹⁾ consequently amended Annex VI to Regulation (EC) No 1272/2008 and classified dimethomorph as toxic for reproduction category 1B.
- (10) The Authority also concluded that dimethomorph meets the criteria for endocrine disruptors for humans and wild mammals as non-target organisms set out in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, due to its oestrogen, androgen and steroidogenesis (EAS)-modalities.
- (11) Negligible exposure cannot be demonstrated for dimethomorph since residues above the default value of 0,01 mg/kg are expected to occur for all representative uses and in rotational crops. Therefore, the requirements set out in points 3.6.4 and 3.6.5 of Annex II to Regulation (EC) No 1107/2009 are not fulfilled.
- (12) The Authority concluded that dimethomorph is not necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, in accordance with Article 4(7) of Regulation (EC) No 1107/2009. For the representative uses of the renewal of the active substance (*Phytophthora* disease in strawberries, downy mildew in lettuce and grapevine), alternative active substances are available in most cases and a derogation may be scientifically justified only in very few cases, e.g. in cases of non-availability and/or non-feasibility of alternative non-chemical methods. Furthermore a combination of chemical and non-chemical methods may be possible to control the pests in some crops. In addition, no serious danger to plant health has been identified which would require the use of dimethomorph. Therefore, the Commission considers that the conditions for the application of the derogation in Article 4(7) of Regulation (EC) No 1107/2009 are not fulfilled.
- (13) The Commission presented a draft renewal report for dimethomorph to the Standing Committee on Plants, Animals, Food and Feed on 12 October 2023.
- (14) The Commission invited the applicants to submit their comments on the conclusion of the Authority. Furthermore, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012, the Commission invited the applicants to submit comments on the renewal report. The applicants submitted their comments, which have been carefully examined.

⁽⁶⁾ Conclusion on the peer review of the pesticide risk assessment of the active substance dimethomorph *EFSA Journal* 2023;21(6):8032.

⁽⁷⁾ European Chemicals Agency (2019). Opinion of the Committee for Risk Assessment proposing harmonised classification and labelling of dimethomorph (ISO): (E,Z)-4-(3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)acryloyl)morpholine (EC Number: 404-200-2; CAS Number: 110488-70-5) (<https://echa.europa.eu/documents/10162/8c2bdfa6-bd1f-15d2-8c76-fd8c0d38695b>).

⁽⁸⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/1272/oj>).

⁽⁹⁾ Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 188, 28.5.2021, p. 27, ELI: http://data.europa.eu/eli/reg_del/2021/849/oj).

- (15) Despite the arguments put forward by the applicants, the concerns regarding the active substance could not be eliminated.
- (16) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of the active substance dimethomorph in accordance with Article 20(1), point (b), of that Regulation.
- (17) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (18) Member States should be given sufficient time to withdraw authorisations for plant protection products containing dimethomorph.
- (19) For plant protection products containing dimethomorph, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should not exceed 12 months from the date of entry into force of this Regulation.
- (20) Commission Implementing Regulation (EU) 2023/918 ⁽¹⁰⁾ extended the period of approval of dimethomorph until 15 February 2025 in order to allow the renewal process to be completed before the expiry of the approval period of that substance. However, given that a decision on the non-renewal of the approval is taken ahead of the expiry of that extended approval period, this Regulation should apply earlier than that date.
- (21) This Regulation does not prevent the submission of a further application for the approval of dimethomorph pursuant to Article 7 of Regulation (EC) No 1107/2009.
- (22) 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

Non-renewal of approval of active substance

The approval of the active substance dimethomorph is not renewed.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 150 on dimethomorph is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing dimethomorph as an active substance by 20 November 2024.

⁽¹⁰⁾ Commission Implementing Regulation (EU) 2023/918 of 4 May 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aclonifen, ametoctradin, beflubutamid, bentiavalicarb, boscalid, captan, clethodim, cycloxydim, cyflumetofen, dazomet, diclofop, dimethomorph, ethephon, fenazaquin, fluopicolide, fluoxastrobin, flurochloridone, folpet, formetanate, *Helicoverpa armigera nucleopolyhedrovirus*, hymexazol, indolylbutyric acid, mandipropamid, metalaxyl, metaldehyde, metam, metazachlor, metribuzin, milbemectin, paclobutrazol, penoxsulam, phenmedipham, pirimiphos-methyl, propamocarb, proquinazid, prothioconazole, S-metolachlor, *Spodoptera littoralis nucleopolyhedrovirus*, *Trichoderma asperellum* strain T34 and *Trichoderma atroviride* strain I-1237 (OJ L 119, 5.5.2023, p. 160, ELI: http://data.europa.eu/eli/reg_impl/2023/918/oj).

*Article 4***Grace period**

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall expire by 20 May 2025.

*Article 5***Entry into force**

This Regulation shall enter into force on 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, 29 April 2024.

For the Commission
The President
Ursula VON DER LEYEN
