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[...] (2023) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the non-renewal of the approval of the active substance dimoxystrobin, 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 and Commission Implementing Regulation (EU) 2015/408

(Text with EEA relevance)

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(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/EEC¹, and in particular Article 20(1) and Article 78(2) thereof,

Whereas:

- (1) Commission Directive 2006/75/EC² included dimoxystrobin as an active substance in Annex I to Council Directive 91/414/EEC³.
- (2) According to Article 78(3) of Regulation (EC) No 1107/2009, 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 540/2011⁴.
- (3) The approval of the active substance dimoxystrobin, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 January 2024.
- (4) An application for the renewal of the approval of the active substance dimoxystrobin was submitted to Hungary, the rapporteur Member State, and Ireland, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012⁵ within the time period provided for in that Article.

¹ OJ L 309, 24.11.2009, p. 1.

² Commission Directive 2006/75/EC of 11 September 2006 amending Council Directive 91/414/EEC to include dimoxystrobin as active substance (OJ L 248, 12.9.2006, p. 3).

³ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.2006, p. 1).

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).

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). This Regulation was replaced by Regulation (EU) 2020/1740, however, it continues to apply to the procedure for the renewal of the approval of active substances: (1) whose approval period ends before 27 March 2024; (2) for

- (5) The applicant submitted the supplementary dossiers required by Article 6 of Implementing Regulation (EU) No 844/2012 to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority'). 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 September 2017. In its draft renewal assessment report, the rapporteur Member State proposed to renew the approval of the active substance dimoxystrobin.
- (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) The Authority conducted expert consultations in the areas of mammalian toxicology, environmental fate and behaviour, and ecotoxicology in January and June 2022. As a result of those consultations the Authority identified concerns, in particular in relation to groundwater contamination by toxicologically relevant metabolites of dimoxystrobin.
- (9) On 12 August 2022, in the light of the concern in relation to groundwater contamination identified by the Authority, the Commission requested the Authority to issue a statement containing a summary of its main findings as regards the assessment of the active substance dimoxystrobin in relation to its environmental fate, its behaviour and its ecotoxicology.
- (10) On 11 October 2022, the Authority communicated that statement to the Commission⁶.
- (11) In its statement, the Authority confirmed that a critical area of concern exists for all the representative uses of the active substance, in particular a high potential for groundwater contamination by toxicologically relevant metabolites of dimoxystrobin (505M08 and 505M09) in all geoclimatic conditions represented by the groundwater assessment scenarios.
- (12) The Commission presented its draft renewal report regarding dimoxystrobin and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 8 December 2022 and on 25 January 2023, respectively.
- (13) The Commission invited the applicant to submit its comments on the statement of the Authority. Furthermore, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012, the Commission invited the applicant to submit comments on the draft renewal report. The applicant submitted its comments, which have been carefully examined.

which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

⁶ EFSA (European Food Safety Authority), 2022. Statement concerning the assessment of environmental fate and behaviour and ecotoxicology in the context of the pesticides peer review of the active substance dimoxystrobin. EFSA Journal 2022; 20(11): e07634 <https://doi.org/10.2903/j.efsa.2022.7634>.

- (14) Despite the arguments put forward by the applicant, the concerns related to the environmental fate, behaviour and ecotoxicology of dimoxystrobin could not be eliminated.
- (15) Consequently, it has not been established that dimoxystrobin fulfils the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. It is therefore appropriate not to renew the approval of that active substance.
- (16) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (17) Commission Implementing Regulation (EU) 2015/408⁷ listed dimoxystrobin as a candidate for substitution. In the light of the non-renewal of the approval of dimoxystrobin that listing is no longer relevant. Accordingly, dimoxystrobin should be deleted from the Annex to Implementing Regulation (EU) 2015/408.
- (18) Member States should be given time to withdraw authorisations for plant protection products containing dimoxystrobin.
- (19) For plant protection products containing dimoxystrobin, where Member States grant a 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) 2023/115⁸ extended the approval period of dimoxystrobin to 31 January 2024 in order to allow the renewal process to be completed before the expiry of the approval period. However, given that a decision on the non-renewal of the approval has been 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 another application for the approval of dimoxystrobin 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 the approval of the active substance

The approval of the active substance dimoxystrobin 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 128 on

⁷ Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution. (OJ L 67, 12.3.2015, p. 18).

⁸ Commission Implementing Regulation (EU) 2023/115 of 16 January 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance dimoxystrobin. (OJ L 15, 17.1.2023, p. 13).

dimoxystrobin is deleted.

Article 3

Amendment to Implementing Regulation (EU) 2015/408

The entry for dimoxystrobin in the Annex to Implementing Regulation (EU) 2015/408 is deleted.

Article 4

Transitional measures

Member States shall withdraw authorisations for plant protection products containing dimoxystrobin as an active substance by [..] [*Office of Publications please insert date 6 months from the date of entry into force of this Regulation*].

Article 5

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall expire by [..] [*Office of Publications please insert date 12 months from the date of entry into force of this Regulation*].

Article 6

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,

For the Commission

The President

Ursula VON DER LEYEN